



**SVET  
EVROPSKE UNIJE**

**Bruselj, 22. september 2011 (23.09)  
(OR. en)**

**14509/1/11  
REV 1**

**INF 162  
ELARG 95**

**DOPIS**

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Pošiljatelj: generalni secretariat

Prejemnik: delegacije

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Zadeva: Pogodba o pristopu Republike Hrvaške

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Delegacije obveščamo, da sta bila dokumenta AC 31/11 in AC 30/11, ki sta priložena temu dopisu kot Priloga I oziroma II, objavljena 21. septembra 2011, in sicer v skladu z Uredbo (ES) št. 1049/2001 Evropskega parlamenta in Sveta o dostopu javnosti do dokumentov Evropskega parlamenta, Sveta in Komisije.

Dokumenta vsebujejo osnutek besedila pristopne pogodbe s Hrvaško, ki ga je v angleškem jeziku v pogajanjih dosegel in odobril Coreper 14. septembra 2011.

Trenutno ju še pregledujejo pravniki lingvisti.

**PRILOGA I**

**SVET  
EVROPSKE UNIJE**

**Bruselj, 13. september 2011 (15.09)  
(OR. en)**

**GENERALNI SEKRETARIAT**

**AC 31/11**

**LIMITE**

**KONČNO BESEDILO PRISTOPNE POGODBE, DOGOVORJENO MED  
EVROPSKO UNIJO IN DRŽAVO KANDIDATKO**

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Zadeva:                  Pristopna pogodba:  
                                Pogodba o pristopu Republike Hrvaške

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## KAZALO

- A. Pogodba med Kraljevino Belgijo, Republiko Bolgarijo, Češko republiko, Kraljevino Dansko, Zvezno republiko Nemčijo, Republiko Estonijo, Irsko, Helensko republiko, Kraljevino Španijo, Francosko republiko, Italijansko republiko, Republiko Ciper, Republiko Latvijo, Republiko Litvo, Velikim vojvodstvom Luksemburg, Republiko Madžarsko, Republiko Malto, Kraljevino Nizozemsko, Republiko Avstrijo, Republiko Poljsko, Portugalsko republiko, Romunijo, Republiko Slovenijo, Slovaško republiko, Republiko Finsko, Kraljevino Švedsko, Združenim kraljestvom Velika Britanija in Severna Irska (državami članicami Evropske unije) ter Republiko Hrvaško o pristopu Republike Hrvaške k Evropski uniji .....
- B. Akt o pogojih pristopa Republike Hrvaške in o prilagoditvah Pogodbe o Evropski uniji, Pogodbe o delovanju Evropske unije in Pogodbe o ustanovitvi Evropske skupnosti za atomsko energijo .....

Prvi del: Načela.....

Drugi del: Prilagoditve pogodb

Naslov I: Institucionalne določbe .....

Naslov II: Druge prilagoditve .....

Treći del: Trajne določbe

Četrти del Začasne določbe

Naslov I: Prehodni ukrepi .....

Naslov II: Institucionalne določbe .....

Title III: Finančne določbe .....

Naslov IV: Druge določbe .....

Peti del: Določbe o izvajanju tega akta.....

Naslov I: Prilagoditve statutov in poslovnikov institucij in odborov .....

Naslov II: Uporaba aktov institucij .....

Title III: Končne določbe .....

## PRILOGE

Priloga I: Seznam konvencij in protokolov, h katerim pristopi Republika Hrvaška ob pristopu (iz člena 3(4) Akta o pristopu).....

Priloga II: Seznam določb schengenskega pravnega reda, kakor so vključene v okvir Evropske unije, in aktov, ki na njem temeljijo ali so z njim kako drugače povezani, ki so za Republiko Hrvaško zavezujoci in se v njej uporabljajo od pristopa (iz člena 4(1) Akta o pristopu) .....

Priloga III: Seznam iz člena 15 Akta o pristopu: prilagoditve aktov, ki so jih sprejele institucije ...

1. Svoboda opravljanja storitev .....
2. Pravo intelektualne lastnine ..
  - I. Blagovna znamka Skupnosti .....
  - II. Dodatni varstveni certifikati.....
  - III. Modeli Skupnosti.....
3. Finančne storitve.....
4. Kmetijstvo .....
5. Ribištvo .....
6. Obdavčitev .....
7. Regionalna politika in usklajevanje strukturnih instrumentov.....
8. Okolje.....

PRILOGA IV: Seznam iz člena 16 Akta o pristopu: druge trajne določbe

1. Pravo intelektualne lastnine .....
2. Politika konkurence .....
3. Kmetijstvo .....
4. Ribištvo .....
5. Carinska unija.....

Dodatek k Prilogi IV

Priloga V: Seznam iz člena 18 Akta o pristopu: prehodni ukrepi

1. Prosti pretok blaga .....
2. Prosto gibanje oseb .....
3. Prosti pretok kapitala .....
4. Kmetijstvo .....
5. Varnost živil, veterinarska in fitosanitarna politika.....
  - I. Kokoši nesnice
  - II. Obrati (meso, mleko, ribe in živalski stranski proizvodi)
  - III. Trženje semen
  - IV. Neum
6. Ribištvo .....
7. Prometna politika.....
8. Obdavčitev .....
9. Pravica, svoboda in varnost.....

10.	Okolje.....
I.	Horizontalna zakonodaja.....
II.	Kakovost zraka .....
III.	Ravnanje z odpadki.....
IV.	Kakovost vode.....
V.	Celovito preprečevanje in nadzor onesnaževanja.....
VI.	Kemikalije

Dodatek k prilogi V .....

Priloga VI: Razvoj podeželja (iz člena 35(2) Akta o pristopu)

Priloga VII: Posebne zaveze, ki jih je Republika Hrvaška prevzela v pristopnih pogajanjih (iz drugega pododstavka člena 36(1) Akta o pristopu)

Priloga VIII: Zaveze, ki jih je Republika Hrvaška prevzela v zvezi s prestrukturiranjem hrvaške ladjedelniške industrije (iz tretjega pododstavka člena 36(1) Akta o pristopu)

Priloga IX: Zaveze, ki jih je Republika Hrvaška prevzela v zvezi s prestrukturiranjem jeklarskega sektorja (iz tretjega pododstavka člena 36(1) Akta o pristopu)

## PROTOKOL

Protokol o nekaterih dogоворih o morebitnem enkratnem prenosu enot dodeljenih količin, ki se izdajo v okviru Kjotskega protokola , Republiki Hrvaški ter o ustreznem nadomestilu

## SKLEPNA LISTINA

- I. Besedilo sklepne listine.....
- II. Izjave
  - [A]. Skupne izjave sedanjih držav članic .....
  - [1.] Skupna izjava o polni uporabi določb schengenskega pravnega reda.....
  - [B]. Skupna izjava nekaterih sedanjih držav članic
    - [1.] Skupna izjava Zvezne republike Nemčije in Republike Avstrije o prostem gibanju delavcev: Hrvaška .....
  - [C.] Skupna izjava sedanjih držav članic in Republike Hrvaške
    - [1.] Skupna izjava o Evropskem razvojnem skladu.....
  - [D.]. Izjava Republike Hrvaške:
    - [1.] Izjava Republike Hrvaške o prehodni ureditvi glede liberalizacije hrvaškega trga kmetijskih zemljišč .....
- III. Izmenjava pisem med Evropsko Unijo in Republiko Hrvaško o postopku obveščanja in posvetovanja za sprejetje nekaterih sklepov in drugih ukrepov v obdobju pred pristopom .....

# **POGODBA**

**MED**

**KRALJEVINO BELGIJO, REPUBLIKO BOLGARIJO, ČEŠKO REPUBLIKO,  
KRALJEVINO DANSKO, ZVEZNO REPUBLIKO NEMČIJO, REPUBLIKO ESTONIJO,  
IRSKO, HELENSKO REPUBLIKO, KRALJEVINO ŠPANIJO, FRANCOSKO  
REPUBLIKO, ITALIJANSKO REPUBLIKO, REPUBLIKO CIPER, REPUBLIKO  
LATVIJO, REPUBLIKO LITVO, VELIKIM VOJVODSTVOM LUKSEMBURG,  
REPUBLIKO MADŽARSKO, REPUBLIKO MALTO, KRALJEVINO NIZOZEMSKO,  
REPUBLIKO AVSTRIJO, REPUBLIKO POLJSKO, PORTUGALSKO REPUBLIKO,  
ROMUNIJO, REPUBLIKO SLOVENIJO, SLOVAŠKO REPUBLIKO, REPUBLIKO  
FINSKO, KRALJEVINO ŠVEDSKO, ZDRAŽENIM KRALJESTVOM VELIKA  
BRITANIJA IN SEVERNA IRSKA**

**(DRŽAVAMI ČLANICAMI EVROPSKE UNIJE)**

**TER**

**REPUBLIKO HRVAŠKO**

**O PRISTOPU REPUBLIKE HRVAŠKE K EVROPSKI UNIJI**

NJEGOVO VELIČANSTVO KRALJ BELGIJCEV,

PREDSEDNIK REPUBLIKE BOLGARIJE,

PREDSEDNIK ČEŠKE REPUBLIKE,

NJENO VELIČANSTVO KRALJICA DANSKE,

PREDSEDNIK ZVEZNE REPUBLIKE NEMČIJE,

PREDSEDNIK REPUBLIKE ESTONIJE,

PREDSEDNICA IRSKE,

PREDSEDNIK HELENSKE REPUBLIKE,

NJEGOVO VELIČANSTVO KRALJ ŠPANIJE,

PREDSEDNIK FRANCOSKE REPUBLIKE,

[INSERT ENTRY FOR CROATIA,]

PREDSEDNIK ITALIJANSKE REPUBLIKE,

PREDSEDNIK REPUBLIKE CIPER,

PREDSEDNIK REPUBLIKE LATVIJE,

PREDSEDNICA REPUBLIKE LITVE,

NJEGOVA KRALJEVA VISOKOST VELIKI VOJVODA LUKSEMBURŠKI,

PREDSEDNIK REPUBLIKE MADŽARSKE,

PREDSEDNIK MALTE,

NJENO VELIČANSTVO KRALJICA NIZOZEMSKE,

ZVEZNI PREDSEDNIK REPUBLIKE AVSTRIJE,

PREDSEDNIK REPUBLIKE POLJSKE,

PREDSEDNIK PORTUGALSKO REPUBLIKE,

PREDSEDNIK ROMUNIJE,

PREDSEDNIK REPUBLIKE SLOVENIJE,

PREDSEDNIK SLOVAŠKE REPUBLIKE,

PREDSEDNICA REPUBLIKE FINSKE,

VLADA KRALJEVINE ŠVEDSKE,

NJENO VELIČANSTVO KRALJICA ZDRAŽENEGA KRALJESTVA VELIKA BRITANIJA IN  
SEVERNA IRSKA,

ZDRAŽENI v želji prizadevati si za doseganje ciljev Evropske unije,

ODLOČENI nadaljevati proces oblikovanja vse tesnejše zveze med narodi Evrope na že  
postavljenih temeljih,

KER člen 49 Pogodbe o Evropski uniji evropskim državam daje možnost, da postanejo članice  
Unije,

KER je Republika Hrvaška zaprosila za članstvo v Uniji,

KER se je Svet po pridobitvi mnenja Komisije in odobritvi Evropskega parlamenta izrekel za  
sprejem Republike Hrvaške,

SO SE DOGOVORILI o pogojih sprejema in prilagoditvah Pogodbe o Evropski uniji, Pogodbe o delovanju Evropske unije in Pogodbe o ustanovitvi Evropske skupnosti za atomsko energijo ter v ta namen imenovali svoje pooblaščence:

ZA NJEGOVO VELIČANSTVO KRALJA BELGIJCEV,

[List signatories]

ZA PREDSEDNIKA REPUBLIKE BOLGARIJE,

[List signatories]

ZA PREDSEDNIKA ČEŠKE REPUBLIKE,

[List signatories]

ZA NJENO VELIČANSTVO KRALJICO DANSKE,

[List signatories]

ZA PREDSEDNIKA ZVEZNE REPUBLIKE NEMČIJE,

[List signatories]

ZA PREDSEDNIKA REPUBLIKE ESTONIJE,

[List signatories]

ZA PREDSEDNICO IRSKE,

[List signatories]

ZA PREDSEDNIKA HELENSKE REPUBLIKE,

[List signatories]

ZA NJEGOVO VELIČANSTVO KRALJA ŠPANIJE,

[List signatories]

ZA PREDSEDNIKA FRANCOSKE REPUBLIKE,

[List signatories]

[INSERT ENTRY FOR CROATIA,]

[List signatories]

ZA PREDSEDNIKA ITALIJANSKE REPUBLIKE,

[List signatories]

ZA PREDSEDNIKA REPUBLIKE CIPER,

[List signatories]

ZA PREDSEDNIKA REPUBLIKE LATVIJE,

[List signatories]

ZA PREDSEDNICO REPUBLIKE LITVE,

[List signatories]

ZA NJEGOVO KRALJEVO VISOKOST VELIKEGA VOJVODO LUKSEMBURŠKEGA,

[List signatories]

ZA PREDSEDNIKA REPUBLIKE MADŽARSKE,

[List signatories]

ZA PREDSEDNIKA MALTE,

[List signatories]

ZA NJENO VELIČANSTVO KRALJICO NIZOZEMSKE,

[List signatories]

ZA ZVEZNEGA PREDSEDNIKA REPUBLIKE AVSTRIJE,

[List signatories]

ZA PREDSEDNIKA REPUBLIKE POLJSKE,

[List signatories]

ZA PREDSEDNIKA PORTUGALSKE REPUBLIKE,

[List signatories]

ZA PREDSEDNIKA ROMUNIJE,

[List signatories]

ZA PREDSEDNIKA REPUBLIKE SLOVENIJE,

[List signatories]

ZA PREDSEDNIKA SLOVAŠKE REPUBLIKE,

[List signatories]

ZA PREDSEDNICO REPUBLIKE FINSKE,

[List signatories]

ZA VLADO KRALJEVINE ŠVEDSKE,

[List signatories]

ZA NJENO VELIČANSTVO KRALJICO ZDRAŽENEGA KRALJESTVA VELIKA BRITANIJA  
IN SEVERNA IRSKA,

[List signatories]

KI SO SE po izmenjavi pooblastil v pravilni in predpisani obliki

DOGOVORILI O NASLEDNJEM:

## ČLEN 1

1. Republika Hrvaška postane članica Evropske unije in Evropske skupnosti za atomsko energijo.
2. Republika Hrvaška postane pogodbenica Pogodbe o Evropski uniji, Pogodbe o delovanju Evropske unije in Pogodbe o ustanovitvi Evropske skupnosti za atomsko energijo, kakor so bile spremenjene ali dopolnjene.
3. Pogoji sprejema in prilagoditve pogodb iz odstavka 2, ki so potrebne zaradi sprejema Hrvaške, so navedeni v Aktu, ki je priložen tej pogodbi. Določbe Akta so sestavni del te pogodbe.

## ČLEN 2

V zvezi s to pogodbo se uporabljajo določbe o pravicah in obveznostih držav članic ter o pooblastilih in pristojnostih institucij Unije, kakor so navedene v pogodbah, katerih pogodbenica postane Republika Hrvaška na podlagi člena 1(2).

## ČLEN 3

1. Visoke pogodbenice ratificirajo to pogodbo v skladu s svojimi ustavnimi pravili. Listine o ratifikaciji se deponirajo pri vladi Italijanske republike do 30. junija 2013.

2. S tem, ko Republika Hrvaška ratificira to pogodbo, se šteje, da ratificira ali odobri tudi vse spremembe pogodb iz člena 1(2), ki so ob ratifikaciji te pogodbe s strani Hrvaške na voljo državam članicam za ratifikacijo ali odobritev v skladu s členom 48 Pogodbe o Evropski uniji, in vse akte institucij, ki se sprejemajo prav v tem času, veljati pa začnejo šele po tem, ko jih odobrijo države članice v skladu s svojimi ustavnimi pravili.
3. Ta pogodba začne veljati 1. julija 2013 pod pogojem, da so vse listine o ratifikaciji deponirane pred tem datumom.
4. Ne glede na odstavek 3 lahko institucije Unije pred pristopom sprejmejo ukrepe iz člena 3(7), drugega pododstavka člena 6(2), drugega pododstavka člena 6(3), drugega in tretjega pododstavka člena 6(6), drugega pododstavka člena 6(7), tretjega pododstavka člena 6(8), členov 17, 29(1), 30(5), 31(5), 35(3) in (4), 38, 39, 41, 42, 43, 44, 49, 50 in 51 ter prilog IV do VI Akta iz člena 1(3).

Ti ukrepi začnejo veljati le pod pogojem, da ta pogodba začne veljati, z dnem začetka njene veljavnosti.

5. Ne glede na odstavek 3 se člen 36 Akta, navedenega v členu 1(3), uporablja od podpisa te pogodbe.

## ČLEN 4

Ta pogodba, sestavljena v enem izvirniku v angleškem, bolgarskem, češkem, danskem, estonskem, finskem, francoskem, grškem, hrvaškem, irskem, italijanskem, latvijskem, litovskem, madžarskem, malteškem, nemškem, nizozemskem, poljskem, portugalskem, romunskem, slovaškem, slovenskem, švedskem in španskem jeziku, pri čemer so besedila v vseh teh jezikih enako verodostojna, se deponira v arhivu vlade Italijanske republike, ki bo poslala overjeno kopijo vsem vladam drugih držav podpisnic.

В ПОТВЪРЖДЕНИЕ НА КОЕТО, долуподписаните упълномощени представители подписаха настоящия договор.

EN FE DE LO CUAL, los plenipotenciarios abajo firmantes suscriben el presente Tratado.

NA DŮKAZ ČEHOŽ připojili níže podepsaní zplnomocnění zástupci k této smlouvě své podpisy.

TIL BEKRÆFTELSE HERAF har undertegnede befudmægtigede underskrevet denne traktat.

ZU URKUND DESSEN haben die unterzeichneten Bevollmächtigten ihre Unterschriften unter diesen Vertrag gesetzt.

SELLE KINNITUSEKS on nimetatud täievolilised esindajad käesolevale lepingule alla kirjutanud.

ΣΕ ΠΙΣΤΩΣΗ ΤΩΝ ΑΝΩΤΕΡΩ, οι κάτωθι υπογεγραμμένοι πληρεξούσιοι υπέγραψαν την παρούσα Συνθήκη.

IN WITNESS WHEREOF the undersigned Plenipotentiaries have signed this Treaty.

EN FOI DE QUOI, les plénipotentiaires soussignés ont apposé leurs signatures au bas du présent traité.

DÁ FHIANÚ SIN, chuir na Lánchumhachtaigh thíos-sínithe a lámh leis an gConradh seo.

U POTVRDU TOGA niže potpisani opunomočenici potpisali su ovaj Ugovor.

IN FEDE DI CHE, i plenipotenziali sottoscritti hanno apposto le loro firme in calce al presente trattato.

TO APLIECINOT, Pilnvarotie ir parakstījuši šo Līgumu.

TAI PALIUDYDAMI šią Sutartį pasirašė toliau nurodyti īgaliotieji atstovai.

FENTIEK HITELÉÜL az alulírott meghatalmazottak aláírták ezt a szerződést.

B'XIEHDA TA' DAN il-Plenipotenzjarji sottoscritti iffirmaw dan it-Trattat.

TEN BLIJKE WAARVAN de ondergetekende gevoldmachigden hun handtekening onder dit Verdrag hebben gesteld.

W DOWÓD CZEGO niżej podpisani pełnomocnicy złożyli swoje podpisy pod niniejszym Traktatem.

EM FÉ DO QUE, os plenipotenciários abaixo-assinados apuseram as suas assinaturas no final do presente Tratado.

DREPT CARE subsemnații plenipotențiari au semnat prezentul tratat.

NA DÔKAZ TOHO splnomocnení zástupcovia podpísali túto zmluvu.

V POTRDITEV TEGA so spodaj podpisani pooblaščenci podpisali to pogodbo.

TÄMÄN VAKUUDEKSI ALLA MAINITUT täysivaltaiset edustajat ovat allekirjoittaneet tämän sopimuksen.

SOM BEKRÄFTELSE PÅ DETTA har undertecknade befullmäktigade ombud undertecknat detta  
fördrag.

[To be inserted in all the official languages: 'Done at...on the...in the year.]

Pour Sa Majesté le Roi des Belges  
Voor Zijne Majesteit de Koning der Belgen  
Für Seine Majestät den König der Belgier

Cette signature engage également la Communauté française, la Communauté flamande, la Communauté germanophone, la Région wallonne, la Région flamande et la Région de Bruxelles-Capitale.

Deze handtekening verbindt eveneens de Vlaamse Gemeenschap, de Franse Gemeenschap, de Duitstalige Gemeenschap, het Vlaamse Gewest, het Waalse Gewest en het Brussels Hoofdstedelijk Gewest.

Diese Unterschrift bindet zugleich die Deutschsprachige Gemeinschaft, die Flämische Gemeinschaft, die Französische Gemeinschaft, die Wallonische Region, die Flämische Region und die Region Brüssel-Hauptstadt.

За Република България

Za prezidenta České republiky

For Hennes Majestæt Danmarks Dronning

Für den Präsidenten der Bundesrepublik Deutschland

Eesti Vabariigi Presidendi nimel

Thar ceann Uachtaráin na hÉireann

For the President of Ireland

Για τον Πρόεδρο της Ελληνικής Δημοκρατίας

Por Su Majestad el Rey de España

Pour le Président de la République française

['Insert entry for Croatia']

Per il Presidente della Repubblica italiana

Για τον Πρόεδρο της Κυπριακής Δημοκρατίας

Latvijas Republikas Valsts prezidenta vārdā

Lietuvos Respublikos Prezidento vardu

Pour Son Altesse Royale le Grand-Duc de Luxembourg

A Magyar Köztársaság Elnöke részéről

Għall-President ta' Malta

Voor Hare Majesteit de Koningin der Nederlanden

Für den Bundespräsidenten der Republik Österreich

Za Prezydenta Rzeczypospolitej Polskiej

Pelo Presidente da República Portuguesa

Pentru Președintele României

Za predsednika Republike Slovenije

Za prezidenta Slovenskej republiky

Suomen Tasavallan Presidentin puolesta

För Republiken Finlands President

För Konungariket Sveriges regering

For Her Majesty the Queen of the United Kingdom of Great Britain and Northern Ireland

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## **AKT**

# **o pogojih pristopa Republike Hrvaške in o prilagoditvah Pogodbe o Evropski uniji, Pogodbe o delovanju Evropske unije in Pogodbe o ustanovitvi Evropske skupnosti za atomsko energijo**

## **PRVI DEL**

### **NAČELA**

#### **ČLEN 1**

V tem aktu:

- izraz "izvirne pogodbe" pomeni:
  - (a) Pogodbo o Evropski uniji ("PEU") in Pogodbo o delovanju Evropske unije ("PDEU"), kakor sta bili spremenjeni ali dopolnjeni s pogodbami ali drugimi akti, ki so začeli veljati pred pristopom Republike Hrvaške;
  - (b) Pogodbo o ustanovitvi Evropske skupnosti za atomsko energijo ("Pogodba ESAE"), kakor je bila spremenjena ali dopolnjena s pogodbami ali drugimi akti, ki so začeli veljati pred tem pristopom;
- izraz "sedanje države članice" pomeni Kraljevino Belgijo, Republiko Bolgarijo, Češko republiko, Kraljevino Dansko, Zvezno republiko Nemčijo, Republiko Estonijo, Irsko, Helensko republiko, Kraljevino Španijo, Francosko republiko, Italijansko republiko, Republiko Ciper, Republiko Latvijo, Republiko Litvo, Veliko vojvodstvo Luksemburg, Republiko Madžarsko, Republiko Malto, Kraljevino Nizozemsko, Republiko Avstrijo, Republiko Poljsko, Portugalsko republiko, Romunijo, Republiko Slovenijo, Slovaško republiko, Republiko Finsko, Kraljevino Švedsko ter Združeno kraljestvo Velika Britanija in Severna Irska;

- izraz "Unija" pomeni Evropsko unijo, temelječo na PEU in na PDEU, in/ali v ustreznih primerih Evropsko skupnost za atomsko energijo;
- izraz "institucije" pomeni institucije, ustanovljene s PEU.

## ČLEN 2

Z dnem pristopa so določbe izvirnih pogodb in aktov, ki so jih institucije sprejele pred pristopom, za Hrvaško zavezajoče in se v njej uporabljajo pod pogoji, ki jih določajo zadevne pogodbe in ta akt.

Če se predstavniki vlad držav članic dogovorijo o spremembi izvirnih pogodb na podlagi člena 48(4) PEU po ratifikaciji Pristopne pogodbe s strani Hrvaške in te ne začnejo veljati pred dnem pristopa, Hrvaška te spremembe ratificira v skladu s svojimi ustavnimi pravili.

## ČLEN 3

1. Hrvaška pristopi k sklepom in sporazumom, ki so jih sprejeli voditelji držav ali vlad držav članic v okviru Sveta.
2. Hrvaška pristopi k sklepom in sporazumom, ki so jih sprejeli predstavniki vlad držav članic v okviru Sveta.

3. Hrvaška je v zvezi z izjavami ali resolucijami ali drugimi stališči Evropskega sveta ali Sveta in v zvezi s tistimi, ki zadevajo Unijo in so jih države članice sprejele v medsebojnem soglasju, v enakem položaju kakor sedanje države članice. Hrvaška bo ustreznou temu spoštovala načela in smernice, izhajajoče iz teh izjav, resolucij ali drugih stališč, ter sprejela ukrepe, ki so potrebni za zagotovitev njihovega izvajanja.
4. Hrvaška pristopi h konvencijam in protokolom s seznama v Prilogi I. Te konvencije in protokoli začnejo za Hrvaško veljati na dan, ki ga določi Svet v sklepih iz odstavka 5.
5. Svet na priporočilo Komisije in po posvetovanju z Evropskim parlamentom soglasno sprejme vse prilagoditve konvencij in protokolov iz odstavka 4, ki so potrebne zaradi pristopa, ter prilagojena besedila objavi v Uradnem listu Evropske unije.
6. Hrvaška se glede konvencij in protokolov iz odstavka 4 zavezuje, da bo uvedla takšne upravne in druge rešitve, kot so jih do dne pristopa sprejele sedanje države članice ali Svet, in zagotavlja lažje praktično sodelovanje med institucijami in organi ter telesi držav članic.
7. Svet lahko na predlog Komisije Priloga I soglasno dopolni z zadevnimi konvencijami, sporazumi in protokoli, podpisanimi pred dnem pristopa.

## ČLEN 4

1. Določbe schengenskega pravnega reda iz Protokola o schengenskem pravnem redu, vključenega v okvir Evropske unije (v nadalnjem besedilu: schengenski protokol), ki je priložen PEU in PDEU, in akti, ki temeljijo na njem ali so z njim kako drugače povezani, navedeni v Prilogi II, ter vsi drugi takšni akti, sprejeti pred dnem pristopa, so za Hrvaško zavezujoči in se na Hrvaškem uporabljajo z dnem pristopa.
2. Določbe schengenskega pravnega reda, kakor so vključene v okvir Evropske unije, in akti, ki na njem temeljijo ali so z njim kako drugače povezani in v odstavku 1 niso omenjeni ter so za Hrvaško zavezujoči z dnem pristopa, se na Hrvaškem uporabljajo šele na podlagi ustreznega sklepa Sveta, potem ko se v skladu z veljavnimi schengenskimi postopki evalvacije preveri, ali so na Hrvaškem izpolnjeni potrebni pogoji za uporabo vseh delov zadevnega pravnega reda, tudi za učinkovito uporabo vseh schengenskih pravil v skladu z dogovorjenimi skupnimi standardi in temeljnimi načeli. Svet sprejme ta sklep v skladu z veljavnimi schengenskimi postopki in ob upoštevanju poročila Komisije, ki potrjuje, da Hrvaška še naprej izpolnjuje svoje obveznosti iz pristopnih pogajanj v zvezi s schengenskim pravnim redom.

Svet odloča po posvetovanju z Evropskim parlamentom s soglasjem svojih članov, ki zastopajo vlade držav članic, za katere določbe tega odstavka že veljajo, in predstavnika vlade Republike Hrvaške. Člani Sveta, ki zastopajo vlasti Irske ter Združenega kraljestva Velike Britanije in Severne Irske, sodelujejo pri sprejemanju tega sklepa, kolikor se ta nanaša na določbe schengenskega pravnega reda in na akte, ki na njem temeljijo ali so z njim kako drugače povezani, pri katerih ti državi članici sodelujeta.

## ČLEN 5

Hrvaška od dne pristopa sodeluje v ekonomski in monetarni uniji kot država članica z odstopanjem v smislu člena 139 PDEU.

## ČLEN 6

1. Sporazumi, ki jih sklene ali začasno uporablja Unija z eno ali več tretjimi državami, mednarodno organizacijo ali državljanom tretje države, so pod pogoji iz izvirnih pogodb in tega akta za Hrvaško zavezajoči.
2. Hrvaška se zavezuje, da bo pod pogoji iz tega akta pristopila k sporazumom, ki so jih z eno ali več tretjimi državami ali mednarodno organizacijo sklenile ali podpisale sedanje države članice in Unija.

Razen če posamezni sporazumi iz prvega pododstavka ne določajo drugače, se pristop Hrvaške k takim sporazumom uredi s sklenitvijo protokolov k tem sporazumom med Svetom, ki odloča soglasno v imenu držav članic, in tretjo zadevno državo oziroma tretjimi državami ali zadevno mednarodno organizacijo. O teh protokolih se v imenu držav članic na podlagi pogajalskih smernic, ki jih soglasno odobri Svet, in ob posvetovanju z odborom, ki ga sestavljajo predstavniki držav članic, pogaja Komisija oziroma – če sporazum zadeva izključno ali pretežno skupno zunanjo in varnostno politiko – visoki predstavnik Unije za zunanje zadeve in varnostno politiko. Komisija Svetu predloži osnutke protokolov, ki jih je treba skleniti.

Ta postopek ne posega v izvajanje lastnih pristojnosti Unije in ne vpliva na razdelitev pristojnosti med Unijo in državami članicami glede prihodnjega sklepanja takih sporazumov ali glede katerih koli drugih sprememb, ki niso povezane s pristopom.

3. Hrvaška od dne pristopa in do začetka veljavnosti potrebnih protokolov iz drugega pododstavka odstavka 2 uporablja določbe sporazumov, omenjenih v prvem pododstavku odstavka 2, ki so bili sklenjeni ali so se začasno uporabljali pred dnem pristopa, z izjemo Sporazuma med Evropsko skupnostjo in njenimi državami članicami na eni strani ter Švicarsko konfederacijo na drugi o prostem pretoku oseb<sup>1</sup>.

Do začetka veljavnosti protokolov iz drugega pododstavka odstavka 2, Unija in države članice skupaj v okviru svojih pristojnosti sprejmejo ustrezne ukrepe.

4. Hrvaška pristopi k Sporazumu o partnerstvu med članicami skupine afriških, karibskih in pacifiških držav (AKP) na eni strani ter Evropsko skupnostjo in njenimi državami članicami na drugi, podpisanim 23. junija 2000<sup>2</sup> v Cotonouju, in k sporazumu o prvi spremembi Sporazuma, podpisanimu 25. junija 2005<sup>3</sup> v Luxembourggu, in k sporazumu o drugi spremembi Sporazuma, danemu na voljo za podpis 22. junija 2010 v Ouagadougouju<sup>4</sup>.
5. Hrvaška se zavezuje, da pod pogoji iz tega akta pristopi k Sporazumu o Evropskem gospodarskem prostoru<sup>5</sup> v skladu s členom 128 tega sporazuma.
6. Od dne pristopa Hrvaška uporablja dvostranske sporazume in dogovore o tekstu, ki jih je Unija sklenila s tretjimi državami.

Količinske omejitve, ki jih Unija uporablja za uvoz tekstilnih izdelkov in oblačil, se prilagodijo tako, da se upošteva pristop Hrvaške k Uniji. V ta namen lahko Unija spremembo dvostranskih sporazumov in dogоворов iz prvega pododstavka doseže v pogajanjih z zadevnimi tretjimi državami pred dnem pristopa.

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<sup>1</sup> UL L 114, 30.4.2002, str. 6.

<sup>2</sup> UL L 317, 15.12.2000, str. 3.

<sup>3</sup> UL L 209, 11.8.2005, str. 27, UL L 287, 28.10.2005, str. 49, in UL L 168M, 21.6.2006, str. 33.

<sup>4</sup> UL L 287, 4.11.2010, str. 3.

<sup>5</sup> UL L 1, 3.1.1994, str. 3.

Če spremembe dvostranskih sporazumov in dogоворов o текстилу ne začnejo veljati do dne pristopa, Unija sprejme potrebne prilagoditve svojih pravil za uvoz tekstilnih izdelkov in oblačil iz tretjih držav, tako da se upošteva pristop Hrvaške k Uniji.

7. Količinske omejitve, ki jih Unija uporablja pri uvozu jekla in izdelkov iz jekla, se prilagodijo na podlagi uvoza izdelkov iz jekla s poreklom iz zadavnih držav dobaviteljc v Hrvaško v zadnjih letih.

V ta namen se pred dnem pristopa v pogajanjih dosežejo potrebne spremembe dvostranskih sporazumov in dogоворов o jeklu ki jih je Unija sklenila s tretjimi državami.

Če spremembe dvostranskih sporazumov in dogоворов ne začnejo veljati do dne pristopa, se uporabijo določbe prvega pododstavka.

8. Od dne pristopa sporazume o ribištvu, ki jih je Hrvaška sklenila s tretjimi državami pred pristopom, upravlja Unija.

Pravice in obveznosti Hrvaške, ki izhajajo iz teh sporazumov, ostanejo v obdobju, v katerem se določbe teh sporazumov prehodno ohranjajo, nespremenjene.

Čim prej, vsekakor pa pred prenehanjem veljavnosti sporazumov iz prvega pododstavka, Svet na predlog Komisije s kvalificirano večino za vsak posamezen primer ustrezno odloči o nadaljevanju ribiških dejavnosti, ki izhajajo iz teh sporazumov, vključno z možnostjo podaljšanja nekaterih sporazumov za obdobje največ enega leta.

9. Hrvaška odstopi od morebitnih sporazumov o prosti trgovini, sklenjenih s tretjimi državami, vključno s Srednjeevropskim sporazumom o prosti trgovini, kakor je bil spremenjen.

Kolikor sporazumi med Hrvaško na eni strani in eno ali več tretjimi državami na drugi niso združljivi z obveznostmi, ki izhajajo iz tega akta, Hrvaška ukrene vse potrebno, da odpravi ugotovljene neskladnosti. Če se Hrvaška sooči s težavami pri prilagoditvi sporazuma, ki ga je sklenila z eno ali več tretjimi državami, od tega sporazuma odstopi.

Hrvaška z vsemi potrebnimi ukrepi poskrbi za izpolnjevanje obveznosti iz tega odstavka od dne pristopa.

10. Hrvaška pod pogoji iz tega akta pristopi k notranjim sporazumom, ki so jih sedanje države članice sklenile za izvajanje sporazumov iz odstavkov 2 in 4.
11. Hrvaška z ustreznimi ukrepi po potrebi prilagodi svoj položaj v razmerju do mednarodnih organizacij in do tistih mednarodnih sporazumov, katerih pogodbenica je tudi Unija ali druge države članice, glede na pravice in obveznosti, ki izhajajo iz pristopa Hrvaške k Uniji.

Hrvaška zlasti odstopi od mednarodnih sporazumov o ribištvu in izstopi iz mednarodnih organizacij za ribištvo, katerih pogodbenica oziroma članica je tudi Unija, razen če se njen članstvo nanaša na zadeve, ki niso povezane z ribištvom.

Hrvaška z vsemi potrebnimi ukrepi poskrbi za izpolnjevanje obveznosti iz tega odstavka od dne pristopa.

## ČLEN 7

1. Določbe tega akta ne smejo biti, razen če v njem ni določeno drugače, začasno odložene, spremenjene ali razveljavljene drugače kakor po postopku, določenem v izvirnih pogodbah, ki omogoča revizijo teh pogodb.
2. Akti, ki so jih sprejele institucije in na katere se nanašajo prehodne določbe iz tega akta, ohranijo svojo pravno naravo; zlasti se še naprej uporabljajo postopki za spremištanje teh aktov.
3. Določbe tega akta, katerih namen ali učinek je, drugače kakor začasno razveljaviti ali spremeniti akte, ki so jih sprejele institucije, imajo isto pravno naravo kakor določbe, ki jih razveljavljajo ali spreminjajo, in zanje veljajo enaka pravila kot za te določbe.

## ČLEN 8

Pri uporabi izvirnih pogodb in aktov, ki so jih sprejele institucije, veljajo odstopanja, predvidena v tem aktu kot prehodni ukrep.

**DRUGI DEL**

**PRILAGODITVE POGODB**

**NASLOV I**

**INSTITUCIONALNE DOLOČBE**

**ČLEN 9**

Protokol o Statutu Sodišča Evropske unije, ki je priložen PEU, PDEU in Pogodbi ESAE, se spremeni:

1. V členu 9 se prvi odstavek nadomesti z naslednjim:

"Ko se vsaka tri leta izvede delna zamenjava sodnikov, se zamenja 14 sodnikov."

2. Člen 48 se nadomesti z naslednjim:

"Splošno sodišče ima 28 sodnikov."

ČLEN 10

Protokol o Statutu Evropske investicijske banke, ki je priložen PEU, PDEU in Pogodbi o ESAE, se spremeni:

1. V prvem pododstavku člena 4(1)

- (a) se uvodni stavek nadomesti z naslednjim:

"1. Kapital banke je 233 247 390 000 EUR, države članice pa so vpisale naslednje deleže.";

- (b) med vnosa za Romunijo in Slovaško se vstavi naslednje:

"Hryaška 854 400 000 EUR".

2. V členu 9(2) se prvi, drugi in tretji podostavek nadomestijo z naslednjim:

"2. Svet direktorjev sestavlja devetindvajset direktorjev in devetnaist namestnikov direktorjev.

Direktorje imenuje svet guvernerjev za pet let, po enega predлага vsaka država članica in enega predлага Komisija.

Namestnike direktorjev imenuje svet guvernerjev za pet let, kakor sledi:

- dva namestnika predlaga Zvezna republika Nemčija,
  - dva namestnika predlaga Francoska republika,

- dva namestnika predlaga Italijanska republika,
- dva namestnika predlaga Združeno kraljestvo Velika Britanija in Severna Irska,
- enega namestnika v medsebojnem soglasju predlagata Kraljevina Španija in Portugalska republika,
- enega namestnika v medsebojnem soglasju predlagajo Kraljevina Belgija, Veliko vojvodstvo Luksemburg in Kraljevina Nizozemska,
- dva namestnika v medsebojnem soglasju predlagajo Kraljevina Danska, Helenska republika, Irska in Romunija,
- dva namestnika v medsebojnem soglasju predlagajo Republika Estonija, Republika Latvija, Republika Litva, Republika Avstrija, Republika Finska in Kraljevina Švedska,
- štiri namestnike v medsebojnem soglasju predlagajo Republika Bolgarija, Češka republika, Republika Hrvaška, Republika Ciper, Republika Madžarska, Republika Malta, Republika Poljska, Republika Slovenija in Slovaška republika,
- enega namestnika predлага Komisija.".

## ČLEN 11

Prvi pododstavek člena 134(2) Pogodbe ESAE o sestavi Znanstveno-tehničnega odbora se nadomesti z naslednjim:

"2. Odbor ima dvainštirideset članov, ki jih Svet imenuje po posvetovanju s Komisijo.".

## NASLOV II

### **DRUGE PRILAGODITVE**

#### **ČLEN 12**

V členu 64(1) PDEU se doda naslednji stavek:

"Glede omejitev, ki veljajo v nacionalnem pravu na Hrvaškem, je ustrezen datum 31. december 2002."

#### **ČLEN 13**

Člen 52(1) PEU se nadomesti z naslednjim:

"1. Pogodbi se uporabljata za Kraljevino Belgijo, Republiko Bolgarijo, Češko republiko, Kraljevino Dansko, Zvezno republiko Nemčijo, Republiko Estonijo, Irsko, Helensko republiko, Kraljevino Španijo, Francosko republiko, Republiko Hrvaško, Italijansko republiko, Republiko Ciper, Republiko Latvijo, Republiko Litvo, Veliko vojvodstvo Luksemburg, Republiko Madžarsko, Republiko Malto, Kraljevino Nizozemsko, Republiko Avstrijo, Republiko Poljsko, Portugalsko republiko, Romunijo, Republiko Slovenijo, Slovaško republiko, Republiko Finsko, Kraljevino Švedsko ter Združeno kraljestvo Velika Britanija in Severna Irska."

## ČLEN 14

1. Člen 55(1) PEU se nadomesti z naslednjim:

"1. Ta pogodba, sestavljena v enem izvirniku v angleškem, bolgarskem, češkem, danskem, estonskem, finskem, francoskem, grškem, hrvaškem, irskem, italijanskem, latvijskem, litovskem, madžarskem, malteškem, nemškem, nizozemskem, poljskem, portugalskem, romunskem, slovaškem, slovenskem, švedskem in španskem jeziku, pri čemer so besedila v vseh teh jezikih enako verodostojna, se deponira v arhivu vlade Italijanske republike, ki bo poslala overjeno kopijo vsem vladam drugih držav podpisnic."

2. Drugi odstavek člena 225 Pogodbe ESAE se nadomesti z naslednjim:

"V skladu s pristopnimi pogodbami so verodostojne tudi različice te pogodbe v angleškem, bolgarskem, češkem, danskem, estonskem, finskem, grškem, hrvaškem, irskem, latvijskem, litovskem, madžarskem, malteškem, poljskem, portugalskem, romunskem, slovaškem, slovenskem, španskem in švedskem jeziku."

## TRETJI DEL

### **TRAJNE DOLOČBE**

#### **ČLEN 15**

Akti, našteti v Prilogi III k temu aktu, se prilagodijo, kakor je določeno v navedeni prilogi.

#### **ČLEN 16**

Ukrepi, našteti v Prilogi IV k temu aktu, se uporabijo pod pogoji, ki jih določa navedena priloga.

#### **ČLEN 17**

Svet lahko na predlog Komisije in po posvetovanju z Evropskim parlamentom soglasno sprejme prilagoditve določb tega akta glede skupne kmetijske politike, ki bi se izkazale za potrebne zaradi spremembe pravil Unije.

## **ČETRTI DEL**

### **ZAČASNE DOLOČBE**

#### **NASLOV I**

#### **PREHODNI UKREPI**

#### **ČLEN 18**

Ukrepi, našteti v Prilogi V k temu aktu, se za Hrvaško uporabijo pod pogoji, ki jih določa navedena priloga.

#### **NASLOV II**

### **INSTITUCIONALNE DOLOČBE**

#### **ČLEN 19**

1. Z odstopanjem od člena 2 Protokola o prehodni ureditvi, priloženega PEU, PDEU in Pogodbi ESAE, in z odstopanjem od največjega možnega števila sedežev, določenega v prvem pododstavku člena 14(2) PEU, se število članov Evropskega parlamenta zaradi upoštevanja pristopa Hrvaške za obdobje od dne pristopa do konca mandatnega obdobia Evropskega parlamenta 2009–2014 poveča za naslednje število članov iz Hrvaške:

Hrvaška	12.
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2. Z odstopanjem od člena 14(3) PEU Hrvaška pred dnem pristopa izvede *ad hoc* splošne neposredne volitve v Evropski parlament, na katerih je v skladu z določbami pravnega reda Unije izvoljeno število članov, določeno v odstavku 1. Vendar pa lahko v primeru, da Hrvaška k EU pristopi manj kot šest mesecev pred naslednjimi volitvami v Evropski parlament, člane Evropskega parlamenta, ki zastopajo hrvaške državljanе, imenuje hrvaški nacionalni parlament iz lastnih vrst, pod pogojem, da so bile zadene osebe izvoljene s splošnim in neposrednim glasovanjem.

## ČLEN 20

Člen 3(3) Protokola o prehodni ureditvi, ki je priložen PEU, PDEU in Pogodbi ESAE, se nadomesti z naslednjim:

"3. Brez poseganja v drugi pododstavek člena 235(1) Pogodbe o delovanju Evropske unije veljajo do 31. oktobra 2014 naslednje določbe:

Pri odločanju Evropskega sveta in Sveta s kvalificirano večino se glasovi članov ponderirajo na naslednji način:

Belgija	12
Bolgarija	10
Češka	12
Danska	7
Nemčija	29
Estonija	4
Irska	7
Grčija	12
Španija	27
Francija	29
Hrvaska	7
Italija	29
Ciper	4
Latvija	4
Litva	7
Luksemburg	4
Madžarska	12
Malta	3
Nizozemska	13
Avstrija	10
Poljska	27
Portugalska	12
Romunija	14
Slovenija	4
Slovaška	7
Finska	7
Švedska	10
Združeno kraljestvo	29

Za sprejetje odločitev je potrebnih najmanj 260 glasov za, ki predstavljajo večino članov, kadar Pogodbe določajo, da morajo biti odločitve sprejete na predlog Komisije. V drugih primerih je za sprejetje odločitev potrebnih najmanj 260 glasov za, ki predstavljajo najmanj dve tretjini članov.

Član Evropskega sveta ali Sveta lahko zahteva, da se, kadar Evropski svet ali Svet sprejema akt s kvalificirano večino, preveri, ali države članice, ki tvorijo to kvalificirano večino, predstavljajo najmanj 62 % celotnega prebivalstva Unije. Če se izkaže, da ta pogoj ni izpolnjen, se akt ne sprejme."

## ČLEN 21

1. Za obdobje od dne pristopa do 31. oktobra 2014 se z dnem pristopa v Komisijo imenuje en državljan Hrvaške. Novega člana Komisije imenuje Svet s kvalificirano večino v skupnem soglasju s predsednikom Komisije, po posvetovanju z Evropskim parlamentom in v skladu z merili iz drugega pododstavka člena 17(3) PEU.
2. Mandat člana, imenovanega v skladu z odstavkom 1, se izteče hkrati z mandatom članov, ki opravljajo funkcijo na dan pristopa.

## ČLEN 22

1. Mandat sodnika Sodišča in sodnika Splošnega sodišča, ki sta ob pristopu imenovana s Hrvaške v skladu s tretjim pododstavkom člena 19(2) PEU, se izteče 6. oktobra 2015 oziroma 31. avgusta 2013.
2. Pri razsojanju na dan pristopa nerešenih zadev, za katere se je ustni postopek začel pred tem dnem, sodišči na občnih sejah ali senati zasedajo v enaki sestavi kakor pred pristopom in uporabljenata poslovnik, veljaven na dan pred dnem pristopa.

## ČLEN 23

1. Z odstopanjem od najvišjega možnega števila članov Ekonomsko-socialnega odbora, določenega v prvem odstavku člena 301 PDEU, se člen 7 Protokola o prehodni ureditvi, ki je priložen PEU, PDEU in Pogodbi ESAE, o sestavi Ekonomsko-socialnega odbora nadomesti z naslednjim:

"Člen 7

Do začetka veljavnosti sklepa iz člena 301 Pogodbe o delovanju Evropske unije je razdelitev števila članov Ekonomsko-socialnega odbora naslednja:

Belgija	12
Bolgarija	12
Česka	12
Danska	9
Nemčija	24
Estonija	7
Irska	9
Grčija	12
Španija	21
Francija	24
Hrvaška	9
Italija	24
Ciper	6
Latvija	7
Litva	9
Luksemburg	6
Madžarska	12
Malta	5
Nizozemska	12
Avstrija	12
Poljska	21
Portugalska	12
Romunija	15
Slovenija	7
Slovaška	9
Finska	9
Švedska	12
Združeno	24"
kraljestvo	

2. Število članov Ekonomsko-socialnega odbora se zaradi upoštevanja pristopa Hrvaške začasno poveča na 353 za obdobje od dne pristopa do konca mandatnega obdobja, v katerem Hrvaška pristopi k Evropski uniji, oziroma do začetka veljavnosti sklepa iz drugega odstavka člena 301 PDEU (kar nastopi prej).
3. Če je sklep iz drugega odstavka člena 301 PDEU sprejet še pred dnem pristopa, se Hrvaški z odstopanjem od najvišjega možnega števila članov Ekonomsko-socialnega odbora, določenega v prvem odstavku člena 301 PDEU, do konca mandatnega obdobja, v katerem pristopi k Evropski uniji, začasno dodeli ustrezno število članov.

#### ČLEN 24

1. Z odstopanjem od najvišjega možnega števila članov Odbora regij, določenega v prvem odstavku člena 305 PDEU, se člen 8 Protokola o prehodni ureditvi, ki je priložen PEU, PDEU in Pogodbi ESAE, o sestavi Odbora regij nadomesti z naslednjim:

"Člen 8

Do začetka veljavnosti sklepa iz člena 305 Pogodbe o delovanju Evropske unije je razdelitev števila članov Odbora regij naslednja:

Belgija	12
Bolgarija	12
Česka	12
Danska	9
Nemčija	24
Estonija	7
Irska	9
Grčija	12
Španija	21
Francija	24
Hrvaška	9
Italija	24
Ciper	6
Latvija	7
Litva	9
Luksemburg	6
Madžarska	12
Malta	5
Nizozemska	12
Avstrija	12
Poljska	21
Portugalska	12
Romunija	15
Slovenija	7
Slovaška	9
Finska	9
Švedska	12
Združeno kraljestvo	24"

2. Število članov Odbora regij se zaradi upoštevanja pristopa Hrvaške začasno poveča na 353 za obdobje od dne pristopa do konca mandatnega obdobja, v katerem Hrvaška pristopi k Uniji, oziroma do začetka veljavnosti sklepa iz drugega odstavka člena 305 PDEU (kar nastopi prej).
3. Če je sklep iz drugega odstavka člena 305 PDEU sprejet še pred dnem pristopa, se Hrvaški z odstopanjem od najvišjega možnega števila članov Odbora regij, določenega v prvem odstavku člena 305 PDEU, do konca mandatnega obdobja, v katerem pristopi k Uniji, začasno dodeli ustrezno število članov.

#### ČLEN 25

Mandat direktorja, ki ga Hrvaška predlaga v svet direktorjev Evropske investicijske banke in je imenovan po pristopu, kakor je določeno v drugem pododstavku člena 9(2) Protokola o statutu Evropske investicijske banke, se izteče ob koncu letnega srečanja sveta guvernerjev, na katerem se obravnava letno poročilo za finančno leto 2017.

#### ČLEN 26

1. Novi člani odborov, skupin, agencij ali drugih organov, ustanovljenih z izvirnimi pogodbami ali z aktom institucij, se imenujejo pod pogoji in po postopkih, predvidenih za imenovanje članov teh odborov, skupin, agencij ali drugih organov. Mandat novo imenovanih članov se izteče hkrati z mandatom članov, ki opravljajo funkcijo na dan pristopa.
2. Članstvo v odborih, skupinah, agencijah ali drugih organih, ustanovljenih z izvirnimi pogodbami ali z aktom institucij, katerih število članov je stalno in neodvisno od števila držav članic, se ob pristopu v celoti obnovi, razen če se mandat tedanjih članov ne izteče v 12 mesecih od pristopa.

### NASLOV III

#### **FINANČNE DOLOČBE**

##### **ČLEN 27**

1. Z dnem pristopa Hrvaška vplača naslednji znesek, ki ustreza njenemu deležu kapitala, vplačanega za vpisani kapital, kakor je opredeljen v členu 4 Statuta Evropske investicijske banke:

Hrvaška	42 720 000 EUR
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Prispevek se vplača v osmih enakih obrokih, ki zapadejo 30. novembra 2013, 30. novembra 2014, 30. novembra 2015, 31. maja 2016, 30. novembra 2016, 31. maja 2017, 30. novembra 2017 in 31. maja 2018.

2. Hrvaška v osmih enakih obrokih, ki zapadejo na datume, določene v odstavku 1, prispeva k rezervam in rezervacijam v višini rezerv ter tudi k znesku, ki bo šele odobren za rezerve in rezervacije in ki ga določa saldo bilance uspeha na koncu meseca pred pristopom, kot je prikazano v bilanci stanja banke, z zneskom v višini naslednjega odstotka rezerv in rezervacij:

Hrvaška 0,368 %

3. Hrvaška vplača kapital in plačila, določena v odstavku 1 in 2, v gotovini v eurih, razen če svet guvernerjev soglasno ne določi odstopanja.

4. Upravljavski organi Evropske investicijske banke lahko znesek za Hrvaško iz odstavka 1 in iz člena 10(1) prilagodijo s sklepom, sprejetim na podlagi najnovejših končnih podatkov o BDP, ki jih Eurostat objavi pred pristopom.

## ČLEN 28

1. Hrvaška vplača naslednji znesek v Raziskovalni sklad za premog in jeklo iz Sklepa 2002/234/ESPJ predstavnikov vlad držav članic, ki so se sestali v okviru Sveta, z dne 27. februarja 2002 o finančnih posledicah izteka Pogodbe ESPJ in o Raziskovalnem skladu za premog in jeklo

<sup>1</sup>.

(v EUR, *tekoče cene*)

Hrvaška	494 000
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2. Prispevek v Raziskovalni sklad za premog in jeklo se opravi v štirih obrokih z začetkom v letu 2015, vplačanih kot sledi, in vedno na prvi delovni dan prvega meseca v letu:

2015: 15%

2016: 20%

2017: 30%

2018: 35%.

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<sup>1</sup> UL L 79, 22.3.2002, str. 42.

## ČLEN 29

1. Javna naročila, dodeljevanje donacij in plačil iz predpristopne finančne pomoči v okviru komponente pomoči pri prehodu in vzpostavljanja institucij ter komponente čezmejnega sodelovanja iz instrumenta za predpristopno pomoč (IPA)<sup>1</sup>, za sredstva, dodeljena pred pristopom, z izjemo čezmejnih programov Hrvaška-Madžarska in Hrvaška-Slovenija, ter za pomoč v okviru prehodnega vira iz člena 30, od dneva pristopa upravljajo hrvaške izvedbene agencije.

V skladu z merili in pogoji iz člena 56(2) finančne uredbe, ki se uporablja za splošni proračun Evropske unije<sup>2</sup>, in člena 18 izvedbene uredbe o IPA<sup>3</sup> Komisija sprejme sklep o opustitvi predhodnega nadzora Komisije nad javnimi razpisi in dodeljevanjem donacij, ko se prepriča o učinkovitem delovanju zadevnega sistema za upravljanje in nadzor.

Če Komisija sklepa o opustitvi predhodnega nadzora ne sprejme pred dnem pristopa, pogodbe, podpisane med dnem pristopa in dnem sprejetja sklepa Komisije, niso upravičene do predpristopne finančne pomoči in prehodnega vira iz prvega pododstavka.

2. Za proračunske obveznosti, prevzete pred pristopom v okviru predpristopne finančne pomoči in prehodnega vira iz odstavka 1, vključno s sklepanjem in vpisom poznejših posamičnih pravnih zavez in plačil, opravljenih po pristopu, se še naprej uporablja pravila, ki veljajo za predpristopne instrumente financiranja, in se do zaključka zadevnih programov in projektov pripšejo ustreznim proračunskim poglavjem.

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<sup>1</sup> Uredba Sveta (ES) št. 1085/2006 z dne 17. julija 2006 o vzpostavitvi instrumenta za predpristopno pomoč (IPA) (UL L 210, 31.7.2006, str. 82).

<sup>2</sup> Uredba Sveta (ES, Euratom) št. 1605/2002 z dne 25. junija 2002 o finančni uredbi, ki se uporablja za splošni proračun Evropskih skupnosti (UL L 248, 19.9.2002, str. 1).

<sup>3</sup> Uredba Komisije (ES) št. 718/2007 z dne 12. junija 2007 o izvajanju Uredbe Sveta (ES) št. 1085/2006 o vzpostavitvi instrumenta za predpristopno pomoč (IPA), UL L 170, 29.6.2007, str. 1).

3. Določbe o izvajanju proračunskih obveznosti iz sporazumov o financiranju, ki se nanašajo na predpristopno finančno pomoč iz prvega pododstavka odstavka 1 in na komponento razvoja podeželja iz IPA ter zadevajo odločitve o financiranju, sprejete pred pristopom, se uporablajo tudi po dnevu pristopa. Zanje se uporablajo pravila, ki veljajo za predpristopne instrumente financiranja. Ne glede na to se postopki javnega naročanja po pristopu vodijo v skladu z ustreznimi direktivami Evropske unije.
4. Predpristopna sredstva za kritje upravnih stroškov, kot so opredeljena v členu 44, se lahko dodelijo v prvih dveh letih po pristopu. Za stroške revizije in vrednotenja se lahko predpristopna sredstva dodelijo za največ pet let po pristopu.

## ČLEN 30

1. Prvo leto po pristopu Unija Hrvaški zagotavlja začasno finančno pomoč, v nadalnjem besedilu "prehodni vir", za vzpostavljanje in okrepitev njene upravne in sodne zmogljivosti pri izvajanju in izvrševanju zakonodaje Unije in za spodbujanje izmenjave najboljše prakse. S to pomočjo se financirajo projekti za vzpostavljanje institucij in z njimi povezane dodatne omejene naložbe majhnega obsega.
2. Pomoč je namenjena stalni potrebi po okrepitevi institucionalne zmogljivosti na določenih področjih z ukrepi, ki jih ni mogoče financirati iz strukturnih skladov ali skladov za razvoj podeželja.
3. Za projekte tesnega sodelovanja med javnimi upravami za vzpostavljanje institucij bo še naprej veljal postopek razpisa za zbiranje predlogov prek mreže kontaktnih točk v državah članicah.
4. Odobrene pravice za prevzem obveznosti za prehodni vir za Hrvaško v letu 2013 skupaj znašajo 29 milijonov EUR, po trenutnih cenah, in so namenjene obravnavanju nacionalnih in horizontalnih prednostnih področij.

5. Pomoč v okviru prehodnega vira bo določena in se bo izvajala v skladu z Uredbo Sveta (ES) št. 1085/2006 ali na podlagi tehničnih določb, ki so potrebne za delovanje prehodnega vira in jih sprejme Komisija.
  
6. Posebna pozornost je namenjena zagotavljanju ustreznega dopolnjevanja s predvideno podporo iz Evropskega socialnega sklada, ki je namenjena upravni reformi in vzpostavljanju institucionalnih zmogljivosti.

### ČLEN 31

1. Kot začasni instrument se uvede schengenski vir (v nadalnjem besedilu: začasni schengenski vir) za pomoč Hrvaški med dnem pristopa in koncem leta 2014 pri financiranju ukrepov na novih zunanjih mejah Unije za izvajanje schengenskega pravnega reda in kontrole na zunanjih mejah.
  
2. Za obdobje od 1. julija 2013 do leta 2014 se dasta Hrvaški na razpolago naslednja zneska (po trenutnih cenah) v obliki pavšalnih plačil v okviru začasnega schengenskega vira:

(v mio. EUR, po trenutnih cenah)

	2013	2014
Hrvaška	40	80

3. Letni znesek za leto 2013 se Hrvaški izplača 1. julija 2013, letni znesek za leto 2014 pa se da na razpolago prvi delovni dan po 1. januarju 2014.
  
4. Pavšalna plačila se porabijo v treh letih od prvega izplačila. Najkasneje v šestih mesecih po izteku tega triletnega obdobja Hrvaška predloži izčrpno poročilo o končni porabi plačil v okviru začasnega schengenskega vira skupaj z obrazložitvijo porabe. Morebitna neporabljena ali neupravičeno porabljena sredstva se povrnejo Komisiji.

5. Komisija lahko sprejme tehnične določbe, potrebne za delovanje začasnega schengenskega vira.

### ČLEN 32

1. Kot začasni instrument se uvedejo sredstva za denarni tok (v nadaljnjem besedilu: začasna sredstva za denarni tok) za pomoč Hrvaški med dnem pristopa in koncem leta 2014 pri izboljšanju denarnega toka v državnem proračunu.
2. Za obdobje od 1. julija 2013 do 31. decembra 2014 se dasta Hrvaški na razpolago naslednja zneska (po trenutnih cenah) v obliki pavšalnih plačil v okviru začasnih sredstev za denarni tok:

(v mio. EUR, po trenutnih cenah)

	2013	2014
Hrvaška	75	28,6

3. Vsak letni znesek se razdeli v enake mesečne obroke in se plača prvi delovni dan v mesecu.

### ČLEN 33

1. Za Hrvaško se iz naslova strukturnih skladov in Kohezijskega sklada v letu 2013 pridrži dodelitev v višini 449,4 milijona EUR (po trenutnih cenah) v odobritvah za prevzem obveznosti.
2. Ena tretjina dodelitve iz odstavka 1 se pridrži Kohezijskemu skladu

3. Za obdobje naslednjega finančnega okvira se Hrvaški dodeljena sredstva iz strukturnih skladov in Kohezijskega sklada izračunajo na podlagi takrat veljavnega pravnega reda Unije. Ti zneski se nato prilagodijo v skladu z naslednjim razporedom postopnega uvajanja:
  - 70% leta 2014
  - 90 % leta 2015
  - 100 % od leta 2016.
4. Kolikor to dopušča novi pravni red Unije, se opravi prilagoditev, s katero se zagotovi 2,33-kratno povišanje sredstev za Hrvaško v letu 2014 v primerjavi z dodelitvijo za leto 2013, v letu 2015 pa 3-kratno povišanje v primerjavi z dodelitvijo za leto 2013.

#### ČLEN 34

1. Hrvaški se iz naslova Evropskega sklada za ribištvo da na razpolago skupaj 8,7 milijona EUR (po trenutnih cenah) v odobritvah za prevzem obveznosti.
2. Predfinanciranje iz Evropskega sklada za ribištvo znaša 25 % celotne dodelitve iz odstavka 1. Ta znesek se izplača v enem obroku.
3. Za obdobje naslednjega finančnega okvira se Hrvaški dodeljena sredstva izračunajo na podlagi takrat veljavnega pravnega reda Unije. Ti zneski se nato prilagodijo v skladu z naslednjim razporedom postopnega uvajanja:
  - 70% leta 2014
  - 90 % leta 2015
  - 100 % od leta 2016.
4. Kolikor to dopušča novi pravni red Unije, se opravi prilagoditev, s katero se zagotovi 2,33-kratno povišanje sredstev za Hrvaško v letu 2014 v primerjavi z dodelitvijo za leto 2013, v letu 2015 pa 3-kratno povišanje v primerjavi z dodelitvijo za leto 2013.

## ČLEN 35

1. Uredba Sveta (ES) št. 1698/2005 z dne 20. septembra 2005 o podpori za razvoj podeželja iz Evropskega kmetijskega sklada za razvoj podeželja (EKSRP)<sup>1</sup> se v celotnem programskem obdobju 2007–2013 za Hrvaško ne uporablja.

V letu 2013 se Hrvaški iz naslova komponente razvoja podeželja iz člena 12 Uredbe Sveta (ES) št. 1085/2006 dodeli 27,7 milijona EUR.

2. Začasni dodatni ukrepi za razvoj podeželja za Hrvaško so navedeni v Prilogi VI.
3. Komisija lahko z izvedbenimi akti sprejme pravila, potrebna za uporabo določb Priloge VI. Komisija sprejme ukrepe, ki so potrebni v ta namen, po postopku iz člena 90(2) Uredbe Sveta (EC) št. 1698/2005 v povezavi s členom 13(1)(b) Uredbe (EU) št. 182/2011 Evropskega parlamenta in Sveta z dne 16. februarja 2011 o določitvi splošnih pravil in načel, na podlagi katerih države članice nadzirajo izvajanje izvedbenih pooblastil Komisije<sup>2</sup>, ali v skladu z ustreznim postopkom, kot je opredeljen v zakonodaji, ki se uporablja.
4. Svet na predlog Komisije in po posvetovanju z Evropskim parlamentom po potrebi prilagodi določbe Priloge VI, da zagotovi skladnost s predpisi o razvoju podeželja.

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<sup>1</sup> UL L 277, 21.10.2005, str. 1, in UL L 286M, 4.11.2010, str. 26.

<sup>2</sup> UL L 55, 28.2.2011, str. 13.

## NASLOV IV

### DRUGE DOLOČBE

#### ČLEN 36

1. Komisija pozorno spremlja vse zaveze, ki jih je Hrvaška prevzela v pristopnih pogajanjih, vključno z zavezami, ki morajo biti izpolnjene pred pristopom ali na dan pristopa .  
Spremljanje, ki ga izvaja Komisija, zajema redne posodobljene preglednice o spremeljanju, dialog v okviru stabilizacijsko-pridružitvenega sporazuma (SPS)<sup>1</sup>, medsebojne strokovne preglede, predpristopni ekonomski program, a proračunska obvestila in po potrebi zgodnja opozorila hrvaškim oblastem. Svetu in Evropskemu parlamentu bo jeseni 2011 poslano poročilo o napredku in jeseni 2012 izčrpno poročilo o spremeljanju. Komisija se v celotnem procesu spremeljanja opira tudi na prispevek držav članic in po potrebi upošteva prispevek mednarodnih organizacij in organizacij civilne družbe.  
Komisija se bo pri spremeljanju osredotočila zlasti na zaveze, ki jih je Hrvaška prevzela na področju sodstva in temeljnih pravic (Priloga VII), vključno z nadaljnjam doseganjem napredka pri reformi in učinkovitosti pravosodja, nepristranske obravnave vojnih zločinov in boja proti korupciji.

Poleg tega se Komisija pri spremeljanju osredotoči tudi na območje pravice, svobode in varnosti, vključno z izvajanjem in uveljavljanjem zahtev EU v zvezi z upravljanjem zunanjih meja, policijskim sodelovanjem, bojem proti organiziranemu kriminalu ter pravosodnim sodelovanjem v civilnih in kazenskih zadevah, pa tudi na zaveze na področju politike konkurence, vključno s prestrukturiranjem ladjedelniške industrije (Priloga VIII) in prestrukturiranjem jeklarskega sektorja (Priloga IX).

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<sup>1</sup> [Dodati sklicevanje na UL.]

Komisija do pristopa Hrvaške objavlja polletne ocene izvajanja zavez Hrvaške na teh področjih, ki so sestavni del rednih preglednic in poročil o spremeljanju.

2. Če so v procesu spremeljanja ugotovljene težave, lahko Svet na predlog Komisije s kvalificirano večino sprejme vse ustrezne ukrepe. Ti ukrepi se ohranijo le toliko časa, kolikor je to nujno potrebno, in jih Svet v vsakem primeru v skladu z enakim postopkom ukine, ko so zadevne težave odpravljene.

### ČLEN 37

1. Če se do konca obdobja, ki traja največ tri leta po pristopu, na katerem koli gospodarskem področju pojavijo resne težave, ki bi utegnile trajati dalj časa ali bi lahko resno poslabšale gospodarske razmere na določenem območju, lahko Hrvaška zaprosi za dovoljenje za sprejetje zaščitnih ukrepov, da bi nastale razmere odpravila in to področje prilagodila gospodarstvu notranjega trga.

V enakih okoliščinah lahko vsaka sedanja država članica zaprosi za dovoljenje za sprejetje zaščitnih ukrepov proti Hrvaški.

2. Na zaprosilo zadevne države Komisija po hitrem postopku določi zaščitne ukrepe, ki so po njenem mnenju potrebni, ter podrobno opredeli pogoje in način njihovega izvajanja.

V primeru resnih gospodarskih težav Komisija na izrecno zaprosilo zadevne države članice odloči v petih delovnih dneh po prejemu zaprosila, ki so mu priloženi ustrezni podatki. Tako sprejeti ukrepi se začnejo uporabljati takoj, upoštevajo interese vseh zadevnih strank in nimajo za posledico mejnih kontrol.

3. Ukrepi, dovoljeni na podlagi odstavka 2, lahko vsebujejo odstopanja od pravil iz PEU, PDEU in tega akta v takšnem obsegu in za toliko časa, kolikor je nujno potrebno za doseganje ciljev tega zaščitnega ukrepa. Prednost imajo ukrepi, ki kar najmanj ovirajo delovanje notranjega trga.

### ČLEN 38

Če Hrvaška ne izpolni zavez, ki jih je prevzela v okviru pristopnih pogajanj, vključno z zavezami v vseh področnih politikah, povezanih z gospodarskimi dejavnostmi s čezmejnim učinkom, in s tem huje ovira delovanje notranjega trga ali ogrozi finančne interese Unije ali če obstaja neposredna nevarnost takšnega oviranja ali ogroditve, lahko Komisija do konca obdobja, ki traja največ tri leta po pristopu, na obrazloženo zaprosilo države članice ali na lastno pobudo sprejme ustrezne ukrepe.

Ukrepi so sorazmerni, pri čemer imajo prednost tisti, ki kar najmanj ovirajo delovanje notranjega trga, kjer pa je primerno, je treba uporabiti obstoječe sektorske zaščitne mehanizme. Zaščitni ukrepi, sprejeti na podlagi tega člena, se ne smejo uveljavljati kot sredstvo samovoljne diskriminacije ali prikritega omejevanja trgovine med državami članicami. Zaščitna klavzula se lahko na podlagi ugotovitev spremeljanja uveljavlja tudi pred pristopom, sprejeti ukrepi pa začnejo veljati z dnem pristopa, razen če se ne določi kasnejši datum. Ukrepi se ohranijo le toliko časa, kolikor je to nujno potrebno, in so v vsakem primeru ukinjeni, ko je ustrezna zaveza izpolnjena. Dokler ustrezne zaveze niso izpolnjene, pa se ukrepi lahko uporabljam tudi po izteku obdobja, ki je določeno v prvem odstavku. Ob upoštevanju napredka Hrvaške pri izpolnjevanju zavez lahko Komisija ukrepe ustrezno prilagodi. Pred preklicem zaščitnih ukrefov Komisija pravočasno obvesti Svet in ustrezno upošteva morebitne pripombe Sveta v zvezi s tem.

## ČLEN 39

Če na Hrvaškem obstajajo hujše pomanjkljivosti ali neposredna nevarnost takih pomanjkljivosti pri prenosu ali izvajanju aktov, ki so jih institucije sprejele na podlagi naslova V tretjega dela PDEU, in aktov, ki so jih institucije sprejele pred začetkom veljavnosti Lizbonske pogodbe na podlagi naslova VI Pogodbe o Evropski uniji ali naslova IV tretjega dela PEU, lahko Komisija do konca obdobja, ki traja največ tri leta po pristopu, na obrazloženo zaprosilo države članice ali na lastno pobudo in po posvetovanju z državami članicami sprejme ustrezne ukrepe ter podrobno opredeli pogoje in način izvajanja teh ukrepov.

Brez poseganja v nadaljnje tesno pravosodno sodelovanje se lahko ti ukrepi sprejmejo v obliki začasne odložitve izvajanja ustreznih določb in sklepov v odnosih med Hrvaško in katero koli drugo državo članico oziroma drugimi državami članicami. Zaščitna klavzula se lahko na podlagi ugotovitev spremeljanja uveljavlja tudi pred pristopom, sprejeti ukrepi pa začnejo veljati z dnem pristopa, razen če se ne določi kasnejši datum. Ukrepi se ohranijo le toliko časa, kolikor je to nujno potrebno, in so v vsakem primeru ukinjeni, ko so pomanjkljivosti odpravljene. Dokler te pomanjkljivosti niso odpravljene, pa se ukrepi lahko uporabljajo tudi po izteku obdobia, ki je določeno v prejšnjem odstavku. Ob upoštevanju napredka Hrvaške pri odpravljanju ugotovljenih pomanjkljivosti lahko Komisija po posvetovanju z državami članicami ukrepe ustrezno prilagodi. Pred preklicem zaščitnih ukrepov Komisija pravočasno obvesti Svet in ustrezno upošteva morebitne pripombe Sveta v zvezi s tem.

## ČLEN 40

Da ne bi bilo ovirano pravilno delovanje notranjega trga, izvrševanje nacionalnih predpisov Hrvaške v prehodnih obdobjih iz Priloge V ne sme imeti za posledico mejnih kontrol med državami članicami.

## ČLEN 41

Če so potrebni prehodni ukrepi za zagotavljanje lažjega prehoda z obstoječe ureditve na Hrvaškem na ureditev, ki izhaja iz uporabe skupne kmetijske politike pod pogoji iz tega akta, jih Komisija sprejme v skladu s postopkom iz člena 195(2) Uredbe Sveta (ES) št. 1234/2007 z dne 22. oktobra 2007 o vzpostavljivosti skupne ureditve kmetijskih trgov in o posebnih določbah za nekatere kmetijske proizvode ("Uredba o enotni SUT")<sup>1</sup> v povezavi s členom 13(1)(b) Uredbe Evropskega parlamenta in Sveta (EU) št. 182/2011<sup>2</sup> ali v skladu z ustreznim postopkom, kot je opredeljen v zakonodaji, ki se uporablja. Ti ukrepi se lahko sprejmejo v obdobju treh let od dne pristopa, na to obdobje pa je omejena tudi njihova uporaba. Svet lahko na predlog Komisije in po posvetovanju z Evropskim parlamentom soglasno podaljša to obdobje.

Prehodni ukrepi iz prvega pododstavka se lahko po potrebi sprejmejo tudi pred dnem pristopa. Svet navedene ukrepe sprejme s kvalificirano večino na predlog Komisije ali pa jih, če vplivajo na instrumente, ki jih je prvotno sprejela Komisija, v skladu s postopki, potrebnimi za sprejetje zadavnih instrumentov, sprejme Komisija.

## ČLEN 42

Če so potrebni prehodni ukrepi za zagotavljanje lažjega prehoda z obstoječe ureditve na Hrvaškem na ureditev, ki izhaja iz uporabe veterinarskih in fitosanitarnih pravil Evropske unije ter njenih pravil o varnosti hrane, Komisija sprejme take ukrepe v skladu z ustreznim postopkom, kot je opredeljen v zakonodaji, ki se uporablja. Ti ukrepi se sprejmejo v obdobju treh let od dne pristopa, na to obdobje pa je omejena tudi njihova uporaba.

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<sup>1</sup> UL L 299, 16.11.2007, str. 1.

<sup>2</sup> UL L 55, 28.2.2011, str. 13.

## ČLEN 43

Svet s kvalificirano večino na predlog Komisije ugotovi, ali:

- (a) je možna oprostitev vlaganja izstopne skupne deklaracije za proizvode iz člena 28(2) PDEU, ki zapustijo Hrvaško zaradi prečkanja ozemlja Bosne in Hercegovine pri Neumu (po "neumskem koridorju"), in
- (b) vstopne skupne deklaracije za proizvode v okoliščinah iz točke (a), ko ti po prečkanju ozemlja Bosne in Hercegovine pri Neumu ponovno vstopijo na ozemlje Hrvaške.

## ČLEN 44

Komisija lahko sprejme vse ustrezne ukrepe, da se v obdobju največ 18 mesecev po pristopu zagotovi ohranitev potrebnih statutarnih uslužbencev na Hrvaškem. V tem obdobju uradniki ter začasni in pogodbeni uslužbenci, ki so bili na delovna mesta na Hrvaškem razporejeni pred pristopom in ki morajo po dnevu pristopa ostati v službi na Hrvaškem, delajo pod istimi finančnimi in materialnimi pogoji, kot so se uporabljali pred pristopom v skladu s Kadrovskimi predpisi za uradnike Evropskih skupnosti in pogoji za zaposlitev drugih uslužbencev Evropskih skupnosti iz Uredbe Sveta (EGS, Euratom, ESPJ) št. 259/68<sup>1</sup>. Upravni odhodki, vključno s plačami za drugo potrebno osebje, se krijejo iz splošnega proračuna Evropske unije.

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<sup>1</sup> UL L 56, 4.3.1968, str. 1.

## PETI DEL

### **DOLOČBE O IZVAJANJU TEGA AKTA**

#### NASLOV I

#### **PRILAGODITVE STATUTOV IN POSLOVNIKOV INSTITUCIJ IN ODBOROV**

##### **ČLEN 45**

Institucije Unije prilagodijo svoje poslovne potrebam, ki jih narekuje pristop, v skladu z ustreznimi postopki, določenimi v izvirnih pogodbah.

Prilagoditve statutov in poslovnikov odborov, ustanovljenih z izvirnimi pogodbami, ki so potrebne zaradi pristopa, se opravijo čim prej po pristopu.

#### NASLOV II

#### **UPORABA AKTOV INSTITUCIJ**

##### **ČLEN 46**

Hrvaška od dne pristopa velja – v skladu z izvirnimi pogodbami – za eno od naslovlenih direktiv in sklepov v smislu člena 288 PDEU. Z izjemo direktiv in sklepov, ki so začeli veljati skladno s tretjim pododstavkom člena 297(1) in drugim pododstavkom člena 297(2) PDEU, se šteje, da je Hrvaška o zadevnih direktivah in sklepih uradno obveščena ob pristopu.

## ČLEN 47

1. Hrvaška izvede ukrepe, potrebne, da bo od dne pristopa ravnala v skladu z določbami direktiv in sklepov v smislu člena 288 PDEU, razen če v tem aktu ni določen drugačen rok. O teh ukrepih obvesti Komisijo najkasneje do dne pristopa, oziroma, če to storiti kasneje, do roka, določenega v tem aktu.
2. Kolikor spremembe direktiv v smislu člena 288 PDEU, uvedene s tem aktom, zahtevajo prilagoditev zakonov in drugih predpisov sedanjih držav članic, sedanje države članice izvedejo ukrepe, potrebne, da bodo od dne pristopa Hrvaške ravnale v skladu s spremenjenimi direktivami, razen če v tem aktu ni določen drugačen rok. O teh ukrepih obvestijo Komisijo do dne pristopa, oziroma to storijo kasneje v roku, določenem v tem aktu.

## ČLEN 48

Hrvaška v skladu s členom 33 Pogodbe ESAE v treh mesecih po pristopu obvesti Komisijo o določbah zakonodaje in drugih predpisov za zagotovitev varovanja zdravja delavcev in prebivalstva na ozemlju Hrvaške pred nevarnostmi ionizirajočega sevanja.

## ČLEN 49

Na ustrezno utemeljeno zaprosilo, ki ga Hrvaška predloži Komisiji najkasneje do dne pristopa, lahko Svet na predlog Komisije oziroma Komisija, če je sama sprejela izvirni akt, sprejme ukrepe, s katerimi omogoči začasno odstopanje od aktov institucij, sprejetih med 1. julijem 2011 in dnem pristopa. Ukrepi se sprejmejo po pravilih glasovanja, ki urejajo sprejemanje akta, na katerega se nanaša zaprosilo za začasno odstopanje. Če so ta odstopanja sprejeta po pristopu, se lahko uporabljajo z dnem pristopa.

## ČLEN 50

Če je treba akte institucij, sprejete pred pristopom, zaradi pristopa prilagoditi, ta akt ali njegove priloge pa potrebnih prilagoditev ne predvidevajo, Svet na predlog Komisije s kvalificirano večino oziroma Komisija, če je sama sprejela izvirni akt, sprejme potrebne akte v ta namen. Če so te prilagoditve sprejete po pristopu, se lahko uporabljajo z dnem pristopa.

## ČLEN 51

Razen če ta akt ne določa drugače, Svet na predlog Komisije s kvalificirano večino sprejme potrebne ukrepe za izvajanje določb tega akta.

## ČLEN 52

Besedila aktov institucij, ki so sprejeta pred pristopom in so jih institucije sestavile v hrvaškem jeziku, so od dne pristopa enako verodostojna kot besedila, sestavljena v sedanjih uradnih jezikih. Besedila se objavijo v Uradnem listu Evropske unije, če so bila v njem objavljena v sedanjih jezikih.

## NASLOV III

### KONČNE DOLOČBE

## ČLEN 53

Priloge I do IX dodatki k tem prilogam in protokol so sestavnii del tega akta.

## ČLEN 54

Vlada Italijanske republike izroči vladi Republike Hrvaške overjen izvod Pogodbe o Evropski uniji, Pogodbe o delovanju Evropske unije in Pogodbe o ustanovitvi Evropske skupnosti za atomsko energijo ter pogodb, ki jih spreminjajo ali dopolnjujejo, vključno s Pogodbo o pristopu Kraljevine Danske, Irske ter Združenega kraljestva Velika Britanija in Severna Irska, Pogodbo o pristopu Helenske republike, Pogodbo o pristopu Kraljevine Španije in Portugalske republike, Pogodbo o pristopu Republike Avstrije, Republike Finske in Kraljevine Švedske, Pogodbo o pristopu Češke republike, Republike Estonije, Republike Ciper, Republike Latvije, Republike Litve, Republike Madžarske, Republike Malte, Republike Poljske, Republike Slovenije in Slovaške ter Pogodbo o pristopu Republike Bolgarije in Romunije v angleškem, bolgarskem, češkem, danskem, estonskem, finskem, francoskem, grškem, irskem, italijanskem, latvijskem, litovskem, madžarskem, malteškem, nemškem, nizozemskem, poljskem, portugalskem, romunskem, slovaškem, slovenskem, španskem in švedskem jeziku.

Besedila teh pogodb, sestavljena v hrvaškem jeziku, se priložijo temu aktu. Ta besedila so enako verodostojna kot besedila pogodb iz prvega odstavka, sestavljena v sedanjih jezikih.

## ČLEN 55

Generalni sekretar izroči vladi Republike Hrvaške overjeno kopijo mednarodnih sporazumov, deponiranih v arhivu generalnega sekretariata Sveta Evropske unije.

*PRILOGA I*

**Seznam konvencij in protokolov, h katerim pristopi Republika Hrvaška ob pristopu (iz člena  
3(4) Akta o pristopu)**

1. Konvencija z dne 23. julija 1990 o odpravi dvojnega obdavčevanja v zvezi s preračunom dobička povezanih podjetij (UL L 225, 20. 8. 1990, str. 10)
  - Konvencija z dne 21. decembra 1995 o pristopu Republike Avstrije, Republike Finske in Kraljevine Švedske h Konvenciji o odpravi dvojnega obdavčevanja v zvezi s preračunom dobička povezanih podjetij (UL C 26, 31. 1. 1996, str. 1)
  - Protokol z dne 25. maja 1999 o spremembi Konvencije z dne 23. julija 1990 o odpravi dvojnega obdavčevanja v zvezi s preračunom dobička povezanih podjetij (UL C 202, 16. 7. 1999, str. 1)
  - Konvencija z dne 8. decembra 2004 o pristopu Češke republike, Republike Estonije, Republike Ciper, Republike Latvije, Republike Litve, Republike Madžarske, Republike Malte, Republike Poljske, Republike Slovenije in Slovaške republike h Konvenciji o odpravi dvojnega obdavčevanja v zvezi s preračunom dobička povezanih podjetij (UL C 160, 30. 6. 2005, str. 1)
2. Konvencija z dne 26. julija 1995, pripravljena na podlagi člena K.3 Pogodbe o Evropski uniji, o zaščiti finančnih interesov Evropskih skupnosti (UL C 316, 27. 11. 1995, str. 49)
  - Protokol z dne 27. septembra 1996, pripravljen na podlagi člena K.3 Pogodbe o Evropski uniji, h Konvenciji o zaščiti finančnih interesov Evropskih skupnosti (UL C 313, 23. 10. 1996, str. 2)

- Protokol z dne 29. novembra 1996, pripravljen na podlagi člena K.3 Pogodbe o Evropski uniji, o razlagi Konvencije o zaščiti finančnih interesov Evropskih skupnosti s predhodnim odločanjem Sodišča Evropskih skupnosti (UL C 151, 20. 5. 1997, str. 2)
  - Drugi protokol z dne 19. junija 1997, pripravljen na podlagi člena K.3 Pogodbe o Evropski uniji, h Konvenciji o zaščiti finančnih interesov Evropskih skupnosti (UL C 221, 19. 7. 1997, str. 12)
3. Konvencija z dne 26. maja 1997, pripravljena na podlagi člena K.3(2)(c) Pogodbe o Evropski uniji, o boju proti korupciji uradnikov Evropskih skupnosti ali uradnikov držav članic Evropske unije (UL C 195, 25. 6. 1997, str. 2)
  4. Konvencija z dne 18. decembra 1997, pripravljena na podlagi člena K.3 Pogodbe o Evropski uniji, o medsebojni pomoči in sodelovanju med carinskimi upravami (UL C 24, 23. 1. 1998, str. 2)
  5. Konvencija z dne 17. junija 1998 o prepovedi vožnje, sestavljena na podlagi člena K.3 Pogodbe o Evropski uniji (UL C 216, 10. 7. 1998, str. 2)
  6. Konvencija z dne 29. maja 2000, ki jo je Svet pripravil na podlagi člena 34 Pogodbe o Evropski uniji, o medsebojni pravni pomoči v kazenskih zadevah med državami članicami Evropske unije, (UL C 197, 12. 7. 2000, str. 3)
    - Protokol z dne 16. oktobra 2001 h Konvenciji, ki jo je Svet pripravil na podlagi člena 34 Pogodbe o Evropski uniji, o medsebojni pravni pomoči v kazenskih zadevah med državami članicami Evropske unije (UL C 326, 21. 11. 2001, str. 2)

## *PRILOGA II*

**Seznam določb schengenskega pravnega reda, kakor so vključene v okvir Evropske unije, in aktov, ki na njem temeljijo ali so z njim kako drugače povezani, ki so za Republiko Hrvaško zavezujoči in se v njej uporabljajo od pristopa (iz člena 4(1) Akta o pristopu)**

1. Sporazum med vladami držav Gospodarske unije Beneluks, Zvezne republike Nemčije in Francoske republike o postopni odpravi kontrol na skupnih mejah z dne 14. junija 1985.<sup>1</sup>

2. Naslednje določbe Konvencije, podpisane v Schengenu dne 19. junija 1990, o izvajanju Schengenskega sporazuma z dne 14. junija 1985 o postopni odpravi kontrol na skupnih mejah, ter z njo povezana Sklepna listina in skupne izjave<sup>2</sup>, kakor so bile spremenjene z določenimi akti iz odstavka 8 spodaj:

Člen 1, kolikor je povezan z določbami tega odstavka, člen 26, člen 39, členi 44 do 49 (razen člena 47(4) in člena 49(a)), člen 51, členi 54 do 58, člen 62(3), členi 67 do 69, člena 71 in 72, člena 75 in 76, člen 82, člen 91, členi 126 do 130, kolikor so povezani z določbami tega odstavka, člen 136, Skupni izjavi 1 in 3 Sklepne listine.

3. Naslednje določbe sporazumov o pristopu h Konvenciji, podpisani v Schengenu dne 19. junija 1990, o izvajanju Schengenskega sporazuma z dne 14. junija 1985 o postopni odpravi kontrol na skupnih mejah, njihovih sklepnih listin in z njimi povezanih izjav, kakor so bile spremenjene z določenimi akti iz odstavka 8 spodaj:

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<sup>1</sup> UL L 239, 22.9.2000, str. 13.

<sup>2</sup> UL L 239, 22.9.2000, str. 19.

(a) Sporazum, podpisani dne 19. decembra 1996, o pristopu Kraljevine Danske:

- člena 5(2) in 6

(b) Sporazum, podpisani dne 19. decembra 1996, o pristopu Republike Finske:

- člen 5
- Izjava vlade Republike Finske o Ålandskeih otokih v Delu III Sklepne listine

(c) Sporazum, podpisani dne 19. decembra 1996, o pristopu Kraljevine Švedske:

- člen 5.

4. Naslednji sporazumi in dogovori, ki temeljijo na schengenskem pravnem redu, ali so drugače z njim povezani:

- Sporazum z dne 18. maja 1999 med Svetom Evropske unije ter Republiko Islandijo in Kraljevino Norveško o pridružitvi obeh držav k izvajanju, uporabi in razvoju schengenskega pravnega reda, vključno s prilogami, Sklepno listino Sporazuma in priloženimi izjavami in izmenjavami pisem, odobren s Sklepom Sveta 1999/439/ES (UL L 176, 10. 7. 1999, str. 35)
- Sporazum z dne 30. junija 1999, sklenjen med Svetom Evropske unije ter Republiko Islandijo in Kraljevino Norveško o določitvi pravic in obveznosti med Irsko ter Združenim kraljestvom Velika Britanija in Severna Irska na eni strani ter Republiko Islandijo in Kraljevino Norveško na drugi strani na področjih schengenskega pravnega reda, ki velja za te države, odobren s Sklepom Sveta 2000/29/ES (UL L 15, 20. 1. 2000, str.1)

- Sporazum med Evropsko unijo, Evropsko skupnostjo in Švicarsko konfederacijo o pridružitvi Švicarske konfederacije k izvajanju, uporabi in razvoju schengenskega pravnega reda, podpisani 26. oktobra 2004 in odobren s Sklepom Sveta 2008/146/ES in Sklepom Sveta 2008/149/PNZ (UL L 53, 27. 2. 2008, str. 1 in 50)
- Protokol med Evropsko unijo, Evropsko skupnostjo, Švicarsko konfederacijo in Kneževino Lihtenštajn o pristopu Kneževine Lihtenštajn k Sporazumu med Evropsko unijo, Evropsko skupnostjo in Švicarsko konfederacijo o pridružitvi Švicarske konfederacije k izvajanju, uporabi in razvoju schengenskega pravnega reda, podpisani 28. februarja 2008<sup>1</sup>
- Dogovor med Evropsko skupnostjo ter Republiko Islandijo in Kraljevino Norveško o podrobnostih sodelovanja slednjih držav v Evropski agenciji za upravljanje in operativno sodelovanje na zunanjih mejah držav članic Evropske unije, vključno s priloženo skupno izjavo, podpisani 1. februarja 2007 in odobren s Sklepom Sveta 2007/511/ES (UL L 188, 20. 7. 2007, str. 15)
- Dogovor med Evropsko skupnostjo na eni strani ter Švicarsko konfederacijo in Kneževino Lihtenštajn na drugi strani o podrobnostih sodelovanja teh držav v Evropski agenciji za upravljanje in operativno sodelovanje na zunanjih mejah držav članic Evropske unije, vključno s Prilogom in priloženima skupnima izjavama, podpisani 30. septembra 2009 in odobren s Sklepom Sveta 2010/490/EU (UL L 243, 16. 9. 2010, str. 2)

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<sup>1</sup> Do sklenitve tega protokola, če se ta uporablja le začasno. Sklepa Sveta o podpisu sta bila objavljena v UL L 83, 26.3.2008, str. 3 in 5.

- Sporazum med Evropsko skupnostjo ter Republiko Islandijo, Kraljevino Norveško, Švicarsko konfederacijo in Kneževino Lihtenštajn o dopolnilnih pravilih v zvezi s Skladom za zunanje meje za obdobje 2007–2013, vključno s priloženimi izjavami, podpisani 19. marca 2010 in v začasni uporabi v skladu s Sklepom Sveta 2010/374/ES (UL L 169, 3. 7. 2010, str. 22)<sup>1</sup>
5. Določbe naslednjih sklepov Izvršnega odbora, ustanovljenega s Konvencijo, podpisano v Schengenu dne 19. junija 1990, o izvajanju Schengenskega sporazuma z dne 14. junija 1985 o postopni odpravi kontrol na skupnih mejah, kakor so bile spremenjene z določenimi akti iz odstavka 8 spodaj:

SCH/Com-ex (93) 10 Sklep Izvršnega odbora z dne 14. decembra 1993 o izjavah ministrov in državnih sekretarjev

SCH/Com-ex (93) 14 Sklep Izvršnega odbora z dne 14. decembra 1993 o izboljšanju praktičnega sodelovanja sodstva v boju proti nedovoljenemu prometu s prepovedano drogo

SCH/Com-ex (94) 16 rev Sklep Izvršnega odbora z dne 21. novembra 1994 o nabavi enotnih vstopnih in izstopnih žigov

SCH/Com-ex (94) 28 rev Sklep Izvršnega odbora z dne 22. decembra 1994 o potrdilu iz člena 75 za prenašanje prepovedanih drog in psihotropnih substanc

SCH/Com-ex (94) 29 rev 2 Sklep Izvršnega odbora z dne 22. decembra 1994 o uveljavitvi Konvencije o izvajanju Schengenskega sporazuma z dne 19. junija 1990

SCH/Com-ex (95) 21 Sklep Izvršnega odbora z dne 20. decembra 1995 o hitri izmenjavi statističnih in specifičnih podatkov med schengenskimi državami o možnih nepravilnostih na zunanjih mejah

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<sup>1</sup> Do sklenitve tega sporazuma, če se ta uporablja začasno.

SCH/Com-ex (98) 1 rev 2 Sklep Izvršnega odbora z dne 21. aprila 1998 o dejavnostih delovne skupine, kolikor se nanaša na določbe odstavka 2 zgoraj

SCH/Com-ex (98) 26 def Sklep Izvršnega odbora z dne 16. septembra 1998 o ustanovitvi stalnega odbora Konvencije o izvajanju Schengenskega sporazuma

SCH/Com-ex (98) 37 def 2 Sklep Izvršnega odbora z dne 27. oktobra 1998 o sprejetju ukrepov za boj proti ilegalnim migracijam, kolikor se nanaša na določbe odstavka 2 zgoraj

SCH/Com-ex (98) 52 Sklep Izvršnega odbora z dne 16. decembra 1998 o Priročniku o čezmejnem policijskem sodelovanju, kolikor se nanaša na določbe odstavka 2 zgoraj

SCH/Com-ex (98) 59 rev Sklep Izvršnega odbora z dne 16. decembra 1998 o usklajeni napotitvi svetovalcev za dokumente

SCH/Com-ex (99) 1 rev 2 Sklep Izvršnega odbora z dne 28. aprila 1999 o schengenskih pravilih na področju prepovedanih drog

SCH/Com-ex (99) 6 Sklep Izvršnega odbora z dne 28. aprila 1999 o schengenskem pravnem redu na področju telekomunikacij

SCH/Com-ex (99) 7 rev 2 Sklep Izvršnega odbora z dne 28. aprila 1999 o uradnikih za zvezo

SCH/Com-ex (99) 8 rev 2 Sklep Izvršnega odbora z dne 28. aprila 1999 o splošnih načelih glede plačevanja informatorjev

SCH/Com-ex (99) 10 Sklep Izvršnega odbora z dne 28. aprila 1999 o nezakoniti trgovini z orožjem.

6. Naslednji izjavi Izvršnega odbora, ustanovljenega s Konvencijo, podpisano v Schengenu dne 19. junija 1990, o izvajanju Schengenskega sporazuma z dne 14. junija 1985 o postopni odpravi kontrol na skupnih mejah, kolikor sta povezani z določbami iz odstavka 2 zgoraj:

SCH/Com-ex (96) decl 6 rev 2 Izjava Izvršnega odbora z dne 26. junija 1996 o izročitvi

SCH/Com-ex (97) decl 13 rev 2 Izjava Izvršnega odbora z dne 9. februarja 1998 o ugrabivah mladoletnikov.

7. Naslednja sklepa Centralne skupine, ustanovljene s Konvencijo, podpisano v Schengenu dne 19. junija 1990, o izvajanju Schengenskega sporazuma z dne 14. junija 1985 o postopni odpravi kontrol na skupnih mejah, kolikor sta povezana z določbami odstavka 2 zgoraj:

SCH/C (98) 117 Sklep Centralne skupine z dne 27. oktobra 1998 o delovnem načrtu za boj proti ilegalnim migracijam

SCH/C (99) 25 Sklep Centralne skupine z dne 22. marca 1999 o splošnih načelih glede plačevanja informatorjev.

8. Naslednji akti, ki temeljijo na schengenskem pravnem redu ali so drugače z njim povezani:

Uredba Sveta (ES) št. 1683/95 z dne 29. maja 1995 o enotni obliki za vizume (UL L 164, 14. 7. 1995, str. 1)

Odločba Sveta 1999/307/ES z dne 1. maja 1999 o podrobнем programu za vključitev schengenskega sekretariata v generalni sekretariat Sveta (UL L 119, 7. 5. 1999, str. 49)

Sklep Sveta 1999/435/ES z dne 20. maja 1999 o opredelitvi schengenskega pravnega reda za namen določanja pravne podlage za vsako določbo ali sklep, ki sestavlja schengenski pravni red, skladno z ustreznimi določbami iz Pogodbe o ustanovitvi Evropske skupnosti in Pogodbe o Evropski uniji (UL L 176, 10. 7. 1999, str. 1)

Sklep Sveta 1999/436/ES z dne 20. maja 1999 o določitvi pravne podlage za vsako določbo ali sklep, ki sestavlja schengenski pravni red, skladno z ustreznimi določbami Pogodbe o ustanovitvi Evropske skupnosti in Pogodbe o Evropski uniji (UL L 176, 10. 7. 1999, str. 17)

Sklep Sveta 1999/437/ES z dne 17. maja 1999 o nekaterih izvedbenih predpisih za uporabo Sporazuma, sklenjenega med Svetom Evropske unije in Republiko Islandijo ter Kraljevino Norveško, v zvezi s pridružitvijo teh dveh držav k izvajanju, uporabi in razvoju schengenskega pravnega reda (UL L 176, 10. 7. 1999, str. 31)

Sklep Sveta 1999/848/ES z dne 13. decembra 1999 o celotni uporabi schengenskega pravnega reda v Helenski republiki (UL L 327, 21. 12. 1999, str. 58)

Sklep Sveta 2000/365/ES z dne 29. maja 2000 o prošnji Združenega kraljestva Velike Britanije in Severne Irske za sodelovanje pri izvajanju nekaterih določb schengenskega pravnega reda (UL L 131, 1. 6. 2000, str. 43)

Sklep Sveta 2000/586/PNZ z dne 28. septembra 2000 o vzpostavitvi postopka za spremembo členov 40(4) in (5), 41(7) in 65(2) Konvencije o izvajanju Schengenskega sporazuma z dne 14. junija 1985 o postopni odpravi kontrol na skupnih mejah (UL L 248, 3. 10. 2000, str. 1)

Sklep Sveta 2000/777/ES z dne 1. decembra 2000 o uporabi Schengenskega pravnega reda na Danskem, Finskem in Švedskem ter v Islandiji in na Norveškem (UL L 309, 9. 12. 2000, str. 24)

Uredba Sveta (ES) št. 539/2001 z dne 15. marca 2001 o seznamu tretjih držav, katerih državljeni morajo pri prehodu zunanjih meja imeti vizume, in držav, katerih državljeni so oproščeni te zahteve (UL L 81, 21. 3. 2001, str. 1)

Direktiva Sveta 2001/51/ES z dne 28. junija 2001 o dopolnitvi določb člena 26 Konvencije o izvajanju schengenskega sporazuma z dne 14. junija 1985 (UL L 187, 10. 7. 2001, str. 45)

Uredba Sveta (ES) št. 333/2002 z dne 18. februarja 2002 o enotni obliku obrazcev, na katere se nalepi vizum, ki ga je izdala država članica imetnikom potnih listin, ki jih država članica, katera je obrazec izdala, ne priznava (UL L 53, 23. 2. 2002, str. 4)

Sklep Sveta 2002/192/ES z dne 28. februarja 2002 o prošnji Irske, da sodeluje pri izvajanju nekaterih določb schengenskega pravnega reda (UL L 64, 7. 3. 2002, str. 20)

Uredba Sveta (ES) št. 1030/2002 z dne 13. junija 2002 o enotni obliku dovoljenja za prebivanje za državljanje tretjih držav (UL L 157, 15. 6. 2002, str. 1)

Okvirni sklep Sveta 2002/946/PNZ z dne 28. novembra 2002 o krepitevici kazenskega okvira na področju preprečevanja nudenja pomoči pri nedovoljenem vstopu, tranzitu in prebivanju (UL L 328, 5. 12. 2002, str. 1)

Direktiva Sveta 2002/90/ES z dne 28. novembra 2002 o opredelitvi pomoči pri nedovoljenem vstopu, tranzitu in prebivanju (UL L 328, 5. 12. 2002, str. 17)

Sklep Sveta 2003/170/PNZ z dne 27. februarja 2003 o skupni uporabi častnikov za zvezo, napotnih s strani organov pregona držav članic (UL L 67, 12. 3. 2003, str. 27)

Sklep Sveta 2003/725/PNZ z dne 2. oktobra 2003 o spremembi določb členov 40(1) in (7) Konvencije o izvajanju Schengenskega sporazuma z dne 14. junija 1985 o postopni odpravi kontrol na skupnih mejah (UL L 260, 11. 10. 2003, str. 37)

Direktiva Sveta 2003/110/ES z dne 25. novembra 2003 o pomoči v primeru tranzita za namene repatriacije po zračni poti (UL L 321, 6. 12. 2003, str. 26)

Uredba Sveta (ES) št. 377/2004 z dne 19. februarja 2004 o vzpostavitvi mreže uradnikov za zvezo za priseljevanje (UL L 64, 2. 3. 2004, str. 1)

Direktiva Sveta 2004/82/ES z dne 29. aprila 2004 o dolžnosti prevoznikov, da posredujejo podatke o potnikih (UL L 261, 6. 8. 2004, str. 24)

Odločba Sveta 2004/573/ES z dne 29. aprila 2004 o organizirjanju skupnih letov zaradi odstranitve državljanov tretjih držav, ki so predmet posameznih odredb o odstranitvi, z ozemlja dveh ali več držav članic (UL L 261, 6. 8. 2004, str. 28)

Odločba Sveta 2004/512/ES z dne 8. junija 2004 o vzpostavitvi vizumskega informacijskega sistema (VIS) (UL L 213, 15. 6. 2004, str. 5, in UL L 142M, 30. 5. 2006, str. 60)

Uredba Sveta (ES) št. 2007/2004 z dne 26. oktobra 2004 o ustanovitvi Evropske agencije za upravljanje in operativno sodelovanje na zunanjih mejah držav članic Evropske unije (UL L 349, 25. 11. 2004, str. 1, in UL L 153M, 7. 6. 2006, str. 136)

Uredba Sveta (ES) št. 2252/2004 z dne 13. decembra 2004 o standardih za varnostne značilnosti in biometrične podatke v potnih listih in potovalnih dokumentih, ki jih izdajo države članice (UL L 385, 29. 12. 2004, str. 1, in UL L 153M, 7. 6. 2006, str. 375)

Sklep Sveta 2004/926/ES z dne 22. decembra 2004 o izvajjanju delov schengenskega pravnega reda s strani Združenega kraljestva Velike Britanije in Severne Irske (UL L 395, 31. 12. 2004, str. 70)

Odločba Sveta 2005/267/ES z dne 16. marca 2005 o vzpostavitvi varnega spletno podprtrega informacijskega in usklajevalnega omrežja, namenjenega službam držav članic za migracije (UL L 83, 1. 4. 2005, str. 48, in UL L 159M, 13. 6. 2006, str. 288)

Uredba (ES) št. 562/2006 Evropskega parlamenta in Sveta z dne 15. marca 2006 o Zakoniku Skupnosti o pravilih, ki urejajo gibanje oseb prek meja (Zakonik o schengenskih mejah) (UL L 105, 13. 4. 2006, str. 1), razen prvega stavka člena 1, člena 5(4)(a), naslova III in določb naslova II ter prilog k Uredbi, ki se nanašajo na schengenski informacijski sistem (SIS)

Okvirni sklep Sveta 2006/960/PNZ z dne 18. decembra 2006 o poenostavitvi izmenjave informacij in obveščevalnih podatkov med organi kazenskega pregona držav članic Evropske unije (UL L 386, 29. 12. 2006, str. 89)

Uredba (ES) št. 1931/2006 Evropskega parlamenta in Sveta z dne 20. decembra 2006 o pravilih za obmejni promet na zunanjih kopenskih mejah držav članic in spremembi določb Schengenske konvencije (UL L 405, 30. 12. 2006, str. 1), razen členov 4(b) in 9(c))

Sklep Sveta 2007/471/ES z dne 12. junija 2007 o uporabi določb schengenskega pravnega reda, ki se navezujejo na schengenski informacijski sistem, v Češki republiki, Republiki Estoniji, Republiki Latviji, Republiki Litvi, Republiki Madžarski, Republiki Malti, Republiki Poljski, Republiki Sloveniji in Slovaški republikni (UL L 179, 7. 7. 2007, str. 46)

Uredba (ES) št. 863/2007 Evropskega parlamenta in Sveta z dne 11. julija 2007 o vzpostavitev mehanizma za ustanovitev skupin za hitro posredovanje na mejah in o spremembah Uredbe Sveta (ES) št. 2007/2004 glede tega mehanizma ter o ureditvi nalog in pooblastil gostujočih uradnikov (UL L 199, 31. 7. 2007, str. 30), razen določb iz člena 6(8) in (9), kolikor se nanašajo na dostop do schengenskega informacijskega sistema

Sklep Sveta 2007/801/ES z dne 6. decembra 2007 o polni uporabi določb schengenskega pravnega reda v Češki republiki, Republiki Estoniji, Republiki Latviji, Republiki Litvi, Republiki Madžarski, Republiki Malti, Republiki Poljski, Republiki Sloveniji in Slovaški republiki (UL L 323, 8. 12. 2007, str. 34)

Sklep Sveta 2008/421/ES z dne 5. junija 2008 o uporabi določb schengenskega pravnega reda, ki se navezujejo na schengenski informacijski sistem, v Švicarski konfederaciji (UL L 149, 7. 6. 2008, str. 74)

Člen 6 Sklepa Sveta 2008/633/PNZ z dne 23. junija 2008 o dostopu imenovanih organov držav članic in Europolja do vizumskega informacijskega sistema (VIS) za iskanje podatkov za namene preprečevanja, odkrivanja in preiskovanja terorističnih dejanj in drugih hudi kaznivih dejanj (UL L 218, 13. 8. 2008, str. 129).

Sklep Sveta 2008/903/ES z dne 27. novembra 2008 o polni uporabi določb schengenskega pravnega reda v Švicarski konfederaciji (UL L 327, 5. 12. 2008, str. 15)

Okvirni sklep Sveta 2008/977/PNZ z dne 27. novembra 2008 o varstvu osebnih podatkov, ki se obdelujejo v okviru policijskega in pravosodnega sodelovanja v kazenskih zadevah (UL L 350, 30. 12. 2008, str. 60.)

Direktiva 2008/115/ES Evropskega parlamenta in Sveta z dne 16. decembra 2008 o skupnih standardih in postopkih v državah članicah za vračanje nezakonito prebivajočih državljanov tretjih držav (UL L 348, 24. 12. 2008, str. 98)

Člen 3 Uredbe (ES) št. 810/2009 Evropskega parlamenta in Sveta z dne 13. julija 2009 o vizumskem zakoniku Skupnosti (Vizumski zakonik) (UL L 243, 15. 9. 2009, str. 1)

Sklep Sveta 2010/252/EU z dne 26. aprila 2010 o dopolnitvi Zakonika o schengenskih mejah glede varovanja zunanjih meja na morju v okviru operativnega sodelovanja, ki ga usklajuje Evropska agencija za upravljanje in operativno sodelovanje na zunanjih mejah držav članic Evropske unije (UL L 111, 4. 5. 2010, str. 20)

Sklep Sveta 2010/365/EU z dne 29. junija 2010 o uporabi določb schengenskega pravnega reda, ki se navezujejo na schengenski informacijski sistem, v Republiki Bolgariji in Romuniji (UL L 166, 1. 7. 2010, str. 17)

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### *PRILOGA III*

#### **Seznam iz člena 15 Akta o pristopu: prilagoditve aktov, ki so jih sprejele institucije**

##### **1. SVOBODA OPRAVLJANJA STORITEV**

32005 L 0036: Direktiva Evropskega parlamenta in Sveta 2005/36/ES z dne 7. septembra 2005 o priznavanju poklicnih kvalifikacij (UL L 255, 30.9.2005, str. 22).

(a) Člen 23(5) se nadomesti z naslednjim:

"5. Brez poseganja v člen 43(b) vsaka država članica prizna dokazila o formalnih kvalifikacijah za zdravnika, ki omogočajo dostop do poklicnih dejavnosti zdravnika z osnovno usposobljenostjo in zdravnika specialista, ter dokazila o formalnih kvalifikacijah za medicinsko sestro za splošno zdravstveno nego, zobozdravnika, zobozdravnika specialista, veterinarja, babico, farmacevta in arhitekta, ki jih imajo državljeni držav članic in ki jih je izdala nekdanja Jugoslavija ali katerih usposabljanje se je začelo,

- (a) pred 25. junijem 1991 za Slovenijo in
- (b) pred 8. oktobrom 1991 za Hrvaško,

kadar organi teh držav članic potrdijo, da imajo taka dokazila na njihovem ozemlju enako pravno veljavnost kot dokazila, ki jih sami izdajajo, ter, v zvezi z arhitekti, kot dokazila o formalnih kvalifikacijah, določena za te države članice v točki 6 Priloge VI, kar zadeva dostop do poklicnih dejavnosti zdravnika z osnovno usposobljenostjo, zdravnika specialista, medicinske sestre za splošno zdravstveno nego, zobozdravnika, zobozdravnika specialista, veterinarja, babice, farmacevta v zvezi z dejavnostmi iz člena 45(2) in arhitekta v zvezi z dejavnostmi iz člena 48 ter opravljanje takih dejavnosti.

Takemu potrdilu mora biti priloženo še potrdilo, ki ga izdajo isti organi, da so take osebe dejansko in zakonito opravljale take dejavnosti na njihovem ozemlju vsaj tri zaporedna leta v petih letih pred datumom izdaje potrdila."

(b) Vstavi se naslednji člen:

"Člen 43(b)

Pridobljene pravice za babištvo ne veljajo za naslednje kvalifikacije, pridobljene na Hrvaškem pred 1. julijem 2013: viša medicinska sestra ginekološko-opstetričkog smjera (viša medicinska sestra ginekološko-porodniške smeri), medicinska sestra ginekološko-opstetričkog smjera (medicinska sestra ginekološko-porodniške smeri), viša medicinska sestra primaljskog smjera (viša medicinska sestra z diplomom iz babištva), medicinska sestra primaljskog smjera (medicinska sestra z diplomom iz babištva), ginekološko-opstetrička primalja (babica ginekološko-porodniške smeri) in primalja (babica)."

## 2. PRAVO INTELEKTUALNE LASTNINE

### I. BLAGOVNA ZNAMKA SKUPNOSTI

32009 R 0207: Uredba Sveta (ES) št. 207/2009 z dne 27. februarja 2009 o blagovni znamki Skupnosti (UL L 78, 24.3.2009, str. 1).

Člen 165(1) se nadomesti z naslednjim:

"1. Z dnem pristopa Bolgarije, Češke, Estonije, Hrvaške, Cipra, Latvije, Litve, Madžarske, Malte, Poljske, Romunije, Slovenije in Slovaške (v nadalnjem besedilu "nove države članice") se znamke Skupnosti, ki so bile registrirane ali za katere je bila vložena prijava na podlagi te uredbe pred zadevnim dnem pristopa, razširijo na območje teh držav članic, da imajo enak učinek v celotni Skupnosti."

## II. DODATNI VARSTVENI CERTIFIKATI

1. 31996 R 1610: Uredba Evropskega parlamenta in Sveta (ES) št. 1610/96 z dne 23. julija 1996 o uvedbi dodatnega varstvenega certifikata za fitofarmacevtska sredstva (UL L 198, 8.8.1996, str. 30).

(a) V členu 19a se doda naslednja točka:

"(m) vsem fitofarmacevtskim sredstvom, ki so varovana z veljavnim osnovnim patentom in za katera je bila prva odobritev, da se izdelek da na trg kot fitofarmacevtsko sredstvo, pridobljena po 1. januarju 2003, se na Hrvaškem sme podeliti certifikat, pod pogojem, da je prijava za pridobitev certifikata vložena v šestih mesecih od dne pristopa."

(b) Člen 20(2) se nadomesti z naslednjim:

"2. Ta uredba se uporablja za dodatne varstvene certifikate, pridobljene v skladu z nacionalno zakonodajo Češke republike, Estonije, Hrvaške, Cipra, Latvije, Litve, Malte, Poljske, Romunije, Slovenije in Slovaške pred zadevnim dnem pristopa."

2. 32009 R 0469: Uredba (ES) št. 469/2009 Evropskega parlamenta in Sveta z dne 6. maja 2009 o dodatnem varstvenem certifikatu za zdravila (UL L 152, 16.6.2009, str. 1).

(a) V členu 20 se doda naslednja točka:

"(m) vsem zdravilom, ki so varovana z veljavnim osnovnim patentom in za katera je bilo prvo dovoljenje za dajanje v promet kot zdravila pridobljeno po 1. januarju 2003, se na Hrvaškem sme podeliti certifikat, pod pogojem, da je prijava za pridobitev certifikata vložena v šestih mesecih od dne pristopa."

(b) Člen 21(2) se nadomesti z naslednjim:

"2. Ta uredba se uporablja za dodatne varstvene certifikate, pridobljene v skladu z nacionalno zakonodajo Češke republike, Estonije, Hrvaške, Cipra, Latvije, Litve, Malte, Poljske, Romunije, Slovenije in Slovaške pred zadevnim dnem pristopa."

### III. MODELI SKUPNOSTI

32002 R 0006: Uredba Sveta (ES) št. 6/2002 z dne 12. decembra 2001 o modelih Skupnosti (UL L 3, 5.1.2002, str. 1).

Člen 110a(1) se nadomesti z naslednjim:

"1. Z dnem pristopa Bolgarije, Češke, Estonije, Hrvaške, Cipra, Latvije, Litve, Madžarske, Malte, Poljske, Romunije, Slovenije in Slovaške (v nadalnjem besedilu "nove države članice") se modeli Skupnosti, ki so bili registrirani ali za katere je bila vložena prijava na podlagi te uredbe pred zadevnim dnem pristopa, razširijo na območje teh držav članic, da imajo enak učinek v celotni Skupnosti."

### 3. FINANČNE STORITVE

32006 L 0048: Direktiva 2006/48/ES Evropskega parlamenta in Sveta z dne 14. junija 2006 o začetku opravljanja in opravljanju dejavnosti kreditnih institucij (UL L 177, 30.6.2006, str. 1).

V členu 2 se za vnosom za Francijo vstavi naslednje:

"– na Hrvaškem za 'kreditne unije' in 'Hrvatsko banko za obnovu i razvitak',"

#### 4. KMETIJSTVO

1. Uredba Sveta (EGS) št. 1601/91 z dne 10. junija 1991 o določitvi splošnih pravil za opredelitev, opis in predstavitev aromatiziranih vin, aromatiziranih pijač na osnovi vina in aromatiziranih mešanih pijač iz vinskih proizvodov (UL L 149, 14.6.1991, str. 1).

V Prilogi II se za geografsko označbo "Nürnberg Glühwein" vnese naslednje:

"Samoborski bermet"

2. Uredba Sveta (ES) št. 1234/2007 z dne 22. oktobra 2007 o vzpostavitvi skupne ureditve kmetijskih trgov in o posebnih določbah za nekatere kmetijske proizvode (Uredba o enotni SUT) (UL L 299, 16.11.2007, str. 1).
  - (a) V členu 66 se vstavi naslednji odstavek:

"4a. Za Hrvaško se oblikuje posebna rezerva za prestrukturiranje, kakor določa točka 2 Priloge IX. Ta rezerva se sprosti s 1. aprilom prvega kvotnega leta po pristopu v obsegu, za kolikor se je poraba mleka in mlečnih izdelkov na kmetijah na Hrvaškem zmanjšala v obdobju 2008–2012.

Odločitev o sprostitvi te rezerve in njeni razdelitvi med kvotama za oddajo in neposredno prodajo sprejme Komisija v skladu s postopkom iz člena 195(2) na podlagi ocene poročila, ki ga Hrvaška predloži Komisiji do 31. decembra 2013. Poročilo vsebuje podrobne rezultate in trende dejanskega procesa prestrukturiranja mlečnega sektorja Hrvaške, predvsem pa rezultate preusmeritve od proizvodnje za porabo na kmetiji k proizvodnji za trg."

(b) V členu 103k(1) se doda naslednji pododstavek:

"Ta odstavek se za Hrvaško ne uporablja v finančnem letu 2013. Hrvaška Komisiji predloži osnutek petletnega podpornega programa za programsko obdobje 2014–2018."

(c) V delu III Priloge III se točka 13 nadomesti z naslednjo:

"13. "stalna rafinerija" pomeni proizvodni obrat:

- katerega edina dejavnost je prečiščevanje uvoženega surovega trsnega sladkorja
- ali
- ki je v tržnem letu 2004/2005 prečistil najmanj 15 000 ton uvoženega surovega trsnega sladkorja. Za namene te alinee je v primeru Hrvaške tržno leto 2007/2008."

(d) Priloga VI se nadomesti z naslednjim:

**"PRILOGA VI**  
**NACIONALNE IN REGIONALNE KVOTE**  
**od tržnega leta 2010/2011 dalje**

**(v tonah)**

Države članice ali regije (1)	Sladkor (2)	Izoglukoza (3)	Inulinski sirup (4)
Belgija	676 235,0	114 580, 2	0
Bolgarija	0	89 198,0	
Češka	372 459,3		
Danska	372 383,0		
Nemčija	2 898 255,7	56 638,2	
Irska	0		
Grčija	158 702,0	0	
Španija	498 480,2	53 810,2	
Francija (matična Francija)	3 004 811, 15		0
Francoski čezmorski departmaji	432 220, 05		
Hrvaška	192 877,0		
Italija	508 379,0	32 492,5	
Latvija	0		
Litva	90 252,0		
Madžarska	105 420,0	220 265,8	
Nizozemska	804 888,0	0	0
Avstrija	351 027,4		
Poljska	1 405 608,1	42 861,4	
Portugalska (celinska)	0	12 500,0	
Avtonomna regija Azori	9 953,0		
Romunija	104 688,8	0	
Slovenija	0		
Slovaška	112 319,5	68 094,5	
Finska	80 999,0	0	
Švedska	293 186,0		
Združeno kraljestvo	1 056 474,0	0	
<b>SKUPAJ</b>	<b>13 529 618,20</b>	<b>690 440,8</b>	<b>0</b>

"

- (e) V točki 1 Priloge IX se za vnosom za Francijo v stolpcih, ki se nanašajo na proizvodna leta 2013/14 in 2014/15, vstavi naslednje:

"

Država članica	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
Hrvaška						765 000	765 000

"

- (f) V točki 2 Priloge IX se preglednica nadomesti z naslednjim:

"

Država članica	(v tonah)
Bolgarija	39 180
Hrvaška	15 000
Romunija	188 400

"

- "(g) V Prilogi X se za vnosom za Francijo vstavi naslednje:

"

Hrvaška	40,70
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"

- "(h) v Prilogi Xb se doda naslednja preglednica:

"v 1 000 EUR

Proračunsko leto	2013	2014	2015	2016	od leta 2017 dalje
HR	0	11 885	11 885	11 885	10 832

"

- (i) V odstavku 2 dodatka k Prilogi XIb se doda naslednja točka:
- "(h) na Hrvaškem: površine, zasajene z vinsko trto v naslednjih podregijah: Moslavina, Prigorje-Bilogora, Plešivica, Pokuplje, Zagorje-Međimurje."
- (j) V odstavku 3 dodatka k Prilogi XIb se doda naslednja točka:
- "(h) na Hrvaškem: površine, zasajene z vinsko trto v naslednjih podregijah: Hrvatsko Podunavlje in Slavonija."
- (k) V odstavku 4 dodatka k Prilogi XIb se doda naslednja točka:
- "(g) na Hrvaškem: površine, zasajene z vinsko trto v naslednjih podregijah: Hrvatska Istra, Hrvatsko primorje, Dalmatinska zagora, Sjeverna Dalmacija ter Srednja i Južna Dalmacija."

3. Uredba (ES) št. 110/2008 Evropskega parlamenta in Sveta z dne 15. januarja 2008 o opredelitvi, opisu, predstavitvi, označevanju in zaščiti geografskih označb žganih pijač ter razveljavitvi Uredbe Sveta (EGS) št. 1576/89 (UL L 39, 13.2.2008, str. 16).

- (a) V členu 20 se doda naslednji odstavek:
- "4. Rok iz prvega odstavka za predložitev tehnične dokumentacije se uporabi tudi za hrvaške geografske označbe, naštete v Prilogi III."
- (b) V točki 9 Priloge II se dodajo naslednje geografske označbe:

"

	<i>Hrvatska loza</i>	Hrvaška
	<i>Hrvatska stara šljivovica</i>	Hrvaška
	<i>Slavonska šljivovica</i>	Hrvaška

"

- (c) V točki 32 Priloge III se doda naslednja geografska označba:

"

	<i>Hrvatski pelinkovac</i>	Hrvaška
--	----------------------------	---------

"

- (d) V Prilogi III se doda naslednja točka:

"

39. Maraschino/ Marrasquino/ Maraskino	<i>Zadarski maraschino</i>	Hrvaška
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"

- (e) V Prilogi III se na koncu seznama pod kategorijo proizvodov "Druge žgane pijače" doda naslednja geografska označba:

"

	<i>Hrvatska travarica</i>	Hrvaška
--	---------------------------	---------

"

4. 32009 R 0073: Uredba Sveta (ES) št. 73/2009 z dne 19. januarja 2009 o skupnih pravilih za sheme neposrednih podpor za kmete v okviru skupne kmetijske politike in o uvedbi nekaterih schem podpor za kmete, sprememb uredb (ES) št. 1290/2005, (ES) št. 247/2006, (ES) št. 378/2007 in razveljavitvi Uredbe (ES) št. 1782/2003 (UL L 30, 31.1.2009, str. 16).

- (a) Člen 2(g) se nadomesti z naslednjim:

"(g) 'nove države članice' pomeni Bolgarijo, Češko, Estonijo, Hrvaško, Ciper, Latvijo, Litvo, Madžarsko, Malto, Poljsko, Romunijo, Slovenijo in Slovaško;"

(b) V členu 6(2) se prvi pododstavek nadomesti z naslednjim:

"2. Države članice, razen novih držav članic, zagotovijo, da zemljišča, ki so se uporabljala kot trajni pašniki na datum, ki je predviden za zahteve za pomoč na površino za leto 2003, ostanejo trajni pašniki. Nove države članice razen Bolgarije, Hrvaške in Romunije zagotovijo, da zemljišča, ki so se uporabljala kot trajni pašniki 1. maja 2004, ostanejo trajni pašniki. Bolgarija in Romunija zagotovita, da zemljišča, ki so se uporabljala kot trajni pašniki 1. januarja 2007, ostanejo trajni pašniki. Hrvaška zagotovi, da zemljišča, ki so se uporabljala kot trajni pašniki 1. julija 2013, ostanejo trajni pašniki."

(c) V členu 33(1) se točka (b)(vi) nadomesti z naslednjim:

"(iv) v skladu s členom 47(2), členom 57a in členom 59, tretjim pododstavkom člena 64(2) ter členom 65 in členom 68(4)(c)."

(d) Členu 51(1) se doda naslednji pododstavek:

"Hrvaška se lahko odloči, da bo uporabila možnosti iz člena 52 in člena 53(1) te uredbe. O tej odločitvi uradno obvesti Komisijo do 15. julija 2013."

(e) Členu 51(2) se doda naslednji pododstavek:

"Z odstopanjem od drugega pododstavka se v primeru Hrvaške ta zgornja meja, kar zadeva plačila za ovčje in kozje meso oziroma plačila za goveje in telečje meso iz člena 52 in 53, določi na podlagi nacionalnih zgornjih mej iz členov 104(4) in 112(5) te uredbe, ob upoštevanju razporeda uvedbe neposrednih plačil iz člena 121."

(f) V členu 52 se za prvim pododstavkom vstavi naslednji pododstavek:

"Z odstopanjem od prvega pododstavka lahko Hrvaška zadrži do 50 % zneska, ki izhaja iz zgornje meje iz tretjega pododstavka člena 51(2), zato da kmetom vsako leto izplača dodatno plačilo."

"(g) V členu 53(1) se za prvim pododstavkom vstavi naslednji pododstavek:

"Z odstopanjem od prvega pododstavka lahko Hrvaška zadrži celoten ali del zneska, ki izhaja iz zgornje meje iz tretjega pododstavka člena 51(2), zato da kmetom vsako leto izplača dodatno plačilo."

"(h) Naslov poglavja 3 se nadomesti z naslednjim:

"Izvajanje v novih državah članicah, ki uporabljajo shemo enotnega plačila na površino, in na Hrvaškem"

(i) Naslov člena 55 se nadomesti z naslednjim:

"Uvedba sheme enotnega plačila v državah članicah, ki uporabljajo shemo enotnega plačila na površino, in na Hrvaškem"

(j) V členu 55(1) se prvi pododstavek nadomesti z naslednjim:

"1. "Če ni drugače predvideno v tem poglavju, se ta naslov uporablja za nove države članice, ki uporabljajo shemo enotnega plačila na površino iz poglavja 2 naslova V, in za Hrvaško."

(k) V členu 57(1) se doda naslednji stavek:

"Za Hrvaško to znižanje ni večje od 20 % letne zgornje meje, kot je navedena v preglednici 3 Priloge VIII."

(l) V členu 57(3) se doda naslednji stavek:

"V primeru Hrvaške mora uporabo nacionalne rezerve odobriti Komisija z izvedbenim aktom brez pomoči odbora iz člena 141. Komisija preuči zlasti vzpostavitev morebitne nacionalne sheme neposrednih plačil, ki se je uporabljala pred dnem pristopa, in pogoje, pod katerimi se je uporabljala. Hrvaška pošlje zahtevek za odobritev nacionalne rezerve Komisiji najpozneje do 15. julija 2013."

(m) Vstavi se naslednji člen:

"Člen 57a

Posebna nacionalna rezerva za razminiranje na Hrvaškem

1. Hrvaška vzpostavi posebno nacionalno rezervo za razminiranje, ki se uporablja za dodeljevanje pravic do plačil kmetom z zemljišči, s katerih so bile odstranjene mine in ki se znova uporabljajo za kmetijske dejavnosti, v obdobju desetih let po pristopu ter v skladu z objektivnimi merili in na način, ki bi zagotavljal enako obravnavanje kmetov ter preprečeval izkriviljanje trga in konkurence.
2. Zemljišča, upravičena do dodelitve pravic do plačil v skladu s tem členom, niso upravičena do dodelitve pravic do plačil v skladu s členom 59 in členom 61.
3. Vrednost pravic do plačil, določena v skladu s tem členom, ne sme biti višja od vrednosti pravic do plačil, določene v skladu s členom 59 oziroma členom 61.
4. Posebni nacionalni rezervi za razminiranje se dodelijo zneski v vrednosti največ 9 600 000 EUR, za katere velja razpored uvedbe neposrednih plačil iz člena 121. Najvišji letni zneski so naslednji:

Hrvaška	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Najvišji znesek za posebno nacionalno rezervo za razminiranje	2 400	2 880	3 360	3 840	4 800	5 760	6 720	7 680	8 640	9 600

5. V prvem letu izvajanja sheme enotnega plačila Hrvaška dodeljuje pravice do plačil kmetom na podlagi zemljišč, s katerih so bile odstranjene mine in ki so jih kmetje prijavili v zahtevkih za pomoč, predloženih v prvem letu izvajanja sheme enotnega plačila, in se znova uporabljajo za kmetijske dejavnosti v obdobju od 1. januarja 2005 do 31. decembra 2012.
6. Za leta 2013 do 2022 se pravice do plačil kmetom dodeljujejo na podlagi zemljišč, s katerih so bile odstranjene mine in ki so jih kmetje prijavili v zadevnem letu, pod pogojem, da so ta zemljišča začeli znova uporabljati za kmetijske dejavnosti v predhodnem koledarskem letu, o čemer so uradno obvestili Komisijo v skladu z odstavkom 9.
7. Komisija za zagotovitev ustrezne uporabe sredstev Unije v skladu s postopkom iz člena 141(2) spremeni zgornjo mejo v preglednici 3 Priloge VIII, in sicer tako, da vanjo doda zneske iz posebne nacionalne rezerve za razminiranje, ki so bili dodeljeni do 31. decembra 2022.
8. Vsa zemljišča, prijavljena za namene tega člena, ustrezajo opredelitvi upravičenega hektarja iz člena 34(2).

9. Hrvaška do 15. julija 2013 uradno obvesti Komisijo o površini, upravičeni v skladu z odstavkom 5, in pri tem navede tako zemljišča, upravičena do ravni podpore v skladu s členom 59, kot zemljišča, upravičena do ravni podpore v skladu s členom 61. To uradno obvestilo vsebuje tudi podatke o ustreznih proračunskih sredstvih in neporabljenih zneskih. Od leta 2014 dalje se Komisiji vsako leto najpozneje do 31. januarja pošlje sporočilo, ki zajema predhodno koledarsko leto, z enakimi podatki v zvezi s površinami, ki se znova uporabljajo za kmetijske dejavnosti, in ustreznimi proračunskimi sredstvi.
10. Do 31. decembra 2012 se vsa zemljišča, za katera bi kmetje utegnili prejeti pravico do plačila iz te posebne nacionalne rezerve za razminiranje – tako tista, s katerih so že bile odstranjene mine, kot tista, s katerih še niso bile –, opredelijo v integriranem administrativnem in kontrolnem sistemu, vzpostavljenem v skladu s poglavjem 4 naslova II."

(n) V členu 59 se doda naslednji odstavek:

"4. Komisija v skladu s postopkom iz člena 141(2) sprejme pravila o prvi dodelitvi pravic do plačila na Hrvaškem."

(o) V členu 61 se doda naslednji odstavek:

"Za Hrvaško je navedeni datum 30. junij 2011."

(p) V prvem pododstavku člena 69(1) se doda naslednje:

"Hrvaška se lahko do dneva pristopa odloči, da bo od prvega leta izvajanja sheme enotnega plačila, kot je določeno v členu 59(2), uporabila do 10 % sredstev iz nacionalne zgornje meje iz člena 40, kot je navedena v preglednici 3 Priloge VIII."

(q) V prvem pododstavku člena 69(9) se doda naslednje:

"(aa) za 2022 v primeru Hrvaške."

(r) Člen 104(4) se nadomesti z naslednjim:

"4. Uporabljajo se naslednje nacionalne zgornje meje:

Države članice	Nacionalne zgornje meje
Bolgarija	2 058 483
Češka	66 733
Danska	104 000
Estonija	48 000
Španija	19 580 000
Francija	7 842 000
Hrvaška	542 651
Ciper	472 401
Latvija	18 437
Litva	17 304
Madžarska	1 146 000
Poljska	335 880
Portugalska	2 690 000
Romunija	5 880 620
Slovenija	84 909
Slovaška	305 756
Finska	80 000
Skupaj	41 273 174

"

(s) V členu 112(5) se za vnosom za Francijo vstavi naslednje:

Hrvaška	105 270
"	

(t) Člen 121 se nadomesti z naslednjim:

"*Člen 121*

**Uvedba neposrednih plačil**

V novih državah članicah, razen v Bolgariji, na Hrvaškem in v Romuniji, se uvedejo neposredna plačila v skladu z naslednjim razporedom povečanj, izraženih kot odstotek tedaj veljavne ravni takih plačil v državah članicah, ki niso nove države članice:

- 60 % v letu 2009,
- 70 % v letu 2010,
- 80 % v letu 2011,
- 90 % v letu 2012,
- 100 % od leta 2013.

V Bolgariji in Romuniji se neposredna plačila uvedejo v skladu z naslednjim razporedom povečanj, izraženih kot odstotek tedaj veljavne ravni takih plačil v državah članicah, ki niso nove države članice:

- 35 % v letu 2009,
- 40 % v letu 2010,
- 50 % v letu 2011,
- 60 % v letu 2012,
- 70 % v letu 2013,
- 80 % v letu 2014,
- 90 % v letu 2015,
- 100 % od leta 2016.

Na Hrvaškem se neposredna plačila uvedejo v skladu z naslednjim razporedom povečanj, izraženih kot odstotek tedaj veljavne ravni takih plačil v državah članicah, ki niso nove države članice:

- 25 % v letu 2013,
- 30 % v letu 2014,
- 35 % v letu 2015,
- 40 % v letu 2016,
- 50 % v letu 2017,
- 60 % v letu 2018,
- 70 % v letu 2019,
- 80 % v letu 2020,
- 90 % v letu 2021,
- 100 % od leta 2022."

(u) V členu 132(2) se doda naslednja točka:

"(c) z odstopanjem od točk (a) in (b) lahko Hrvaška neposredna plačila dopolni do 100 % ravni, veljavne v državah članicah, ki niso nove države članice,"

(v) V Prilogi VII se za vnosom za Francijo vstavi naslednje:

"

Hrvaška	100	1
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"

(w) v Prilogi VIII se doda naslednja preglednica:

"Preglednica 3(\*)

Država članica	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Hrvaška	93 250	111 900	130 550	149 200	186 500	223 800	261 100	298 400	335 700	373 000

(\*) Zgornje meje so izračunane ob upoštevanju razporeda povečanj iz člena 121."

5. **RIBIŠTVO**

- 32002 R 2371: Uredba Sveta (ES) št. 2371/2002 z dne 20. decembra 2002 o ohranjevanju in trajnostnem izkoriščanju ribolovnih virov v okviru skupne ribiške politike (UL L 358, 31.12.2002, str. 59).

(a) v Prilogi I se dodajo naslednji deli:

**"11. OBALNE VODE HRVAŠKE\***

Zemljepisno območje	Država članica	Vrsta	Obseg ali posebne značilnosti
12 milj, omejeno na morski prostor pod suverenostjo Hrvaške, ki leži severno od vzporednika 45 stopinj in 10 minut severne zemljepisne širine ob zahodni obali Istre, od zunanjega roba teritorialnega morja Hrvaške, kjer se ta vzporednik stika s kopnim zahodne obale Istre (Grgatov rt Funtana)	Slovenija	pridnene in majhne pelagične vrste, vključno s sardinami in sardoni	100 ton za največ 25 ribiških plovil, kar vključuje tudi 5 ribiških plovil, opremljenih z vlečnimi mrežami

\* Navedena ureditev se uporablja, ko se začne v celoti izvajati arbitražna odločba na podlagi arbitražnega sporazuma med Slovenijo in Hrvaško, podpisanega 4. novembra 2009 v Stockholm.

## 12. OBALNE VODE SLOVENIJE\*

Zemljepisno območje	Država članica	Vrsta	Obseg ali posebne značilnosti
12 milj, omejeno na morski prostor pod suverenostjo Slovenije, ki leži severno od vzporednika 45 stopinj in 10 minut severne zemljepisne širine ob zahodni obali Istre, od zunanjega roba teritorialnega morja Hrvaške, kjer se ta vzporednik stika s kopnim zahodne obale Istre (Grgatov rt Funtana)	Hrvaška	pridnene in majhne pelagične vrste, vključno s sardinami in sardoni	100 ton za največ 25 ribiških plovil, kar vključuje tudi 5 ribiških plovil, opremljenih z vlečnimi mrežami

\* Navedena ureditev se uporablja, ko se začne v celoti izvajati arbitražna odločba na podlagi arbitražnega sporazuma med Slovenijo in Hrvaško, podisanega 4. novembra 2009 v Stockholmu."

2. 32006 R 1198: Uredba Sveta (ES) št. 1198/2006 z dne 27. julija 2006 o Evropskem skladu za ribištvo (UL L 223, 15.8.2006, str. 1).

(a) V členu 27 se doda naslednji odstavek:

"5. ESR lahko prispeva k financiranju sheme individualnih premij za ribiče, za katere bo veljala ureditev o dostopu iz dela 11 Priloge I k Uredbi (ES) št. 2371/2002, kakor je bila spremenjena z aktom o pristopu. Shema se lahko uporablja le med letoma 2014 in 2015, oziroma do datuma, ko se začne v celoti izvajati arbitražna odločba na podlagi arbitražnega sporazuma med Slovenijo in Hrvaško, podpisanega 4. novembra 2009 v Stockholmu, če je to prej."

(b) Člen 29(3) se nadomesti z naslednjim:

"3. Z odstopanjem od odstavka 2 se pomoč v najbolj oddaljenih regijah in na odročnih grških otokih ter hrvaških otokih Dugi otok, Vis, Mljet in Lastovo lahko dodeli vsem podjetjem."

(c) Člen 35(4) se nadomesti z naslednjim:

"4. Z odstopanjem od odstavka 3 se pomoč v najbolj oddaljenih regijah in na odročnih grških otokih ter hrvaških otokih Dugi otok, Vis, Mljet in Lastovo lahko dodeli vsem podjetjem."

(d) V členu 53(9) se prvi pododstavek nadomesti z naslednjim:

"9. Kadar ESR financira operacije na odročnih grških otokih, ki so zaradi oddaljenosti v slabšem položaju, in v najbolj obrobnih regijah ter na hrvaških otokih Dugi otok, Vis, Mljet in Lastovo, se zgornja meja prispevka za vsako prednostno os ESR poveča do 10 odstotnih točk v regijah, ki izpolnjujejo pogoje za pridobitev pomoči v okviru cilja 'konvergenca', ter do 35 odstotnih točk za regije, ki ne izpolnjujejo pogojev za pridobitev pomoči v okviru cilja 'konvergenca'."

(e) V točki (a) Priloge II se tabela nadomesti z naslednjim:

"

	Skupina 1	Skupina 2	Skupina 3	Skupina 4
Regije, ki jih zajema cilj 'konvergenca', in odročni grški otoki ter hrvaški otoki Dugi otok, Vis, Mljet in Lastovo	A $\leq$ 100 % B $\geq$ 0 %	A $\leq$ 40 % B $\geq$ 60 % (*) (**)	A $\leq$ 80 % B $\geq$ 20 %	A $\leq$ 60 % B $\geq$ 40 % (***)
Regije, ki jih ne zajema cilj 'konvergenca'	A $\leq$ 100 % B $\geq$ 0 %	A $\leq$ 40 % B $\geq$ 60 % (*) (**)	A $\leq$ 60 % B $\geq$ 40 %	A $\leq$ 40 % B $\geq$ 60 % (***)
Najbolj oddaljene regije	A $\leq$ 100 % B $\geq$ 0 %	A $\leq$ 50 % B $\geq$ 50 % (*) (**)	A $\leq$ 80 % B $\geq$ 20 %	A $\leq$ 75 % B $\geq$ 25 %

(\*) V primeru operacij iz člena 25(3) se stopnje B za Skupino 2 povečajo za 20 odstotnih točk.

Stopnje (A) se ustrezno zmanjšajo.

(\*\*) V primeru operacij iz člena 26(2) (naložbe v ribiška plovila za mali priobalni ribolov v smislu člena 25), se stopnje B za Skupino 2 lahko zmanjšajo za 20 odstotnih točk. Stopnje (A) se ustrezno povečajo.

(\*\*\*) V primeru operacij iz člena 29 in člena 35, ki jih izvajajo podjetja, za katere ne velja opredelitev iz člena 3(f), z manj kot 750 zaposlenimi ali s prihodki, manjšimi od 200 milijonov EUR, se stopnje B povečajo v regijah, ki jih zajema cilj 'konvergenca', razen na odročnih grških otokih ter hrvaških otokih Dugi otok, Vis, Mljet in Lastovo, za 30 odstotnih točk in v regijah, ki jih ne zajema cilj "konvergenca", za 20 odstotnih točk. Stopnje (A) se ustrezno zmanjšajo."

(f) V točki (a) Priloge II se drugi odstavek podnaslova "Skupina 2" nadomesti z naslednjim:

"V primeru financiranja operacij iz ESR, določenih v členu 25(3), v prid plovilom za mali priobalni ribolov, so stopnje B za Skupino 2 po začetku uporabe (\*) in (\*\*):

za regije, ki jih zajema cilj 'konvergenca', odročne grške otoke in hrvaške otoke Dugi otok, Vis, Mljet in Lastovo ter regije, ki jih ne zajema cilj 'konvergenca', enake ali večje od 60 odstotnih točk ( $B \geq 60\%$ ),

in

za najbolj oddaljene regije enake ali večje od 50 odstotnih točk ( $B \geq 50\%$ )."

## **6. OBDAVČITEV**

1. 32006 L 0112: Direktiva Sveta 2006/112/ES z dne 28. novembra 2006 o skupnem sistemu davka na dodano vrednost (UL L 347, 11.12.2006, str. 1).

V členu 287 se doda naslednje:

"(19) Hrvaška: 35 000 EUR."

2. 32008L0118: Direktiva Sveta 2008/118/ES z dne 16. decembra 2008 o splošnem režimu za trošarino in o razveljavitvi Direktive 92/12/EGS (UL L 9, 14.1.2009, str. 12).

Člen 46(3) se nadomesti z naslednjim:

"3. Brez poseganja v člen 32 lahko države članice, ki niso navedene v tretjem in četrtem pododstavku člena 2(2) Direktive 92/79/EGS od 1. januarja 2014 uporabljajo količinsko omejitev v višini vsaj 300 kosov cigaret, ki se lahko vnesejo na njihovo ozemlje brez dodatnega plačila trošarin iz države članice, v kateri v skladu s tretjim in četrtim pododstavkom člena 2(2) navedene direktive veljajo trošarine, nižje od tistih, ki izhajajo iz prvega pododstavka člena 2(2) navedene direktive.

Države članice, navedene v tretjem in četrtem pododstavku člena 2(2) Direktive 92/79/EGS, ki obračunavajo trošarino v višini najmanj 77 EUR za 1 000 cigaret ne glede na ponderirano povprečno maloprodajno ceno, lahko od 1. januarja 2014 uporabljajo količinsko omejitev v višini vsaj 300 kosov cigaret, ki se lahko vnesejo na njihovo ozemlje brez dodatnega plačila trošarin iz države članice, v kateri v skladu s tretjim pododstavkom člena 2(2) navedene direktive veljajo nižje trošarine.

Države članice, ki uporabijo količinsko omejitev v skladu s prvim in drugim pododstavkom tega odstavka, o tem obvestijo Komisijo. Opravijo lahko potrebne preglede, pod pogojem, da ti pregledi ne vplivajo na pravilno delovanje notranjega trga."

7. **REGIONALNA POLITIKA IN USKLAJEVANJE STRUKTURNIH  
INSTRUMENTOV**

1. Uredba Sveta (ES) št. 1083/2006 z dne 11. julija 2006 o splošnih določbah o Evropskem skladu za regionalni razvoj, Evropskem socialnem skladu in Kohezijskem skladu in razveljavitvi Uredbe (ES) št. 1260/1999 (UL L 210, 31.7.2006, str. 25).

1. V členu 15(4) se za drugim pododstavkom vstavi naslednji pododstavek:

"Komisija v sodelovanju s Hrvaško 31. decembra 2017 naknadno preveri spoštovanje načela dodatnosti."

2. V členu 18(1) se prvi pododstavek nadomesti z naslednjim:

"1. Razpoložljiva sredstva za prevzem obveznosti skladov za obdobje 2007–2013 znašajo 308 417 037 817 EUR v cenah iz leta 2004, v skladu z letno razdelitvijo, ki je prikazana v Prilogi I."

3. Člen 19 se nadomesti z naslednjim:

"Člen 19

**Sredstva za cilj 'konvergenca'**

Skupna sredstva za cilj 'konvergenca' znašajo 81,56 % sredstev iz člena 18(1) (tj. skupno 251 529 800 379 EUR) in se med različnimi deli razdelijo na sledeč način:

(a) 70,50 % (tj. skupno 177 324 921 223 EUR) za financiranje iz člena 5(1), z uporabo upravičenega prebivalstva, regionalne blaginje in nezaposlenosti kot merit za izračun okvirne razdelitve po državah članicah;

- (b) 4,98 % (tj. skupno 12 521 289 405 EUR) za prehodno in posebno pomoč iz člena 8(1), z uporabo upravičenega prebivalstva, regionalne blaginje, nacionalne blaginje in nezaposlenosti kot meril za izračun okvirne razdelitve po državah članicah;
  - (c) 23,23 % (tj. skupno 58 433 589 750 EUR) za financiranje iz člena 5(2), z uporabo prebivalstva, nacionalne blaginje in površine kot meril za izračun okvirne razdelitve po državah članicah;
  - (d) 1,29 % (tj. skupno 3 250 000 000 EUR) za prehodno in posebno pomoč iz člena 8(3)."
4. V členu 20 se prvi podostavek nadomesti z naslednjim:
- "Skupna sredstva za cilj 'regionalna konkurenčnost in zaposlovanje' znašajo 15,93 % sredstev iz člena 18(1) (tj. skupno 49 127 784 318 EUR) in se med različnimi deli razdelijo na sledeč način:"
5. V členu 21 se odstavka 1 in 2 nadomestita z naslednjim:

- "1. Skupna sredstva za cilj 'evropsko teritorialno sodelovanje' znašajo 2,52 % sredstev iz člena 18(1) (kar znaša 7 759 453 120 EUR) in se, razen zneska iz odstavka 22 Priloge II, med različnimi deli razdelijo na sledeč način:
- (a) 73,86 % (tj. skupno 5 583 386 893 EUR) za financiranje čezmejnega sodelovanja iz člena 7(1), z uporabo upravičenega prebivalstva kot merila za izračun okvirne razdelitve po državah članicah;

- (b) 20,95 % (tj. skupno 1 583 594 654 EUR) za financiranje transnacionalnega sodelovanja iz člena 7(2), z uporabo upravičenega prebivalstva kot merila za izračun okvirne razdelitve po državah članicah;
- (c) 5,19 % (tj. skupno 392 471 574 EUR) za financiranje medregionalnega sodelovanja, mrež sodelovanja in izmenjave izkušenj iz člena 7(3).

2. Prispevek ESRR k čezmejnim programom in programom skupnega morskega bazena v skladu z instrumentom o evropskem sosedstvu in partnerstvu in k čezmejnim programom v okviru instrumenta za predpristopno pomoč v skladu z Uredbo (ES) št. 1085/2006 znaša 817 691 234 EUR na podlagi navedbe vsake zadevne države članice, odšteto od njihovih dodeljenih sredstev iz odstavka 1(a). Ti prispevki ESRR niso vnovič porazdeljeni med zadevnimi državami članicami."

6. V členu 22 se doda naslednji pododstavek:

"Z odstopanjem od prvega pododstavka lahko Hrvaška v okviru cilja 'evropsko teritorialno sodelovanje' dodeljena finančna sredstva zaradi čim večje učinkovitosti in enostavnosti prerazdeli med tri komponente iz člena 21(1)(a) do (c)."

7. Člen 23 se nadomesti z naslednjim:

"Člen 23

**Sredstva za rezervo na podlagi doseženih rezultatov**

3 % sredstev iz člena 19(a) in (b) ter člena 20 lahko države članice, razen Hrvaške, dodelijo v skladu s členom 50."

8. Člen 28 se spremeni:

(a) V odstavku 1 se med prvi in drugi pododstavek vstavi naslednji pododstavek:

"Za Hrvaško nacionalni strateški referenčni okvir zajema obdobje od dne pristopa do 31. decembra 2013."

(b) V odstavku 2 se med prvi in drugi pododstavek vstavi naslednji pododstavek:

"Hrvaška pošlje Komisiji nacionalni strateški referenčni okvir v petih mesecih po dnevu pristopa."

9. V členu 29 se doda naslednji odstavek:

"5. Za Hrvaško se odstavki 1 do 4 ne uporabljajo."

10. Členu 32(3) se doda naslednji pododstavek:

"V primeru Hrvaške, Komisija sklep o odobritvi operativnega programa, ki naj bi se financiral v okviru programskega obdobja 2007–2013, sprejme najpozneje 31. decembra 2013. Hrvaška ta operativni program predloži najpozneje v treh mesecih od dne pristopa, pod pogojem da so bile upoštevane morebitne pripombe Komisije."

11. Členu 33(1) se doda naslednji pododstavek:

"Za Hrvaško se operativni programi, sprejeti pred datumom pristopa, lahko pregledajo z izključnim namenom boljše usklajenosti s to uredbo."

12. Členu 49(3) se doda naslednji pododstavek:

"Naknadno vrednotenje za operativne programe Hrvaške se zaključi do 31. decembra 2016."

13. Vstavi se naslednji člen:

"Člen 51a

Za Hrvaško se člena 50 in 51 ne uporabljata."

14. Člen 53(3) se nadomesti z naslednjim:

"3. Za operativne programe v okviru cilja 'evropsko teritorialno sodelovanje', pri katerih vsaj en udeleženec spada med države članice, katerih povprečni bruto domači proizvod na prebivalca (BDP) za obdobje 2001–2003 ni presegal 85 % povprečja EU-25 v istem obdobju, ali za takšne programe, v katerih Hrvaška sodeluje, prispevek iz ESRR ne sme biti višji od 85 % upravičenih izdatkov. Za vse druge operativne programe prispevek iz ESRR ne sme biti višji od 75 % upravičenih izdatkov, ki jih sofinancira ESRR."

15. Členu 56(1) se doda naslednji pododstavek:

"Za Hrvaško so izdatki upravičeni do prispevka iz skladov med začetnim datumom upravičenosti izdatkov, kakor je določen v skladu z instrumenti, sprejetimi na podlagi Uredbe (ES) št. 1085/2006, in 31. decembrom 2016. Vendar so izdatki za operativne programe, sprejete po datumu pristopa, upravičeni do prispevka iz skladov od datuma pristopa, razen če je v sklepu o zadevnem operativnem programu določen poznejši datum."

16. Členu 56(3) se doda naslednji pododstavek:

"Ne glede na posebne določbe o upravičenosti iz člena 105a se merila, ki jih določi nadzorni odbor operativnih programov za Hrvaško, ne uporabljajo za operacije, katerih odobritev je bila sprejeta pred datumom pristopa in so del instrumentov, sprejetih na podlagi Uredbe (ES) št. 1085/2006."

17. Člen 62(1) se spremeni:

(a) V točki (c) se med prvi in drugi pododstavek vstavi naslednji pododstavek:

"Za Hrvaško revizijski organ operativnega programa v treh mesecih po datumu pristopa Komisiji predloži posodobljen letni načrt revizijskega dela, kakor je opredeljeno v členu 29(2)(a) Uredbe Komisije (ES) št. 718/2007 z dne 12. junija 2007 o izvajanju Uredbe Sveta (ES) št. 1085/2006 o vzpostavitvi instrumenta za predpristopno pomoč (IPA)<sup>1</sup>."

(b) V točki (d)(i) se doda naslednji pododstavek:

"Za Hrvaško se prvo letno poročilo o nadzoru predloži do 31. decembra 2013, zajemajoč obdobje od 1. oktobra 2012 do 30. junija 2013. Naslednja poročila, ki zajemajo obdobja od 1. julija 2013 do 30. junija 2014, od 1. julija 2014 do 30. junija 2015 in od 1. julija 2015 do 30. junija 2016, se Komisiji predložijo do 31. decembra 2014, 31. decembra 2015 oziroma 31. decembra 2016. Podatki v zvezi z revizijami, izvedenimi po 1. juliju 2016, se vključijo v končno poročilo o nadzoru k izjavi o zaključitvi iz točke (e);"

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<sup>1</sup> UL L 170, 29.6.2007, str. 1.

(c) V točki (e) se doda naslednji pododstavek:

"Za Hrvaško se izjava o zaključitvi, osnovana na končnem poročilu o nadzoru, Komisiji predloži do 31. marca 2018."

18. Členu 67(1) se doda naslednji pododstavek:

"Organ upravljanja v imenu Hrvaške pošlje končno poročilo o izvajanju operativnega programa do 31. marca 2018."

19. Člen 71 se spremeni:

(a) Vstavi se naslednji odstavek:

"1a. Ne glede na odstavek 1 Hrvaška v najkrajšem možnem času po datumu pristopa ali najpozneje pred vsakršnim plačilom Komisije tej predloži opis sistemov, ki zajema elemente iz točk (a) in (b) tega odstavka."

(b) Vstavi se naslednji odstavek:

"2a. Odstavek 2 se smiselno uporablja za Hrvaško. Poročilo iz prvega pododstavka se šteje za sprejeto pod istimi pogoji, kakor so določeni v drugem pododstavku. Vendar pa je takšno sprejetje predpogoj za znesek vnaprejšnjega financiranja iz člena 82."

20. V členu 75 se vstavi naslednji odstavek:

"1a. Ustrezne proračunske obveznosti za Hrvaško iz ESRR, Kohezijskega sklada in ESS za leto 2013 se prevzamejo na podlagi odločitve iz člena 28(3), preden Komisija sprejme kakršno koli odločitev o spremembi sprejetega programa. Odločitev iz člena 28(3) se za proračunske obveznosti v korist Hrvaške šteje za odločitev o financiranju v smislu člena 75 Uredbe (ES, Euratom) št. 1605/2002."

21. Členu 78(2)(c) se doda naslednji stavek:

"V primeru Hrvaške jih pokrivajo izdatki, ki so jih plačali upravičenci pri izvajaju projekta, in so utemeljeni s prejetimi računi ali računovodskimi listinami z enako dokazno vrednostjo najpozneje tri leta po letu plačila predujma ali 31. decembra 2016, kar je prej; če niso, se naslednji izkaz o izdatkih ustreznno popravi."

22. V členu 82 se vstavi naslednji odstavek 1a:

"1a. Po sprejetju poročila iz člena 71(2a) in v skladu z ustreznimi proračunskimi obveznostmi iz člena 75(1a) se enkratni znesek vnaprejšnjega financiranja za preostanek obdobja 2007–2013 Hrvaški izplača v enem obroku, ustreza pa 30 % prispevka iz strukturnih skladov in 40 % prispevka iz Kohezijskega sklada za operativni program."

23. V členu 89(1) se doda naslednji pododstavek:

"V primeru Hrvaške se zahtevek za plačilo, ki vsebuje dokumente iz točk (a)(i) do (iii), pošlje do 31. marca 2018."

24. V členu 93 se vstavi naslednji odstavek:

"3a. Z odstopanjem od odstavkov 1 do 3 Komisija v primeru Hrvaške uporabi mehanizem prenehanja prevzetih obveznosti iz odstavka 1 na naslednji način:

(i) rok za kateri koli odprti del prevzetih obveznosti iz leta 2010 je 31. december 2013;

(i) rok za kateri koli odprti del prevzetih obveznosti iz leta 2011 je 31. december 2014;

(i) rok za kateri koli odprti del prevzetih obveznosti iz leta 2012 je 31. december 2015;

(iv) kateri koli del prevzetih obveznosti iz leta 2013, ki so 31. decembra 2016 še vedno odprte, samodejno preneha, če Komisija do 31. marca 2018 ne prejme ustreznega zahtevka za plačilo."

25. V členu 95 se za drugim pododstavkom vstavi naslednji pododstavek:

"Z odstopanjem od prvega in drugega pododstavka se za Hrvaško roki iz člena 93(3a) prekinejo pod pogoji iz prvega pododstavka tega odstavka, ki veljajo za znesek za zadevne operacije."

26. Členu 98(2) se doda naslednji pododstavek:

"V primeru Hrvaške lahko sredstva iz skladov, ki so bila sproščena na ta način, Hrvaška porablja do 31. decembra 2016."

27. Vstavi se naslednji člen:

"*Člen 105a*

### **Posebne določbe po pristopu Hrvaške**

1. Za programe in velike projekte, ki so bili na dan pristopa Hrvaške odobreni na podlagi Uredbe Sveta (ES) št. 1085/2006 z dne 17. julija 2006 o vzpostavitev instrumenta za predpristopno pomoč (IPA)<sup>1</sup> in ki do tega dne niso bili zaključeni, se šteje, da jih je odobrila Komisija v okviru te uredbe, z izjemo programov, odobrenih v okviru komponent iz člena 3(1)(a) do (e) navedene uredbe.

Poleg tega se izključijo tudi naslednji programi, zajeti v komponenti iz člena 3(1)(b) Uredbe (ES) št. 1085/2006:

- (a) 'program čezmejnega sodelovanja IPA Adriatic';
- (b) čezmejni program 'Hrvaška-Bosna in Hercegovina';
- (c) čezmejni program 'Hrvaška-Črna gora';
- (d) čezmejni program 'Hrvaška-Srbija'.

Brez poseganja v odstavke 2 do 7 se za te operacije in velike projekte uporablajo določbe o izvajanju operacij in velikih projektov, odobrenih v skladu s to uredbo.

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<sup>1</sup> UL L 210, 31.7.2006, str. 82.

2. Postopki javnih naročil v zvezi z operacijami znotraj programov ali v zvezi z velikimi projekti iz odstavka 1, za katere je bil do dne pristopa že objavljen javni razpis v *Uradnem listu Evropske unije*, se izvedejo v skladu s pravili iz tega razpisa. Določbe iz člena 165 Uredbe Sveta (ES, Euratom) št. 1605/2002 z dne 25. junija 2002 o finančni uredbi, ki se uporablja za splošni proračun Evropskih skupnosti<sup>1</sup>, se ne uporabljajo.

Postopki javnih naročil v zvezi z operacijami znotraj programov ali v zvezi z velikimi projekti iz odstavka 1, za katere do dne pristopa še ni bil objavljen javni razpis v *Uradnem listu Evropske unije*, se izvedejo v skladu z določbami Pogodb ali aktov, sprejetih v okviru Pogodb, in v skladu s členom 9 te uredbe.

Operacije, ki niso operacije iz prvega in drugega pododstavka in za katere so bili razpisi za predloge objavljeni v skladu s členom 158 Uredbe Komisije (ES) št. 718/2007 z dne 12. junija 2007 o izvajaju Uredbe Sveta (ES) št. 1085/2006 ali za katere so bili zahtevki predloženi pristojnim organom pred datumom pristopa in bi jih bilo mogoče pogodbeno skleniti šele po tem datumu, se izvedejo v skladu s pogoji in pravili o upravičenosti, objavljenimi v ustremnem razpisu za predloge, oziroma pogoji in pravili o upravičenosti, o katerih so bili potencialni upravičenci predhodno obveščeni.

3. Plačila Komisije v okviru programov iz odstavka 1 se štejejo za prispevek iz skladov v skladu s to uredbo in se knjižijo na najstarejšo odprto obveznost, vključno z obveznostmi v zvezi z IPA.

Ta uredba od datuma pristopa ureja kateri koli del obveznosti, ki jih je Komisija prevzela v okviru programov iz odstavka 1 in ki so še odprte na dan pristopa.

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<sup>1</sup> UL L 248, 16.9.2002, str. 1.

4. Za operacije, odobrene v okviru Uredbe Sveta (ES) št. 1085/2006, ki so bile odobrene ali za katere so bili ustreznii sporazumi o donaciji s končnimi upravičenci podpisani pred dnem pristopa, se še naprej uporablajo pravila o upravičenosti izdatkov v skladu z Uredbo Sveta (ES) št. 718/2007 ali na podlagi te uredbe, razen v upravičenih primerih, o katerih na prošnjo Hrvaške odloča Komisija.

Pravilo o upravičenosti iz prvega pododstavka se uporablja tudi za velike projekte iz odstavka 1, za katere so bili pred dnem pristopa podpisani sporazumi o dvostranskih projektih.

5. Glede Hrvaške se vsak sklic na sklade, kakor so opredeljeni v drugem pododstavku člena 1, šteje, kot da vključuje tudi instrument za predpristopno pomoč iz Uredbe Sveta (ES) št. 1085/2006.

6. Posebni roki, ki se uporablajo za Hrvaško, se uporablajo tudi za naslednje čezmejne programe, zajete v komponenti iz člena 3(1)(b) Uredbe (ES) št. 1085/2006, v katerih sodeluje Hrvaška:

- (a) čezmejni program 'Madžarska-Hrvaška' in
- (b) čezmejni program 'Slovenija-Hrvaška'.

Posebni roki, ki se v skladu s to uredbo uporablajo za Hrvaško, se ne uporablajo za operativne programe iz transnacionalnih in medregionalnih komponent v okviru cilja 'evropsko teritorialno sodelovanje', v katerem sodeluje Hrvaška.

7. Če so potrebni ukrepi za lažji prehod Hrvaške iz predpristopne ureditve na ureditev, ki izhaja iz uporabe tega člena, te potrebne ukrepe sprejme Komisija."

28. Priloga I se nadomesti z naslednjim:

*"PRILOGA I*

**Letna razdelitev odobritev za prevzem obveznosti za obdobje 2007–2013  
(iz člena 18)**

(EUR, po cenah iz leta 2004)

2007	2008	2009	2010	2011	2012	2013
42 863 000 000	43 318 000 000	43 862 000 000	43 860 000 000	44 073 000 000	44 723 000 000	45 718 037 817

"

29. Priloga II se spremeni:

(a) Prvemu pododstavku odstavka 5 se dodajo naslednje točke:

"(c) za Hrvaško sredstva za finančiranje čezmejnega sodelovanja znašajo 7 028 744 EUR po cenah iz leta 2004;

(d) za Hrvaško sredstva za financiranje transnacionalnega sodelovanja znašajo 1 874 332 EUR po cenah iz leta 2004."

(b) Vstavi se naslednji odstavek:

"7a. Za Hrvaško bo največja stopnja prenosa iz skladov 3,5240 % njenega BDP."

(c) Vstavi se naslednji odstavek:

"9a. Za Hrvaško bodo izračuni BDP, ki jih opravi Komisija, temeljili na statističnih podatkih in napovedih, objavljenih maja 2011."

30. Priloga III se nadomesti z naslednjim:

*"PRILOGA III*

Zgornje meje, ki veljajo za stopnje sofinanciranja  
(iz člena 53)

Merila	Države članice	ESRR in ESS Odstotek upravičenih izdatkov	Kohezijski sklad Odstotek upravičenih izdatkov
1. Države članice, katerih povprečni BDP na prebivalca za obdobje 2001–2003 ni presegal <b>85 %</b> povprečja EU-25 v istem obdobju.	Bolgarija, Češka, Estonija, Ciper, Grčija, Hrvaška, Latvija, Litva, Madžarska, Malta, Poljska, Portugalska, Romunija, Slovenija Slovaška	<b>85 %</b> za cilja 'konvergenca' ter 'regionalna konkurenčnost in zaposlovanje'	<b>85 %</b>
2. Države članice, ki ne spadajo v (1), upravičene do prehodne ureditve Kohezijskega sklada 1. januarja 2007	Španija	<b>80 %</b> za cilj 'konvergenca in regije v postopnem uvajanju' v okviru cilja 'regionalna konkurenčnost in zaposlovanje' <b>50 %</b> za cilj 'regionalna konkurenčnost in zaposlovanje' izven regij v postopnem uvajanju	<b>85 %</b>
3. Države članice, ki niso navedene v (1) in (2).	Belgija, Danska, Nemčija, Francija, Irska, Italija, Luksemburg, Nizozemska, Avstrija, Finska, Švedska in Združeno kraljestvo	<b>75 %</b> za cilj 'konvergenca'	

4. Države članice, ki niso navedene v (1) in (2).	Belgija, Danska, Nemčija, Francija, Irska, Italija, Luksemburg, Nizozemska, Avstrija, Finska, Švedska in Združeno kraljestvo	<b>50 % za cilj 'regionalna konkurenčnost in zaposlovanje'</b>	
5. Najbolj oddaljene regije iz člena 349 PDEU, upravičene do dodatne dodelitve za te regije iz točke 20 Priloge II.	Španija, Francija in Portugalska	<b>50 %</b>	
Najbolj oddaljene regije iz člena 349 PDEU	Španija, Francija in Portugalska	<b>85 % v okviru ciljev 'konvergenca' ter 'regionalna konkurenčnost in zaposlovanje'</b>	

2. Uredba Sveta (ES) št. 1084/2006 z dne 11. julija 2006 o ustanovitvi Kohezijskega sklada in razveljavitvi Uredbe (ES) št. 1164/94 (UL L 210, 31.7.2006, str. 79).

Vstavi se naslednji člen:

"Člen 5a

**Posebne določbe po pristopu Hrvaške**

1. Ukrepi, za katere na dan pristopa Hrvaške veljajo sklepi Komisije o pomoči na podlagi Uredbe Sveta (ES) št. 1267/1999 z dne 21. junija 1999 o vzpostavitvi instrumenta strukturne politike v predpristopnem obdobju (ISPA)<sup>1</sup> in katerih izvajanje se do dne pristopa še ni zaključilo, se štejejo za odobrene s strani Komisije na podlagi te uredbe.

Brez poseganja v odstavke 2 do 5 se za te ukrepe uporabljam določbe o izvajanju dejavnosti, odobrenih v skladu s to uredbo in Uredbo Sveta (ES) št. 1083/2006.

2. Postopki javnih naročil v zvezi z ukrepi iz odstavka 1, za katere je bil do dne pristopa že objavljen javni razpis v *Uradnem listu Evropske unije*, se izvedejo v skladu s pravili iz tega razpisa. Določbe iz člena 165 Uredbe Sveta (ES, Euratom) št. 1605/2002 z dne 25. junija 2002 o finančni uredbi, ki se uporablja za splošni proračun Evropskih skupnosti<sup>2</sup>, se ne uporabljam.

Postopki javnih naročil v zvezi z ukrepom iz odstavka 1, za katere do dne pristopa še ni bil objavljen javni razpis v *Uradnem listu Evropske unije*, se izvedejo v skladu z določbami Pogodb ali aktov, sprejetih v okviru Pogodb, in v skladu s členom 9 Uredbe Sveta (ES) št. 1083/2006.

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<sup>1</sup> UL L 161, 26.6.1999, str. 73.

<sup>2</sup> UL L 248, 16.9.2002, str. 1.

3. Plačila Komisije v okviru ukrepa iz odstavka 1 štejejo za prispevek iz sklada po tej uredbi.

Plačila Komisije v okviru ukrepa iz odstavka 1 se knjižijo na najstarejšo odprto obveznost, nastalo najprej v skladu z Uredbo Sveta (ES) št. 1267/1999, nato pa v skladu s to uredbo in Uredbo Sveta (ES) št. 1083/2006.

Za vmesna plačila ali za končno plačilo veljajo pogoji iz odstavkov 2(b) do (d) in odstavkov 3 do 5 člena D Priloge II k Uredbi Sveta (ES) št. 1164/94.

4. Za ukrepe iz odstavka 1 se še naprej uporabljam pravila o upravičenosti izdatkov, ki so v skladu z Uredbo Sveta (ES) št. 1267/1999 ali posebej določena v ustreznih sporazumih o financiranju, razen v upravičenih primerih, o katerih na prošnjo Hrvaške odloča Komisija.

5. Če so potrebni ukrepi za lažji prehod Hrvaške iz predpristopne ureditev na ureditev, ki izhaja iz uporabe tega člena, te potrebne ukrepe sprejme Komisija."

8. **OKOLJE**

1. Direktiva 2003/87/ES Evropskega parlamenta in Sveta z dne 13. oktobra 2003 o vzpostavitvi sistema za trgovanje s pravicami do emisije toplogrednih plinov v Skupnosti in o spremembah Direktive Sveta 96/61/ES (UL L 275, 25.10.2003, str. 32).

(a) V členu 9 se prvemu pododstavku doda naslednje:

"Količina pravic za celotno Skupnost se kot posledica pristopa Hrvaške poveča le za količino pravic, ki jih Hrvaška da na dražbo v skladu s členom 10(1)."

(b) V Prilogi IIa se pred vnosom za Italijo vstavi naslednje:

"Hrvaška 26 %"

2. Odločba št. 406/2009/ES Evropskega parlamenta in Sveta z dne 23. aprila 2009 o prizadevanju držav članic za zmanjšanje emisij toplogrednih plinov, da do leta 2020 izpolnijo zavezo Skupnosti za zmanjšanje emisij toplogrednih plinov (UL L 140, 5.6.2009, str. 136).

V Prilogi IIa se pred vnosom za Italijo vstavi naslednje:

"Hrvaška 11 %"

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## *PRILOGA IV*

### **Seznam iz člena 16 Akta o pristopu: druge trajne določbe**

#### **1. PRAVO INTELEKTUALNE LASTNINE**

##### **Pogodba o delovanju Evropske unije, naslov II tretjega dela, Prosti pretok blaga**

##### **POSEBNI MEHANIZEM**

Na Hrvaškem se lahko imetnik patenta ali dodatnega varstvenega certifikata (DVC) za farmacevtski izdelek, ki je prijavljen v državi članici, ker taka zaščita ni mogla biti pridobljena na Hrvaškem, ali njegov upravičenec, sklicuje na pravice, podeljene s tem patentom ali DVC, da bi preprečil uvoz in trženja tega proizvoda v državah članicah oziroma državah, kjer ta proizvod uživa patentno varstvo ali varstvo z dodatnim certifikatom, tudi če je proizvod prvič dal na hrvaški trg imetnik ali se je to zgodilo z njegovim soglasjem.

Vsakdo, ki namerava uvažati ali tržiti farmacevtski proizvod iz prvega odstavka v državi članici, kjer proizvod uživa patentno varstvo ali varstvo DVC, pristojnim organom v prijavi za uvoz dokaže, da je bil imetnik tega varstva ali njegov upravičenec o tem mesec dni prej uradno obveščen.

## 2. POLITIKA KONKURENCE

### **Pogodba o delovanju Evropske unije, poglavje 1 naslova VII tretjega dela, Pravila o konkurenči**

1. Naslednji programi pomoči in posamična pomoč, ki so se na Hrvaškem začeli izvajati pred dnem pristopa in se izvajajo tudi po tem dnevu, se od pristopa štejejo za obstoječo pomoč v smislu člena 108(1) PDEU:
  - (a) ukrepi pomoči, ki so se začeli izvajati pred 1. marcem 2002;
  - (b) ukrepi pomoči, ki so našteti v dodatku k tej prilogi;
  - (c) ukrepi pomoči, ki jih je pred dnem pristopa ocenila hrvaška agencija za konkurenco in ugotovila, da so združljivi s pravnim redom Unije, ter jim Komisija v skladu s postopkom iz odstavka 2 ni nasprotovala zaradi resnih dvomov o združljivosti ukrepa z notranjim trgom.

Za uporabo člena 108(3) PDEU se vsi ukrepi, ki se po pristopu še vedno uporabljajo in pomenijo državno pomoč ter ne izpolnjujejo zgornjih pogojev, od pristopa štejejo za novo pomoč.

Zgornje določbe se ne uporabljajo za pomoč dejavnostim, povezanim s proizvodnjo, predelavo ali trženjem proizvodov, ki so našteti v Prilogi I k PDEU.

2. Če Hrvaška želi, da Komisija preuči ukrep pomoči po postopku iz odstavka 1(c), Komisiji redno pošilja:

- (a) seznam obstoječih ukrepov pomoči, ki jih je ocenila hrvaška agencija za konkurenco in ugotovila, da so združljivi s pravnim redom Unije, in
- (b) kakršnekoli druge informacije, ki so bistvene za oceno združljivosti obravnavanega ukrepa pomoči,

v skladu s predpisanim obrazcem za poročilo, ki ga pripravi Komisija.

Če Komisija v treh mesecih od prejema popolnih informacij o obstoječem ukrepu pomoči ali po prejemu izjave nove države članice, v kateri ta obvešča Komisijo, da šteje predložene informacije za popolne, ker dodatne zahtevane informacije niso dostopne ali so že bile predložene, glede tega ukrepa pomoči nima pripomb zaradi resnih dvomov glede njegove združljivosti z enotnim trgom, se šteje, da ukrepu ni nasprotovala.

Zgornji postopek velja za vse ukrepe pomoči, ki so pred dnem pristopa predloženi Komisiji po postopku iz odstavka 1(c), ne glede na dejstvo, da je v času preučevanja ukrepa Hrvaška že postala članica Unije.

3. Odločba Komisije, da nasprotuje ukrepu v smislu odstavka 1(c), šteje za odločbo o začetku formalnega postopka preiskave v smislu Uredbe Sveta (ES) št. 659/1999 z dne 22. marca 1999 o določitvi podrobnih pravil za uporabo člena 93 Pogodbe ES

<sup>1</sup> (zdaj člen 108 PDEU).

Če je taka odločba sprejeta pred dnem pristopa, bo začela veljati šele z dnem pristopa.

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<sup>1</sup> UL L 83, 27.3.1999, str. 1.

### 3. KMETIJSTVO

#### (a) Pogodba o delovanju Evropske unije, naslov III tretjega dela, Kmetijstvo in ribištvo

1. Javne zaloge, ki jih ima Hrvaška na dan pristopa in so posledica njene politike tržne podpore, prevzame Unija po vrednosti, izračunani na ob uporabi člena 4(1)(d) in Priloge VIII k Uredbi Komisije (ES) št. 884/2006 z dne 21. junija 2006 o določitvi podrobnih pravil za uporabo Uredbe Sveta (ES) št. 1290/2005 v zvezi s financiranjem intervencijskih ukrepov s strani Evropskega kmetijskega jamstvenega sklada (EKJS) in knjiženjem postopkov javnega skladiščenja s strani plačilnih agencij držav članic<sup>1</sup>. Omenjene zaloge se prevzamejo le pod pogojem, da je javna intervencija za zadevne proizvode opravljena v Uniji in da zaloge izpolnjujejo zahteve za intervencijo Unije.
2. Hrvaški je treba za vse zaloge, zasebne ali javne, v prostem prometu, ki na dan pristopa Hrvaške presegajo količino, ki velja za običajen presežek zalog, naložiti plačilo v obliki nakazila v splošni proračun Evropske unije.

Višina plačila mora odražati stroške, povezane s posledicami presežka zalog na trgu kmetijskih proizvodov.

Količino presežka je treba določiti za vsak proizvod posebej glede na njegove značilnosti in ustrezne trge ter zakonodajo Unije, ki se zanj uporablja.

3. Zaloge iz odstavka 1 se odštejejo od količine, ki presega običajen prenos zalog.

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<sup>1</sup> UL L 171, 23.6.2006, str. 35, in UL L 326 M, 10.12.2010, str. 70.

4. Komisija izvaja in uporablja ureditve iz odstavkov 1 do 3 v skladu s postopkom iz člena 41(2) Uredbe Sveta (ES) št. 1290/2005 z dne 21. junija 2005 o financiranju skupne kmetijske politike<sup>1</sup> ali, če je to primerno, v skladu s postopkom iz člena 195(2) Uredbe Sveta (ES) št. 1234/2007 z dne 22. oktobra 2007 o vzpostavitvi skupne ureditve kmetijskih trgov in o posebnih določbah za nekatere kmetijske proizvode (Uredba o enotni SUT)<sup>2</sup> ali v skladu z ustreznim postopkom v odboru, kot je opredeljen v zakonodaji, ki se uporablja.

(b) **Pogodba o delovanju Evropske unije, poglavje 1 naslova VII tretjega dela, Pravila o konkurenči**

Brez poseganja v postopke o obstoječih pomočeh iz člena 108 PDEU se programi pomoči in posamična pomoč, podeljena dejavnostim, povezanim s proizvodnjo ali trgovino s proizvodi, navedenimi v Prilogi I k PEU in PDEU, z izjemo ribiških proizvodov in iz njih pridobljenih proizvodov, ki so se na Hrvaškem začeli izvajati pred dnem pristopa in se izvajajo tudi po tem dnevu, štejejo za obstoječo pomoč v smislu člena 108(1) PDEU, ob upoštevanju naslednjih pogojev:

- Komisija je o ukrepih pomoči obveščena v štirih mesecih od dneva pristopa. To obvestilo vključuje podatke o pravni podlagi vsakega ukrepa. Za obstoječe ukrepe pomoči in načrte o podelitvi ali spremembji pomoči, o katerih je Komisija obveščena pred dnem pristopa, se šteje, da je bila Komisija o njih obveščena na dan pristopa. Komisija objavi seznam takšne pomoči.

Ti ukrepi pomoči v obdobju treh let od datuma pristopa veljajo za "obstoječo" pomoč v smislu člena 108(1) PDEU.

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<sup>1</sup> UL L 209, 11.8.2005, str. 1.

<sup>2</sup> UL L 299, 16.11.2007, str. 1.

Hrvaška po potrebi spremeni te ukrepe pomoči, da bi v treh letih od datuma pristopa upoštevala smernice, ki jih uporablja Komisija. Po tem obdobju se vsaka pomoč, za katero se ugotovi, da je nezdružljiva s temi smernicami, šteje za novo pomoč.

#### 4. RIBIŠTVO

##### **Pogodba o delovanju Evropske unije, poglavje 1 naslova VII tretjega dela, Pravila o konkurenči**

Brez poseganja v postopke o obstoječi pomoči iz člena 108 PDEU se programi pomoči in posamična pomoč, dodeljena dejavnostim, ki so povezane s proizvodnjo in trgovino ribiških proizvodov in proizvodov, ki izvirajo iz njih, navedenih v Prilogi I k PEU in PDEU, in ki so v Hrvaški začeli učinkovati pred dnem njenega pristopa in se uporabljajo tudi po tem dnevu, štejejo za obstoječo pomoč v smislu člena 108(1) PDEU, ob upoštevanju naslednjih pogojev:

- Komisija je o ukrepih pomoči obveščena v štirih mesecih od dneva pristopa. To obvestilo vključuje podatke o pravni podlagi vsakega ukrepa. Za obstoječe ukrepe pomoči in načrte o podelitvi ali spremembji pomoči, o katerih je Komisija obveščena pred dnem pristopa, se šteje, da je bila Komisija o njih obveščena na dan pristopa. Komisija objavi seznam takšne pomoči.

Ti ukrepi pomoči v obdobju treh let od datuma pristopa veljajo za "obstoječo" pomoč v smislu člena 108(1) PDEU.

Hrvaška po potrebi spremeni te ukrepe pomoči, da bi v treh letih od datuma pristopa upoštevala smernice, ki jih uporablja Komisija. Po tem obdobju se vsaka pomoč, za katero se ugotovi, da je nezdružljiva s temi smernicami, šteje za novo pomoč.

## 5. CARINSKA UNIJA

### Pogodba o delovanju Evropske unije, naslov II tretjega dela, Prosti pretok blaga, poglavje 1, Carinska unija

31992 R 2913: Uredba Sveta (EGS) št. 2913/92 z dne 12. oktobra 1992 o carinskem zakoniku Skupnosti (UL L 302, 19.10.1992, str. 1).

31993 R 2454: Uredba Komisije (EGS) št. 2454/93 z dne 2. julija 1993 o določbah za izvajanje Uredbe Sveta (EGS) št. 2913/92 o carinskem zakoniku Skupnosti (UL L 253, 11.10.1993, str. 1).

Uredba (EGS) št. 2913/92 in Uredba (EGS) št. 2454/93 se za Hrvaško uporablja ob upoštevanju naslednjih posebnih določb:

#### DOKAZILO O STATUSU UNIJE (TRGOVINA V RAZŠIRJENI UNIJI)

1. Ne glede na člen 20 Uredbe (EGS) št. 2913/92 je blago, ki je na dan pristopa v razširjeni Uniji v začasni hrambi ali v carinski rabi in v postopkih iz členov 4(15)(b) in (16)(b) do (h) te uredbe ali ki se prevaža v razširjeni Uniji po opravljenih izvoznih formalnostih, ob deklaraciji za sprostitev v prosti promet v razširjeni Uniji oproščeno carin in drugih carinskih ukrepov, pod pogojem, da se predloži eno izmed naslednjih dokazil:
  - (a) dokazilo o preferencialnem poreklu, ki je bilo ustrezno izdano ali sestavljeno pred dnem pristopa v skladu s Stabilizacijsko-pridružitvenim sporazumom med Evropskima skupnostma in njunimi državami članicami na eni strani in Republiko Hrvaško na drugi strani (Stabilizacijsko-pridružitveni sporazum)<sup>1</sup>;

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<sup>1</sup> UL L 26, 28.1.2005, str. 3.

- (b) katerokoli dokazilo o statusu Unije iz člena 314c Uredbe (EGS) št. 2454/93;
- (c) zvezek ATA, ki je bil izdan v sedanji državi članici ali na Hrvaškem pred dnem pristopa.
2. Za namene izdajanja dokazil iz odstavka 1(b) zgoraj, upoštevajoč položaj na dan pristopa in poleg določb člena 4(7) Uredbe (EGS) št. 2913/92, "blago Skupnosti" pomeni blago, ki je:
- v celoti pridobljeno na območju Hrvaške pod pogoji, enakimi tistim iz člena 23 Uredbe (EGS) št. 2913/92, in ne vsebuje blaga, uvoženega iz drugih držav ali območij,
  - uvoženo iz držav ali območij razen Hrvaške in sproščeno v prosti promet na Hrvaškem ali
  - pridobljeno ali proizvedeno na Hrvaškem bodisi izključno iz blaga, navedenega v drugi alinei tega odstavka, bodisi iz blaga, navedenega v prvi in drugi alinei tega odstavka.
3. Za namene preverjanja dokazil iz zgornjega odstavka 1(a) se uporabljam določbe o opredelitvi pojma "izdelki s poreklom" in načinu upravnega sodelovanja iz Stabilizacijsko-pridružitvenega sporazuma. Zahtevke za naknadno preverjanje teh dokazil sprejemajo pristojni carinski organi sedanjih držav članic in Hrvaške v obdobju treh let po izdaji ali sestavi zadevnega dokazila o poreklu ter jih lahko vlagajo ti organi v obdobju treh let po sprejemu dokazila o poreklu v podporo deklaraciji o prostem prometu.

DOKAZILO O PREFERENCIALNEM POREKLU (TRGOVINA S TRETIJMI DRŽAVAMI,  
VKLJUČNO S TURČIJO, V OKVIRU PREFERENCIALNIH SPORAZUMOV O KMETIJSKIH  
IZDELKIH TER IZDELKIH IZ PREMOGA IN JEKLA)

4. Brez poseganja v uporabo kateregakoli ukrepa, ki izhaja iz skupne trgovinske politike, je dokazilo o poreklu, ki ga ustrezno izdajo tretje države ali se ga sestavi v okviru preferencialnih sporazumov, ki jih Hrvaška sklene s temi državami, sprejeto na Hrvaškem, pod pogojem, da:
- (a) pridobitev takega porekla pomeni priznanje preferencialne tarifne obravnave na podlagi preferencialnih tarifnih ukrepov iz člena 20(3)(d) in (e) Uredbe (EGS) št. 2913/92, ki jih predvidevajo sporazumi ali dogovori, ki jih je Unija sklenila s temi tretjimi državami ali skupinami držav oziroma jih je sprejela v zvezi z njimi,
  - (b) so bili dokazilo o poreklu in prevozni dokumenti izdani ali sestavljeni najkasneje na dan pred dnem pristopa, in
  - (c) se dokazilo o poreklu predloži carinskim organom v obdobju štirih mesecev od dneva pristopa.

Če je bilo blago na Hrvaškem deklarirano za sprostitev v prosti promet pred dnem pristopa, je tudi naknadno izdano ali sestavljeno dokazilo o poreklu na podlagi preferencialnih sporazumov, ki na Hrvaškem veljajo na dan sprostitve v prosti promet, lahko sprejeto na Hrvaškem, pod pogojem, da je predloženo carinskim organom v obdobju štirih mesecev od dne pristopa.

5. Hrvaški se dovoli ohraniti pooblastila, s katerimi je bil v okviru sporazumov, sklenjenih s tretjimi državami, podeljen status "pooblaščenih izvoznikov", pod pogojem, da:
  - (a) je tako določba predvidena tudi v sporazumih, sklenjenih med temi tretjimi državami in Unijo pred dnem pristopa, in
  - (b) pooblaščeni izvozniki uporabljajo pravila o poreklu iz teh sporazumov.

Ta pooblastila Hrvaška najkasneje eno leto od dne pristopa nadomesti z novimi pooblastili, ki se izdajo v skladu s pogoji iz zakonodaje Unije.

6. Za namene preverjanja dokazil iz odstavka 4 se uporabijo določbe o opredelitvi pojma "izdelki s poreklom" in načinih upravnega sodelovanja iz ustreznih sporazumov ali ureditev. Zahtevke za naknadno preverjanje teh dokazil sprejemajo pristojni carinski organi sedanjih držav članic in Hrvaške v obdobju treh let po izdaji ali sestavi zadevnega dokazila o poreklu ter jih lahko vlagajo ti organi v obdobju treh let po sprejemu dokazila o poreklu v podporo deklaraciji o prostem prometu.
7. Brez poseganja v uporabo katerega koli ukrepa, ki izhaja iz skupne trgovinske politike, je dokazilo o poreklu, ki ga naknadno izdajo ali sestavijo tretje države v okviru preferencialnih sporazumov ali ureditev, ki jih je Unija sklenila s temi državami oziroma sprejela v zvezi z njimi, sprejeto na Hrvaškem za sprostitev v prosti promet blaga, ki je bilo na dan pristopa v postopku prevoza ali začasni hrambi, v carinskem skladišču ali prosti coni v eni od teh tretjih držav ali na Hrvaškem, pod pogojem, da na Hrvaškem za zadevne izdelke v času izdaje prevoznih dokumentov ne velja sporazum o prosti trgovini s tretjo državo, in pod pogojem, da:

- (a) pridobitev takega porekla podeli preferencialno tarifno obravnavo na podlagi preferencialnih tarifnih ukrepov iz člena 20(3)(d) in (e) Uredbe (EGS) št. 2913/92, ki jih vsebujejo sporazumi ali ureditve, ki jih je sklenila ali sprejela Unija glede tretjih držav ali skupin držav,
  - (b) so bili prevozni dokumenti izdani najkasneje na dan pred dnem pristopa in
  - (c) se naknadno izdano ali sestavljeni dokazilo o poreklu predloži carinskim organom v obdobju štirih mesecev od dne pristopa.
8. Za namene preverjanja dokazil iz odstavka 7 se uporabijo določbe o opredelitvi pojma "izdelki s poreklom" in načinu upravnega sodelovanja iz ustreznih sporazumov ali ureditev.

#### DOKAZILO O STATUSU NA PODLAGI DOLOČB O PROSTEM PROMETU ZA INDUSTRIJSKE IZDELKE V CARINSKI UNIJI ES-TURČIJA

9. Dokazila o poreklu, ki jih je pravilno izdala ali sestavila Turčija ali Hrvaška v okviru preferencialnih trgovinskih sporazumov, ki se uporablajo med njima, in določajo prepoved povračila ali oprostitve plačila carinskih dajatev za zadevno blago, so v zadevnih državah sprejeta kot dokazilo o statusu v skladu z določbami o prostem prometu za industrijske izdelke iz Sklepa št. 1/95 Pridružitvenega sveta ES-Turčija<sup>1</sup>, pod pogojem, da:

- (a) so bili dokazilo o poreklu in prevozni dokumenti izdani ali sestavljeni najkasneje na dan pred dnem pristopa in

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<sup>1</sup> Sklep št. 1/95 Pridružitvenega sveta ES-Turčija z dne 22. 12. 1995 o izvajanju zaključne faze carinske unije (UL L 35, 13.2.1996, str. 1).

- (b) se dokazilo o poreklu predloži carinskim organom v obdobju štirih mesecev od dneva pristopa.

Če je bilo blago v Turčiji ali na Hrvaškem deklarirano za sprostitev v prosti promet pred dnem pristopa v okviru preferencialnih trgovinskih sporazumov iz prvega pododstavka, se lahko sprejme tudi dokazilo o poreklu, izdano ali sestavljen naknadno na podlagi teh sporazumov, pod pogojem, da je carinskim organom predloženo v obdobju štirih mesecev od dne pristopa.

10. Za namene preverjanja dokazil iz odstavka 9 se uporabijo določbe o opredelitvi pojma "izdelki s poreklom" in načinih upravnega sodelovanja iz ustreznih preferencialnih sporazumov. Zahteve za naknadno preverjanje teh dokazil sprejemajo pristojni carinski organi sedanjih držav članic in Hrvaške v obdobju treh let po izdaji ali sestavi zadevnega dokazila o poreklu ter jih lahko vlagajo ti organi v obdobju treh let po sprejemu dokazila o poreklu v podporo deklaraciji o prostem prometu.
11. Brez poseganja v uporabo katerega koli ukrepa, ki izhaja iz skupne trgovinske politike, se potrdilo o gibanju blaga A.TR, izdano na podlagi določb o prostem pretoku za industrijske izdelke iz Sklepa št. 1/95 Pridružitvenega sveta ES-Turčija z dne 22. decembra 1995, sprejme na Hrvaškem za sprostitev v prosti promet blaga, ki je na dan pristopa v prevozu po Uniji ali Turčiji po opravljenih izvoznih formalnostih, v začasni hrambi ali carinskem postopku iz člena 4(16)(b) do (h) Uredbe (EGS) št. 2913/92 v Turčiji ali na Hrvaškem, pod pogojem, da:
  - (a) za zadevno blago ni predloženo dokazilo o poreklu iz odstavka 9,
  - (b) je blago v skladu s pogoji za izvajanje določb o prostem pretoku za industrijske izdelke,

- (c) so bili prevozni dokumenti izdani najkasneje na dan pred dnem pristopa in
  - (d) se potrdilo o gibanju blaga A.TR predloži carinskim organom v obdobju štirih mesecev od dne pristopa.
12. Za namene preverjanja potrdil o gibanju blaga A.TR iz odstavka 11 se uporabijo določbe o izdaji potrdil o gibanju blaga A.TR in načinu upravnega sodelovanja iz Sklepa št. 1/2006 Odbora za carinsko sodelovanje ES-Turčija<sup>1</sup>.

## CARINSKI POSTOPKI

13. Začasna hramba in carinski postopki iz člena 4(16)(b) do (h) Uredbe (EGS) št. 2913/92, ki so začeli pred pristopom, se zaključijo ali opravijo pod pogoji iz zakonodaje Unije.

Če zaključek ali dovršitev postopka povzroči nastanek carinskega dolga, je uvozna dajatev, ki jo je treba plačati, enaka tisti, ki je v veljavi v času nastanka carinskega dolga v skladu s skupno carinsko tarifo, plačani znesek pa se šteje za lastna sredstva Unije.

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<sup>1</sup> Sklep št. 1/2006 Odbora za carinsko sodelovanje ES-Turčija z dne 26. septembra 2006 o določitvi podrobnih pravil za uporabo Sklepa št. 1/95 Pridružitvenega sveta ES-Turčija (UL L 265, 26.9.2006, str. 18).

14. Postopki iz členov 84 do 90 in 98 do 113 Uredbe (EGS) št. 2913/92 in iz členov 496 do 535 Uredbe (EGS) št. 2454/93, ki urejajo carinsko skladiščenje, se za Hrvaško uporabljajo ob upoštevanju naslednjih posebnih določb:
- če je znesek carinskega dolga določen na podlagi narave uvoznega blaga in če je bila deklaracija o vnosu blaga v postopek sprejeta pred dnem pristopa, tarifna uvrstitev, količina, carinska vrednost in poreklo uvoznega blaga v trenutku vnosa blaga v postopek izhajajo iz zakonodaje, ki se je na Hrvaškem uporabljala na dan, ko carinski organi sprejmejo deklaracijo.
15. Postopki iz členov 84 do 90 in 114 do 129 Uredbe (EGS) št. 2913/92 ter členov 496 do 523 in 536 do 550 Uredbe (EGS) št. 2454/93, ki urejajo aktivno oplemenitenje, se za Hrvaško uporabljajo ob upoštevanju naslednjih posebnih določb:
- če je znesek carinskega dolga določen na podlagi narave uvoznega blaga in če je bila deklaracija o vnosu blaga v postopek sprejeta pred dnem pristopa, tarifna uvrstitev, količina, carinska vrednost in poreklo uvoznega blaga v trenutku vnosa blaga v postopek izhajajo iz zakonodaje, ki se je na Hrvaškem uporabljala na dan, ko carinski organi sprejmejo deklaracijo;
  - če zaključek postopka povzroči nastanek carinskega dolga, so izplačane kompenzacijске obresti na uvozne dajatve, ki so od dne pristopa dolgovane v skladu s pogoji iz zakonodaje Unije, da bi se tako ohranila enakost med imetniki dovoljenj v sedanjih državah članicah in na Hrvaškem;
  - če je bila deklaracija za aktivno oplemenitenje sprejeta po sistemu povračila in je carinski dolg, za katerega se zahteva povračilo, nastal pred dnem pristopa, povračilo izvede Hrvaška na lastne stroške v skladu s pogoji iz zakonodaje Unije.

16. Postopki iz členov 84 do 90 in 137 do 144 Uredbe (EGS) št. 2913/92 ter členov 496 do 523 in 553 do 584 Uredbe (EGS) št. 2454/93, ki urejajo začasni uvoz, se za Hrvaško uporabljajo ob upoštevanju naslednjih posebnih določb:
- če je znesek carinskega dolga določen na podlagi narave uvoznega blaga in če je bila deklaracija o vnosu blaga v postopek sprejeta pred dnem pristopa, tarifna uvrstitev, količina, carinska vrednost in poreklo uvoznega blaga v trenutku vnosa blaga v postopek izhajajo iz zakonodaje, ki se je na Hrvaškem uporabljala na dan, ko carinski organi sprejmejo deklaracijo;
  - če zaključek postopka povzroči nastanek carinskega dolga, so izplačane kompenzacijске obresti na uvozne dajatve, ki so od dne pristopa dolgovane v skladu s pogoji iz zakonodaje Unije, da bi se tako ohranila enakost med imetniki dovoljenj v sedanjih državah članicah in na Hrvaškem.
17. Postopki iz členov 84 do 90 in 145 do 160 Uredbe (EGS) št. 2913/92 ter členov 496 do 523 in 585 do 592 Uredbe (EGS) št. 2454/93, ki urejajo pasivno oplemenitenje, se za Hrvaško uporabljajo ob upoštevanju naslednjih posebnih določb:
- drugi odstavek člena 591 Uredbe (EGS) št. 2454/93 se smiselno uporablja za blago v začasnem izvozu, ki je bilo začasno izvoženo iz Hrvaške pred dnem pristopa.

## DRUGE DOLOČBE

18. Dovoljenja, ki jih je Hrvaška izdala pred dnem pristopa za uporabo carinskih postopkov iz člena 4(16)(d), (e) in (g) ali statusa pooblaščenih gospodarskih subjektov iz člena 5a(2) Uredbe (EGS) št. 2913/92, veljajo do konca svoje veljavnosti oziroma eno leto od dne pristopa, kar se zgodi prej.
19. Postopki iz členov 201 do 232 Uredbe (EGS) št. 2913/92 in členov 859 do 876a Uredbe (EGS) št. 2454/93, ki urejajo nastanek carinskega dolga, vknjižbo in naknadno izterjavo, se za Hrvaško uporabljajo ob upoštevanju naslednjih posebnih določb:
  - izterjava se izvede v skladu s pogoji iz zakonodaje Unije. Če je carinski dolg nastal pred dnem pristopa, izterjavo izvede Hrvaška v svojo korist v skladu s pogoji, ki so veljali na Hrvaškem pred pristopom.
20. Postopki iz členov 235 do 242 Uredbe (EGS) št. 2913/92 in členov 877 do 912 Uredbe (EGS) št. 2454/93, ki urejajo povračilo in odpust dajatev, se za Hrvaško uporabljajo ob upoštevanju naslednjih posebnih določb:
  - povračilo in odpust dajatev se izvede v skladu s pogoji iz zakonodaje Unije. Če se dajatve, katerih povračilo ali odpust se zahteva, nanašajo na carinski dolg, ki je nastal pred dnem pristopa, povračilo in odpust dajatev izvede Hrvaška na lastne stroške v skladu s pogoji, ki so veljali na Hrvaškem pred pristopom.

*Dodatek k Prilogi IV*

**Seznam obstoječih ukrepov pomoči iz odstavka 1(b) mehanizma za obstoječe pomoči, ki je določen v poglavju 2 Priloge IV**

Opomba: Ukrepi pomoči, našteti v tem dodatku, štejejo za obstoječo pomoč za namene uporabe mehanizma za obstoječe pomoči iz poglavja 2 Priloge IV le, če spadajo v področje uporabe odstavka 1 navedenega poglavja.

Št.			Naslov (v izvirkiku)	Datum odobritve s strani hrvaške agencije za konkurenco	Trajanje
DČ	Št.	Leto			
HR	1	2011	Zakon o slobodnim zonama (NN 44/96, 92/05 i 85/08)	17/06/2008	31/12/2016
HR	3	2011	Zakon o Hrvatskoj radioteleviziji (NN 137/10)	21/10/2010	Neomejeno
HR	4	2011	Odluka o otvorenosti Zračne luke Osijek d.o.o. u razdoblju od 2009. do 2013. godine, od 20. veljače 2009. i 24. travnja 2009	25/05/2009	31/12/2013
HR	5	2011	Program financiranja nakladništva od 2011. do 2013	10/02/2011	31/12/2013
HR	6	2011	Naknadno odobrenje državnih potpora poduzetniku Rockwool Adriatic d.o.o.	30/12/2010	31/12/2015
HR	9	2011	Zakon o znanstvenoj djelatnosti i visokom obrazovanju (NN 123/03, 198/03, 105/04, 174/04, 46/07)	01/02/2007	31/12/ 2014
HR	10	2011	Odluka o obvezi otvorenosti Zračne luke Rijeka d.o.o. za javni zračni promet u razdoblju od 2010. do 2014, od 25. siječnja 2010. i 3. studenoga 2010	10/03/2011	31/12/ 2014

**PRILOGA V**  
**Seznam iz člena 18 Akta o pristopu: prehodni ukrepi**

**1. PROSTI PRETOK BLAGA**

32001 L 0083: Direktiva 2001/83/ES Evropskega parlamenta in Sveta z dne 6. novembra 2001 o zakoniku Skupnosti o zdravilih za uporabo v humani medicini (UL L 311, 28.11.2001, str. 67).

Z odstopanjem od zahtev po kakovosti, varnosti in učinkovitosti, določenih v Direktivi 2001/83/EC, bodo dovoljenja za promet z zdravili, za katera ne velja člen 3(1) Uredbe (ES) št. 726/2004 in ki so na seznamu (v dodatku k tej prilogi, kot ga je v enem jeziku predložila Hrvaška), izdanem na podlagi hrvaške zakonodaje pred datumom pristopa, ostala v veljavi do podaljšanja veljavnosti v skladu s pravnim redom Unije oziroma štiri leta od datuma pristopa, odvisno od tega, kaj nastopi prej.

Dovoljenj za promet, zajetih v tem odstopanju, v državah članicah ni mogoče vzajemno priznavati, dokler ta zdravila ne dobijo potrebnih dovoljenj v skladu z Direktivo 2001/83/ES.

Nacionalna dovoljenja za promet, ki so izdana v okviru nacionalne zakonodaje pred pristopom in ki niso zajeta v tem odstopanju, ter vsako novo dovoljenje za promet morajo biti od datuma pristopa v skladu z Direktivo 2001/83/ES.

## 2. PROSTO GIBANJE OSEB

### **Pogodba o delovanju Evropske unije**

31996 L 0071: Direktiva 96/71/ES Evropskega parlamenta in Sveta z dne 16. decembra 1996 o napotitvi delavcev na delo v okviru opravljanja storitev (UL L 18, 21.1.1997, str. 1);

32004 L 0038: Direktiva 2004/38/ES Evropskega parlamenta in Sveta z dne 29. aprila 2004 o pravici državljanov Unije in njihovih družinskih članov do prostega gibanja in prebivanja na ozemlju držav članic, ki spreminja Uredbo (EGS) št. 1612/68 in razveljavlja Direktive 64/221/EGS, 68/360/EGS, 72/194/EGS, 73/148/EGS, 75/34/EGS, 75/35/EGS, 90/364/EGS, 90/365/EGS in 93/96/EGS (UL L 158, 30.4.2004, str. 77);

32011 R 0492: Uredba (EU) št 492/2011 Evropskega parlamenta in Sveta z dne 5. aprila 2011 o prostem gibanju delavcev v Uniji (UL L 141, 27.5.2011, str. 1).

1. Člen 45 in prvi odstavek člena 56 PDEU se v zvezi s prostim gibanjem delavcev in svobodo opravljanja storitev, ki vključuje začasno gibanje delavcev, kakor je opredeljeno v členu 1 Direktive 96/71/ES, med Hrvaško na eni strani in vsako od sedanjih držav članic na drugi strani v celoti uporabljata le ob upoštevanju prehodnih določb iz odstavkov 2 do 13.
2. Ne glede na člene 1 do 6 Uredbe (EU) št. 492/2011 in do konca dveletnega obdobja od dne pristopa bodo sedanje države članice uporabljale nacionalne ukrepe ali ukrepe iz dvostranskih sporazumov, ki urejajo dostop hrvaških državljanov na njihove trge dela. Sedanje države članice lahko uporabljajo take ukrepe do konca petletnega obdobja od dne pristopa.

Hrvaški državljeni, ki na dan pristopa zakonito delajo v sedanji državi članici in se jim je dovolil dostop na trg dela v tej državi članici za neprekinjeno obdobje 12 mesecev ali več, bodo imeli dostop na trg dela te države članice, vendar ne na trg dela drugih držav članic, ki uporabljajo nacionalne ukrepe.

Hrvaški državljeni, ki se jim je dovolil dostop na trg dela v sedanji državi članici po pristopu za neprekinjeno obdobje 12 mesecev ali več, tudi uživajo iste pravice.

Hrvaški državljeni iz drugega in tretjega pododstavka prenehajo uživati pravice iz teh pododstavkov, če prostovoljno zapustijo trg dela zadevne sedanje države članice.

Hrvaški državljeni, ki na dan pristopa ali v obdobju, ko se uporabljajo nacionalni ukrepi, zakonito delajo v sedanji državi članici in ki se jim je dovolil dostop na trg dela te države članice za obdobje krajše od 12 mesecev, ne uživajo teh pravic.

3. Pred koncem dveletnega obdobja od dne pristopa Svet na podlagi poročila Komisije ponovno preuči delovanje prehodnih določb iz odstavka 2.

Ob zaključku tega ponovnega pregleda in najkasneje pred koncem dveletnega obdobja od dne pristopa sedanje države članice uradno obvestijo Komisijo, če bodo še naprej uporabljale nacionalne ukrepe ali ukrepe iz dvostranskih sporazumov oziroma če bodo od takrat dalje uporabljale člene 1 do 6 Uredbe (EU) št. 492/2011. Če takega uradnega obvestila ni, se uporabljajo členi 1 do 6 Uredbe (EU) št. 492/2011.

4. Na prošnjo Hrvaške se lahko izvede nadaljnji ponovni pregled. Uporabi se postopek iz odstavka 3, ki se konča v šestih mesecih od prejema prošnje Hrvaške.

5. Država članica, ki do konca petletnega obdobja iz odstavka 2 ohrani nacionalne ukrepe ali ukrepe iz dvostranskih sporazumov, lahko v primeru resnih motenj na svojem trgu dela ali grožnje le-teh in po tem, ko uradno obvesti Komisijo, nadaljuje z uporabo teh ukrepov do konca sedemletnega obdobja od dne pristopa. Če takega uradnega obvestila ni, se uporabljajo členi 1 do 6 Uredbe (EU) št. 492/2011.
6. V sedemletnem obdobju od dne pristopa tiste države članice, v katerih se na podlagi odstavkov 3, 4 ali 5 za hrvaške državljanove uporabljajo členi 1 do 6 Uredbe (EU) št. 492/2011 in ki hrvaškim državljanom v tem obdobju izdajajo delovna dovoljenja za namene spremeljanja, ta dovoljenja izdajajo avtomatično.
7. Tiste države članice, v katerih se na podlagi tretjega, četrtega ali petega odstavka za hrvaške državljanove uporabljajo členi 1 do 6 Uredbe (EU) št. 492/2011, lahko do konca sedemletnega obdobja od dne pristopa uporabljajo postopke iz drugega in tretjega pododstavka.

Če država članica iz prvega pododstavka ima ali pričakuje motnje na svojem trgu dela, ki bi lahko resno ogrozile življenjsko raven ali raven zaposlenosti v določeni regiji ali poklicu, ta država članica o tem obvesti Komisijo in druge države članice in jim priskrbi vse potrebne podrobnosti. Na podlagi teh podatkov lahko država članica zaprosi, da Komisija popolnoma ali delno odloži uporabo členov 1 do 6 Uredbe (EU) št. 492/2011, da bi se ponovno vzpostavilo normalno stanje v tej regiji oz. poklicu. Komisija odloči o odložitvi uporabe ter o njenem trajanju in obsegu najpozneje v dveh tednih po prejemu takega zaprosila in o svoji odločitvi uradno obvesti Svet. Vsaka država članica lahko v dveh tednih od dne odločitve Komisije Svet zaprosi, da odločitev razveljavlja ali spremeni. Svet o zaprosilu odloči s kvalificirano večino v dveh tednih.

Država članica iz prvega pododstavka lahko v nujnih in izjemnih primerih odloži uporabo členov 1 do 6 Uredbe (EU) št. 492/2011 in o tem Komisiji predloži naknadno utemeljeno uradno obvestilo.

8. Dokler je uporaba členov 1 do 6 Uredbe (EU) št. 492/2011 odložena na podlagi drugega do petega in sedmega odstavka, se člen 23 Direktive 2004/38/ES o pravici družinskih članov delavcev do pridobitve zaposlitve uporablja na Hrvaškem glede državljanov sedanjih držav članic in v sedanjih državah članicah glede hrvaških državljanov pod naslednjimi pogoji:

- zakonec delavca in njuni potomci, ki so stari manj kot 21 let ali so vzdrževani družinski člani in na dan pristopa zakonito prebivajo z delavcem na ozemlju države članice, imajo po pristopu neposreden dostop na trg dela te države članice. Ta določba se ne uporablja za družinske člane delavca, ki se mu je zakonito dovolil dostop na trg dela te države članice za obdobje, krajše od 12 mesecev;
- zakonec delavca in njuni potomci, ki so stari manj kot 21 let ali so vzdrževani družinski člani in zakonito prebivajo z delavcem na ozemlju države članice od dne po dnevnu pristopa, vendar imajo v obdobju uporabe zgoraj navedenih prehodnih določb dostop na trg dela zadevne države članice, ko v zadevni državi članici prebivajo najmanj 18 mesecev ali od tretjega leta od dne pristopa, odvisno od tega, kaj nastopi prej.

Te določbe ne posegajo v ugodnejše nacionalne ukrepe ali ukrepe, sprejete z dvostranskimi sporazumi.

9. Če določb Direktive 2004/38/ES, ki prevzemajo določbe Direktive 68/360/EGS<sup>1</sup>, ni mogoče uporabljati ločeno od tistih iz Uredbe (EU) št. 492/2011, katerih uporaba je odložena v skladu z odstavki 2 do 5 ter 7 in 8, smejo Hrvaška in sedanje države članice odstopati od teh določb, kolikor je to potrebno za uporabo odstavkov 2 do 5 ter 7 in 8.
10. Kadar sedanje države članice na podlagi zgoraj navedenih prehodnih določb uporabljujo nacionalne ukrepe ali ukrepe iz dvostranskih sporazumov, lahko Hrvaška ohrani v veljavi enakovredne ukrepe za državljane zadevne države članice ali zadevnih držav članic.
11. Vse sedanje države članice, ki v skladu z odstavki 2 do 5 in 7 do 9 uporabljujo nacionalne ukrepe, lahko z notranjimi predpisi uvedejo večjo svobodo prostega gibanja od tiste, ki velja na dan pristopa, vključno s popolnim dostopom na trg dela. Od tretjega leta od dne pristopa se lahko sedanje države članice, ki uporabljujo nacionalne ukrepe, kadarkoli odločijo za uporabo členov 1 do 6 Uredbe (EU) št. 492/2011. O takih odločitvah se obvesti Komisija.
12. Nemčija in Avstrija lahko v primeru resnih motenj ali nevarnosti, da do njih pride, na posebno občutljivih storitvenih področjih svojih trgov dela, ki bi lahko nastale v določenih regijah zaradi čezmejnega opravljanja storitev, kot je opredeljeno v členu 1 Direktive 96/71/ES, in dokler na podlagi zgornjih prehodnih določb uporabljata nacionalne ukrepe ali ukrepe iz dvostranskih sporazumov o prostem gibanju hrvaških delavcev, po tem, ko uradno obvestita Komisijo, odstopata od člena 56 PDEU, da bi v okviru opravljanja storitev podjetij s sedežem na Hrvaškem omejili začasno gibanje delavcev, za katere se uporabljujo nacionalni ukrepi glede njihove pravice do začetka opravljanja dela v Nemčiji in Avstriji.

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<sup>1</sup> Direktiva Sveta 68/360/EGS z dne 15. oktobra 1968 o odpravi omejitve gibanja in prebivanja v Skupnosti za delavce držav članic in za njihove družine (UL L 257, 19.10.1968, str. 13). Direktiva, kakor je bila nazadnje spremenjena z Aktom o pristopu iz leta 2003 (UL L 236, 23.9. 2003, str. 33) in razveljavljena z učinkom od 30. aprila 2006 z Direktivo 2004/38/ES Evropskega parlamenta in Sveta (UL L 158, 30.4.2004, str. 77).

Seznam storitvenih področij, za katere se lahko uporablja odstopanje, je naslednji:

– v Nemčiji:

Sektor	NACE * koda, razen če ni določeno drugače
Gradbeništvo s sorodnimi panogami	45.1 do 4; Dejavnosti iz Priloge k Direktivi 96/71/ES
Čiščenje objektov in opreme	74.70 Čiščenje objektov in opreme
Druge storitve	74.87 Samo dejavnosti notranjega dekoraterstva

(\*) NACE: glej 31990 R 3037: Uredba Sveta (EGS) št. 3037/90 z dne 9. oktobra 1990 o statistični klasifikaciji gospodarskih dejavnosti v Evropski skupnosti (UL L 293, 24.10.1990, str. 1).

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– v Avstriji:

Sektor	NACE (*) koda, razen če ni določeno drugače
Storitve za rastlinsko pridelavo; urejanje parkov	01.41
Rezanje, oblikovanje in dodelava kamna	26.7
Proizvodnja kovinskih konstrukcij in njihovih delov	28.11
Gradbeništvo s sorodnimi panogami	45.1 do 4; Dejavnosti iz Priloge k Direktivi 96/71/ES
Poizvedovalne dejavnosti in varovanje	74.60
Čiščenje objektov in opreme	74.70
Nega na domu	85.14
Dejavnosti socialnega varstva brez nastanitve	85.32

(\*) NACE: glej 31990 R 3037: Uredba Sveta (EGS) št. 3037/90 z dne 9. oktobra 1990 o statistični klasifikaciji gospodarskih dejavnosti v Evropski skupnosti (UL L 293, 24.10.1990, str. 1).

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Če Nemčija ali Avstrija v skladu s prejšnjimi pododstavki odstopata od prvega odstavka člena 56 PDEU, lahko Hrvaška po tem, ko uradno obvesti Komisijo, sprejme enakovredne ukrepe.

Učinek uporabe tega odstavka ne vodi do bolj restriktivnih pogojev za začasno gibanje delavcev v okviru čezmejnega opravljanja storitev med Nemčijo ali Avstrijo in Hrvaško od tistih, ki obstajajo na dan podpisa Pogodbe o pristopu.

13. Učinek uporabe odstavkov 2 do 5 in 7 do 11 ne vodi do bolj restriktivnih pogojev za dostop hrvaških državljanov na trge dela sedanjih držav članic od tistih, ki obstajajo na dan podpisa Pogodbe o pristopu.

Ne glede na uporabo določb iz odstavkov 1 do 12 sedanje države članice v katerem kolikoboji, ko se uporabljam nacionalni ukrepi ali ukrepi iz dvostranskih sporazumov, glede dostopa na njihov trg dela prednostno obravnavajo delavce, ki so državljeni držav članic, v primerjavi z delavci, ki so državljeni tretjih držav.

Hrvaški delavci migranti in njihove družine, ki zakonito prebivajo in delajo v drugi državi članici, ali delavci migranti iz drugih držav članic in njihove družine, ki zakonito prebivajo in delajo na Hrvaškem, se ne obravnavajo bolj restriktivno kot delavci iz tretjih držav in njihovi družinski člani, ki delajo v tej državi članici oziroma na Hrvaškem. Poleg tega se ob uporabi načela prednostne obravnave v Uniji delavci migranti iz tretjih držav, ki prebivajo in delajo na Hrvaškem, ne obravnavajo bolj ugodno kot državljeni Hrvaške.

### 3. PROSTI PRETOK KAPITALA

**Pogodba o Evropski uniji,**

**Pogodba o delovanju Evropske unije.**

Ne glede na obveznosti iz Pogodb, na katerih temelji Evropska unija, lahko Hrvaška sedem let od dne pristopa ohrani na dan podpisa Pogodbe o pristopu veljavne omejitve iz zakona o kmetijskih zemljiščih (OG 152/08), povezane z nakupom kmetijskih zemljišč s strani državljanov drugih držav članic ali držav pogodbenic Sporazuma o Evropskem gospodarskem prostoru (Sporazum EGP) in pravnih oseb, ustanovljenih v skladu z zakoni druge države članice ali države pogodbenice Sporazuma EGP. Vendar pa se državljan države članice ali pravna oseba, ustanovljena v skladu z zakoni druge države članice, glede nakupa kmetijskih zemljišč v nobenem primeru ne sme obravnavati manj ugodno, kot bi takšnega državljanega oziroma pravno osebo obravnavali na dan podpisa Pristopne pogodbe, ali bolj restriktivno kot državljanje ali pravne osebe tretjih držav.

Za samozaposlene kmete, ki so državljeni druge države članice in želijo imeti sedež ter prebivati na Hrvaškem, ne veljajo določbe prejšnjega odstavka ali kakršni koli postopki, ki ne veljajo za hrvaške državljanje.

Pred iztekom tretjega leta od dne pristopa se opravi splošni ponovni pregled tega prehodnega ukrepa. V ta namen Komisija Svetu predloži poročilo. Svet lahko na predlog Komisije soglasno odloči, da se prehodno obdobje, ki je navedeno v prvem odstavku, skrajša ali konča.

Če obstajajo zadostni dokazi, da bo po izteku prehodnega obdobja na trgu s kmetijskimi zemljišči na Hrvaškem prišlo do resnih motenj ali da bo obstajala nevarnost resnih motenj, Komisija na zahtevo Hrvaške odloči o podaljšanju prehodnega obdobja za tri leta. To podaljšanje lahko po potrebi velja samo za določena geografska območja, ki so močno ogrožena.

#### 4. KMETIJSTVO

##### I. PREHODNI UKREPI ZA HRVAŠKO

1. 32001 L 0113: Direktiva Sveta 2001/113/ES z dne 20. decembra 2001 o sadnih džemih, želejih, marmeladah in sladkanem kostanjevem pireju, namenjenih za prehrano ljudi (UL L 10, 12.1.2002, str. 67).

Z odstopanjem od obveznosti iz člena 8 se trženje proizvodov, ki so označeni kot "domača marmelada" in "ekstra domača marmelada", dovoli na hrvaškem trgu do razprodaje zalog, ki obstajajo na dan pristopa.

2. Uredba Sveta (ES) št. 510/2006 z dne 20. marca 2006 o zaščiti geografskih označb in označb porekla za kmetijske proizvode in živila (UL L 93, 31.3.2006, str. 12 in UL L 335 M, 13.12.2008, str. 213).

(a) V členu 5(8) se drugi pododstavek nadomesti z naslednjim:

Bolgarija, Romunija in Hrvaška sprejmejo navedene zakone ali druge predpise najpozneje eno leto od zadavnega dne pristopa."

(b) V členu 5(11) se prvi pododstavek nadomesti z naslednjim:

'11. Za Bolgarijo, Romunijo in Hrvaško lahko nacionalna zaščita geografskih označb in označb geografskega porekla, ki obstajajo na dan pristopa, poteka še dvanaest mesecev od zadavnega dne pristopa.

3. 32007 R 1234: Uredba Sveta (ES) št. 1234/2007 z dne 22. oktobra 2007 o vzpostavitev skupne ureditve kmetijskih trgov in o posebnih določbah za nekatere kmetijske proizvode (Uredba o enotni SUT) (UL L 299, 16.11.2007, str. 1).

(a) V členu 118m se doda naslednji odstavek:

"5. Z odstopanjem od odstavkov 1 do 4 sme Hrvaška do razprodaje zalog, ki jih ima na dan pristopa, dajati na trg na Hrvaškem ali izvažati v tretje države vina, poimenovana 'Mlado vino portugizac'. Hrvaška vzpostavi računalniško zbirko podatkov z informacijami o zalogah na dan pristopa in zagotovi, da se te zaloge preverijo in prijavijo Komisiji."

(b) V členu 118s se doda naslednji odstavek:

"5. Za Hrvaško se na podlagi te uredbe zaščitijo imena vin, objavljena v UL C 116 z dne 14. aprila 2011, s pridržkom ugodnega izida postopka ugovora. Komisija jih vključi v register iz člena 118n.

Odstavki 2 do 4 tega člena se uporabijo pod naslednjimi pogoji: Rok iz odstavka 3 je eno leto od dne pristopa Hrvaške. Rok iz odstavka 4 je štiri leta od dne pristopa Hrvaške."

4. 32009 R 0073: Uredba Sveta (ES) št. 73/2009 z dne 19. januarja 2009 o skupnih pravilih za sheme neposrednih podpor za kmete v okviru skupne kmetijske politike in o uvedbi nekaterih shem podpor za kmete, sprememb uredb (ES) št. 1290/2005, (ES) št. 247/2006, (ES) št. 378/2007 in razveljavitvi Uredbe (ES) št. 1782/2003 (UL L 30, 31.1.2009, str. 16).

- (a) Z odstopanjem od obveznosti iz člena 4(1) Uredbe (ES) št. 73/2009 namreč spoštovanja predpisanih zahtev ravnanja, naštetih v Prilogi II k navedeni uredbi, kmetje na Hrvaškem, ki prejemajo neposredna plačila, v področje uporabe navzkrižne skladnosti vključijo predpisane zahteve ravnanja iz točk A, B in C Priloge II v skladu z naslednjim časovnim razporedom: zahteve iz točke A od 1. januarja 2014, zahteve iz točke B od 1. januarja 2016 in zahteve iz točke C od 1. januarja 2018.
- (b) Za poglavjem 1 naslova V Uredbe (ES) št. 73/2009 se vključita naslednje poglavje in člen:

*"POGLAVJE 1a*  
***Shema enotnega plačila***

***Člen 121a***  
***Shema enotnega plačila na Hrvaškem***

Za Hrvaško je uporaba členov 4, 5, 23, 24 in 25 neobvezna do 31. decembra 2013, če se navedene določbe nanašajo na predpisane zahteve ravnanja. Od 1. januarja 2014 mora kmet, ki prejema plačila v okviru sheme enotnega plačila v teh državah članicah, spoštovati predpisane zahteve ravnanja iz Priloge II v skladu z naslednjim časovnim razporedom:

- (a) zahteve iz točke A Priloge II se uporabljajo od 1. januarja 2014;
- (b) zahteve iz točke B Priloge II se uporabljajo od 1. januarja 2016;
- (c) zahteve iz točke C Priloge II se uporabljajo od 1. januarja 2018."

## II. ZAČASNA TARIFNA KVOTA ZA SUROVI SLADKOR IZ SLADKORNEGA TRSA ZA PRECIŠČEVANJE

Za Hrvaško se za surovi sladkor iz sladkornega trsa za rafiniranje pridrži letna avtonomna uvozna kvota 40 000 ton (*erga omnes*), in sicer za obdobje do treh tržnih let po pristopu z uvozno dajatvijo 98,00 EUR na tono. Če bi pogajanja z drugimi članicami Svetovne trgovinske organizacije v skladu s členom XXIV.6 Splošnega sporazuma o carinah in trgovini glede kompenzacijске spremembe zaradi pristopa Hrvaške privedla do odprtja kompenzacijskih kvot za sladkor pred koncem prehodnega obdobja, se kvota 40 000 ton, dodeljena Hrvaški, po odprtju kompenzacijskih kvot za sladkor delno ali v celoti ukine. Komisija sprejme ukrepe za izvajanje, ki so potrebni v ta namen, po postopku iz člena 195(2) Uredbe Sveta (ES) št. 1234/2007 z dne 22. oktobra 2007 o vzpostavitevi skupne ureditve kmetijskih trgov in o posebnih določbah za nekatere kmetijske proizvode ("Uredba o enotni SUT") v povezavi s členom 13(1)(b) Uredbe (EU) št. 182/2011 Evropskega parlamenta in Sveta z dne 16. februarja 2011 o določitvi splošnih pravil in načel, na podlagi katerih države članice nadzirajo izvajanje izvedbenih pooblastil Komisije.

### III. ZAČASNI UKREPI NEPOSREDNIH PLAČIL ZA HRVAŠKO

Povračilo neposrednih plačil, dodeljenih kmetom za leto 2013, je mogoče pod pogojem, da Hrvaška pred pristopom uporablja pravila, ki so enaka pravilom za taka neposredna plačila iz Uredbe Sveta (ES) št. 73/2009 z dne 19. januarja 2009 o skupnih pravilih za sheme neposrednih podpor za kmete v okviru skupne kmetijske politike in o uvedbi nekaterih shem podpor za kmete, sprememb uredb (ES) št. 1290/2005, (ES) št. 247/2006, (ES) št. 378/2007 in razveljavitvi Uredbe (ES) št. 1782/2003<sup>1</sup> ter uredb Komisije (ES) št. 1120/2009, (ES) št. 1121/2009 in (ES) št. 1122/2009<sup>2</sup>.

## 5. VARNOST ŽIVIL, VETERINARSKA IN FITOSANITARNA POLITIKA

### I. KOKOŠI NESNICE

31999 L 0074: Direktiva Sveta 1999/74/ES z dne 19. julija 1999 o minimalnih standardih za zaščito kokoši nesnic (UL L 203, 3.8.1999, str. 53).

Z odstopanjem od člena 6 Direktive Sveta 1999/74/ES se kokoši nesnice na dan pristopa lahko redijo v kletkah, ki niso v skladu s strurnimi zahtevami iz navedenega člena. Hrvaška zagotovi, da se take kletke prenehajo uporabljati najpozneje 12 mesecev po pristopu.

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<sup>1</sup> UL L 30, 31.1.2009, str. 16.

<sup>2</sup> Uredba Komisije (ES) št. 1120/2009 z dne 29. oktobra 2009 o podrobnih pravilih za izvajanje sheme enotnega plačila iz naslova III Uredbe Sveta (ES) št. 73/2009 o skupnih pravilih za sheme neposrednih podpor za kmete v okviru skupne kmetijske politike in o uvedbi nekaterih shem podpor za kmete, Uredba Komisije (ES) št. 1121/2009 z dne 29. oktobra 2009 o določitvi podrobnih pravil za izvajanje Uredbe Sveta (ES) št. 73/2009 v zvezi s shemami podpor za kmete iz naslovov IV in V Uredbe in Uredba Komisije (ES) št. 1122/2009 z dne 30. novembra 2009 o podrobnih pravilih za izvajanje Uredbe Sveta (ES) št. 73/2009 v zvezi z navzkrižno skladnostjo, modulacijo ter integriranim administrativnim in kontrolnim sistemom v okviru shem neposrednih podpor za kmete, določenih za navedeno uredbo, ter za izvajanje Uredbe Sveta (ES) št. 1234/2007 v zvezi z navzkrižno skladnostjo v okviru sheme podpore, določene za sektor vina (UL L 316, 2.12.2009, str. 1, 27 in 65).

Jajca iz teh neizpopolnjenih kletk se dajo le na domači trg Hrvaške. Ta jajca in njihova embalaža so jasno označena s posebno oznako, ki omogoča potreben nadzor. Jasen opis te posebne oznake se sporoči Komisiji najpozneje eno leto pred datumom pristopa.

## II. OBRATI (MESO, MLEKO, RIBE IN ŽIVALSKI STRANSKI PROIZVODI)

32004 R 0852: Uredba (ES) št. 852/2004 Evropskega parlamenta in Sveta z dne 29. aprila 2004 o higieni živil (UL L 139, 30.4.2004, str. 1);

32004 R 0853: Uredba (ES) št. 853/2004 Evropskega parlamenta in Sveta z dne 29. aprila 2004 o posebnih higienskih pravilih za živila živalskega izvora (UL L 139, 30.4.2004, str. 55);

32009 R 1069: Uredba (ES) št. 1069/2009 Evropskega parlamenta in Sveta z dne 21. oktobra 2009 o določitvi zdravstvenih pravil za živalske stranske proizvode in pridobljene proizvode, ki niso namenjeni prehrani ljudi, ter razveljavitvi Uredbe (ES) št. 1774/2002 (UL L 300, 14.11.2009, str. 1).

(a) Strukturne zahteve iz:

- (i) Uredbe (ES) št. 852/2004:
  - poglavja II Priloge II,
- (ii) Uredbe (ES) št. 853/2004:
  - poglavij II in III Oddelka I Priloge III,
  - poglavij II in III Oddelka II Priloge III,
  - poglavja I Oddelka V Priloge III,

(iii) Uredbe (EU) št. 142/2011:

- poglavja I Priloge IV,
- poglavij I, II in III Priloge IX,
- poglavij I in II Priloge X ter
- Priloga XIII

se na Hrvaškem do 31. decembra 2015 ne uporabljajo za nekatere obrate v sektorjih mesa, mleka, rib in živalskih stranskih proizvodov, ob upoštevanju spodnjih pogojev.

- (b) Dokler so obrati iz odstavka (a) upravičeni do koristi iz določb tega odstavka, se proizvodi, ki izvirajo iz teh obratov, dajo le na domači trg Hrvaške ali na trge tretjih držav v skladu z zadevno zakonodajo Unije oziroma se uporabljo za nadaljnjo predelavo v hrvaških obratih, za katere tudi veljajo določbe iz odstavka (a), ne glede na datum trženja.
- (c) Živila iz obratov iz odstavka (a) so opremljena z drugačno oznako zdravstvene ustreznosti oziroma drugačno identifikacijsko oznako, kot je predvidena v členu 5 Uredbe (ES) št. 853/2004. Jasen opis drugačne oznake zdravstvene ustreznosti oziroma drugačne identifikacijske oznake se sporoči Komisiji najpozneje eno leto pred dnem pristopa.
- (d) Odstavka (b) in (c) se uporabljava tudi za vse proizvode, ki izvirajo iz integriranih obratov za proizvodnjo mesa, mleka ali ribiških proizvodov, kjer za del obrata veljajo določbe odstavka (a).

- (e) Hrvaška stalno spremlja izvajanje nacionalnega programa za posodobitev obratov in Komisiji predloži letni načrt napredka v zvezi s tem. Hrvaška zagotovi, da se pripravi individualen načrt posodobitve vsakega teh obratov z roki za popravo strukturnih zahtev; ta načrt se na zahtevo da na voljo Komisiji.
- (f) Komisija pravočasno pred pristopom sestavi seznam obratov iz odstavka (a). Seznam je javen in vsebuje ime in naslov vseh obratov.

Hrvaška zagotovi, da bodo vsi obrati, ki do pristopa niso popolnoma skladni s pravnim redom s področja varnosti živil, razen če jih ne urejajo določbe tega prehodnega ukrepa, prenehali svoje dejavnosti.

Izvedbena pravila za zagotovitev nemotenega delovanja prehodne ureditve z zvezi z uredbama (ES) št. 852/2004 in št. 853/2004 se lahko sprejmejo v skladu z drugim odstavkom člena 12 oziroma drugim odstavkom člena 9 uredb.

Izvedbena pravila za zagotovitev nemotenega delovanja prehodne ureditve v zvezi z Uredbo (ES) št. 1069/2009 se lahko sprejmejo v skladu s členom 52(4) Uredbe.

### III. TRŽENJE SEMEN

32002 L 0053: Direktiva Sveta 2002/53/ES z dne 13. junija 2002 o skupnem katalogu sort poljščin (UL L 193, 20.7.2002, str. 1);

32002 L 0055: Direktiva Sveta 2002/55/ES z dne 13. junija 2002 o trženju semena zelenjadnic (UL L 193, 20.7.2002, str. 33).

Hrvaška lahko do 31. decembra 2014 odloži uporabo člena 4(1) Direktive 2002/53/ES in člena 4(1) Direktive 2002/55/ES za trženje semen na svojem ozemlju, ki so uvrščena na seznam v njeni nacionalni sortni listi poljščin in zelenjadnic, za sorte, ki niso bile uradno sprejete v skladu z določbami teh direktiv. V tem obdobju se ta semena ne tržijo na ozemlju drugih držav članic.

#### IV. NEUM

31997 L 0078: Direktiva Sveta 97/78/ES z dne 18. decembra 1997 o določitvi načel, ki urejajo organizacijo veterinarskih pregledov proizvodov, ki vstopajo v Skupnost iz tretjih držav (UL L 24, 30.1.1998, str. 9).

Člen 1 se nadomesti z naslednjim:

#### "Člen 1

1. Veterinarske preglede proizvodov iz tretjih držav, ki se vnesejo na eno od ozemelj, navedenih v Prilogi I, opravijo države članice v skladu s to direktivo in Uredbo (ES) št. 882/2004 Evropskega parlamenta in Sveta o izvajanju uradnega nadzora, da se zagotovi preverjanje skladnosti z zakonodajo o krmi in živilih ter s pravili o zdravstvenem varstvu živali in zaščiti živali<sup>(1)</sup>.
2. Z odstopanjem od odstavka 1 pošiljk proizvodov, ki prihajajo z ozemlja Hrvaške in prečkajo ozemlje Bosne in Hercegovine pri Neumu (neumski koridor ) pred ponovnim vstopom na ozemlje Hrvaške prek vstopnih točk Klek ali Zaton Doli, ni treba veterinarsko pregledati, če izpolnjujejo naslednje zahteve:

- (a) Hrvaška mora imeti na dan pristopa ali pred njim vstopne točke na severu in jugu koridorja, ki so opremljene, kadrovsko zapolnjene in pripravljene na zagotavljanje skladnosti z zahtevami tega odstavka.
- (b) Hrvaška mora zagotoviti, da:
  - (i) se za prevoz pošiljk uporabljajo le zaprta vozila;
  - (ii) se vozila za prevoz pošiljk pred prečkanjem neumskega koridorja zapečatijo z enkratno oštevilčenimi plombami;
  - (iii) se izdela register, v katerem bodo podrobno navedene številčne oznake plomb v povezavi z ustreznimi vozili, s čimer bo omogočen potreben nadzor;
  - (iii) se zabeležita datum in ura izstopa in ponovnega vstopa na ozemlje Hrvaške vozil, ki prevažajo pošiljke, tako da se lahko izračuna celoten čas prečkanja.
- (c) Hrvaška zagotovi, da se pošiljki ne dovoli ponovnega vstopa na njeno ozemlje, če:
  - (i) se je pečat na vozilu med prečkanjem neumskega koridorja prelomil ali je bil zamenjan in/ali
  - (ii) celotni čas prečkanja znatno presega sprejemljivi celotni čas prečkanja, glede na celotno razdaljo prečkanja, razen če je pristojni organ opravil oceno tveganja za zdravje živali in javno zdravje ter sprejel učinkovite, sorazmerne in ciljno usmerjene ukrepe, ki temeljijo na tej oceni.
- (d) Hrvaška mora redno in po potrebi obveščati Komisijo o neizpolnjevanju zahtev točke
  - (b) in o ukrepih, sprejetih v skladu s točko (c).
- (e) Po potrebi se v skladu s postopkom iz člena 29 sprejme sklep o začasni odpravi ali ukinitvi odstopanja od odstavka 1.
- (f) V skladu s postopkom iz člena 29 se po potrebi lahko sprejmejo podrobna pravila za uporabo tega odstavka."

## 6. RIBIŠTVO

32006 R 1967: Uredba Sveta (ES) št. 1967/2006 z dne 21. decembra 2006 o ukrepih za upravljanje za trajnostno izkoriščanje ribolovnih virov v Sredozemskem morju, spremembi Uredbe (EGS) št. 2847/93 in razveljavitvi Uredbe (ES) št. 1626/94 (UL L 409, 30.12.2006, str. 11. Popravljena različica v UL L 36, 8.2.2007, str. 6).

- (a) Z odstopanjem od člena 13(1) in (2) se plovilom, ki so registrirana le na območju zahodne Istre in tam izvajajo ribolov, začasno dovoli, da na globini manj kot 50 metrov do 30. junija 2014 uporabljajo pridnene mreže na razdalji najmanj 1,5 navtične milje od obale.

To odstopanje se uporablja za območje zahodne Istre, ki je določeno z zemljepisnima koordinatama  $\varphi=44,52135$  in  $\lambda=14,29244$  z mejo po črti proti severu in po črti proti zahodu.

Hrvaški se začasno zagotovi, da se do 30. junija 2014 za vsa plovila z manj kot 15 metrov skupne dolžine na globini manj kot 50 metrov dovoli uporaba pridnenih mrež na razdalji najmanj 1 navtične milje od obale, pri tem pa še naprej veljajo vse druge prostorske in časovne omejitve, ki se uporabljam na dan pristopa.

- (b) Z odstopanjem od člena 17(1) se za določeno število plovil iz posebne kategorije nekomercialnega ribolova – priobalni ribolov majhnega obsega za osebne potrebe –, ki ne presega 2 000 plovil, do 31. decembra 2014 dovoli, da uporabijo največ 200 metrov zabodnih mrež, pri čemer se še naprej uporabljajo vse druge omejitve, veljavne na dan pristopa. Hrvaška najpozneje na dan pristopa Komisiji predloži seznam plovil, za katera velja prehodno obdobje, vključno z značilnostmi in zmogljivostjo, izraženo v BT in kW.

## 7. PROMETNA POLITIKA

1. 31992 R 3577: Uredba Sveta (EGS) št. 3577/92 z dne 7. decembra 1992 o uporabi načela prostega pretoka storitev v pomorskem prometu med državami članicami (pomorska kabotaža), (UL L 364, 12.12.1992, str. 7).

Členu 6 se dodajo naslednji odstavki:

- '4. Z odstopanjem od drugega pododstavka člena 4(1) se lahko pogodbe o gospodarski javni službi, sklenjene pred datumom pristopa Hrvaške k EU, uporabljajo do 31. decembra 2016.
5. Z odstopanjem od člena 1(1) so do 31. decembra 2014 križarjenja med hrvaškimi pristanišči, ki se opravljam z ladjami bruto tonaže 650 ali manj, rezervirana za ladje, ki so registrirane na Hrvaškem in plujejo pod zastavo Hrvaške, jih upravljam ladjarska podjetja, ustanovljena v skladu s hrvaškim pravom, in katerih glavne poslovne enote so na Hrvaškem, kjer se izvaja tudi učinkovit nadzor.
6. Z odstopanjem od člena 1(1) lahko Komisija v prehodnem obdobju do 31. decembra 2014 na utemeljeno zahtevo države članice v 30 delovnih dneh po prejemu take zahteve odloči, da ladje, za katere velja odstopanje iz odstavka 5 tega člena, ne opravljam križarjenj med pristanišči nekaterih območij držav članic, razen Hrvaške, v katerih se izkaže, da opravljanje teh storitev resno moti notranji trg v pomorskem prometu na zadevnih območjih ali da obstaja nevarnost za takšne motnje. Če po preteklu obdobja 30 delovnih dni Komisija ne sprejme nobene odločitve, lahko zadevna država članica uporablja zaščitne ukrepe, dokler Komisija ne sprejme odločitve. V nujnih primerih lahko država članica enostransko sprejme ustrezne začasne ukrepe, ki smejo veljati največ tri mesece. O tem je treba nemudoma obvestiti Komisijo. Komisija lahko ukrepe razveljavlja ali potrdi, dokler ne sprejme končne odločitve. Države članice so stalno obveščene."

2. 32009 R 1072: Uredba (ES) št. 1072/2009 Evropskega parlamenta in Sveta z dne 21. oktobra 2009 o skupnih pravilih za dostop do trga mednarodnega cestnega prevoza blaga (UL L 300, 14.11.2009, str. 72).

Z odstopanjem od člena 8 Uredbe (ES) št. 1072/2009 se uporabljajo naslednje določbe:

- podjetja s sedežem na Hrvaškem v obdobju dveh let po pristopu Hrvaške ne bodo opravljala kabotaže v drugih državah članicah;
- druge države članice lahko v obdobju dveh let po pristopu Hrvaške obvestijo Komisijo o tem, ali nameravajo prehodno obdobje iz prve alinee podaljšati za največ dve leti ali uporabljati člen 8 Uredbe (ES) št. 1072/2009 za podjetja s sedežem na Hrvaškem. Če Komisije o tem ne obvestijo, se uporablja člen 8;
- vsaka od sedanjih 27 držav članic lahko kadar koli v obdobju dveh let po pristopu Hrvaške obvesti Komisijo o nameri, da bo za podjetja s sedežem na Hrvaškem uporabljala člen 8 Uredbe Sveta (ES) št. 1072/2009;
- kabotažo na Hrvaškem lahko opravljajo le prevozniki s sedežem v državah članicah, ki za podjetja s sedežem na Hrvaškem uporabljajo člen 8 Uredbe Sveta (ES) št. 1072/2009;
- vsaka država članica, ki uporablja člen 8 Uredbe Sveta (EGS) št. 1072/2009, lahko v obdobju štirih let po pristopu Hrvaške v primeru resnih motenj na nacionalnem trgu ali v nekaterih njegovih segmentih, ki jih je povzročila ali poslabšala kabotaža, kot sta občutni presežek ponudbe nad povpraševanjem ali ogrozitev finančne stabilnosti ali preživetja znatnega števila podjetij, ki se ukvarjajo s cestnim prevozom, zaprosi Komisijo, naj v celoti ali delno prekine uporabo člena 8 Uredbe Sveta (ES) št. 1072/2009 za podjetja s sedežem na Hrvaškem. V tem primeru se uporablja člen 10 Uredbe (ES) št. 1072/2009.

Države članice, ki uporabljajo prehodne ukrepe iz prve in druge alinee prvega odstavka, lahko na podlagi dvostranskih sporazumov s Hrvaško postopoma izmenjajo dovoljenja za kabotažo.

Prehodne ureditve iz prvega in drugega odstavka za hrvaške prevoznike v nobeni državi članici ne smejo imeti slabšega dostopa do kabotaže kot ob podpisu pristopne pogodbe.

## 8. OBDAVČITEV

1. 31992 L 0079: Direktiva Sveta 92/79/EGS z dne 19. oktobra 1992 o približevanju davkov na cigarete (UL L 316, 31.10.1992, str. 8).

Členu 2(2) se doda naslednji pododstavek:

"Hrvaški se za izpolnitev zahtev iz prvega in drugega pododstavka dovoli prehodno obdobje do 31. decembra 2017. Kljub temu pa od 1. januarja 2014 trošarina ne sme biti nižja od 77 EUR za 1 000 cigaret ne glede na ponderirano povprečno maloprodajno ceno."

2. 32006 L 0112: Direktiva Sveta 2006/112/ES z dne 28. novembra 2006 o skupnem sistemu davka na dodano vrednost (UL L 347, 11.12.2006, str. 1).

(a) Člen 13(2) se nadomesti z naslednjim:

'2. Države članice lahko obravnavajo dejavnosti oseb javnega prava kot dejavnosti, ki jih opravljamjo kot državni organi, če so oproščene po členih 132, 135, 136 in 371, členih 374 do 377, členu 378(2), členu 379(2) ali členih 380 do 390c.'

(b) Člen 80(1)(b) se nadomesti z naslednjim:

"(b) ko je plačilo nižje od tržne vrednosti in dobavitelj nima pravice do popolnega odbitka po členih 167 do 171 in 173 do 177 ter za dobavo velja oprostitev po členih 132, 135, 136, 371, 375, 376, 377, 378(2), 379(2) ali členih 380 do 390c;"

(c) Pododstavek (a) člena 136 se nadomesti z naslednjim:

"(a) dobave blaga, ki se v celoti uporabi za dejavnost, oproščeno po členih 132, 135, 371, 375, 376 in 377, členu 378(2), členu 379(2) in členih 380 do 390c, če za to blago ni bilo mogoče uveljavljati pravice do odbitka;"

(d) Člen 221(3) se nadomesti z naslednjim:

'3. Države članice lahko davčne zavezance oprostijo obveznosti, predpisane v členu 220, da izdajo račun za blago, ki ga dobavijo ali storitve, ki jih opravijo na njihovem ozemlju in so oproščene, bodisi s pravico do odbitka DDV, plačanega v predhodni fazi, ali brez te pravice, v skladu s členoma 110 in 111, členom 125(1), členom 127, členom 128(1), členi 132, 135, 136, 371, 375, 376 in 377, členom 378(2), členom 379(2) in členi 380 do 390c."

(e) Za členom 390b se vstavi naslednji člen:

*"Člen 390c*

Hrvaška lahko pod pogoji, ki so v tej državi članici veljali na dan njenega pristopa, še naprej oprošča naslednje transakcije:

(a) dobavo pozidanih ali nepozidanih stavbnih zemljišč, kakor je določeno v členu 135(1)(j) in v točki 9 dela B Priloge X, do 31. decembra 2014 brez možnosti podaljšanja;

(b) mednarodni prevoz potnikov iz točke 10 dela B Priloge X, dokler se ista oprostitev uporablja v eni od držav članic, ki je bila članica Unije pred pristopom Hrvaške."

(f) Člen 391 se nadomesti z naslednjim:

"*Člen 391*

Države članice, ki oprostijo transakcije iz členov 371, 375, 376 ali 377, iz člena 378(2), člena 379(2) ali členov 380 do 390c, lahko davčnim zavezancem odobrijo izbiro glede obdavčevanja teh transakcij."

(g) Naslov Priloge X (in ustrezeno tudi v kazalu) se nadomesti z naslednjim:

"SEZNAM TRANSAKCIJ, ZA KATERE VELJAJO ODSTOPANJA IZ ČLENOV 370 IN 371 TER ČLENOV 375 DO 390c"

## **9. PRAVICA, SVOBODA IN VARNOST**

32006 R 0562: Uredba (ES) št. 562/2006 Evropskega parlamenta in Sveta z dne 15. marca 2006 o Zakoniku Skupnosti o pravilih, ki urejajo gibanje oseb prek meja (Zakonik o schengenskih mejah) (UL L 105, 13.4.2006, str. 1).

Za členom 19 se vstavi naslednji člen:

"*Člen 19a*

Z odstopanjem od določb te uredbe, ki se nanašajo na vzpostavitev mejnih prehodov, in do začetka veljavnosti sklepa Sveta Evropske unije o uporabi vseh določb schengenskega pravnega reda na Hrvaškem v skladu s členom 4(2) Akta o pristopu ali do takrat, ko bo ta uredba spremenjena tako, da bo vključevala določbe, ki urejajo mejni nadzor na skupnih mejnih prehodih, karkoli nastopi prej, lahko Hrvaška na svojih mejah z Bosno in Hercegovino ohrani skupne mejne prehode. Na teh skupnih mejnih prehodih mejni policiisti ene strani izvajajo vstopne in izstopne pregledne na ozemlju druge strani. Hrvaški mejni policiisti morajo vse vstopne in izstopne pregledne izvajati v skladu s pravnim redom Unije, vključno z obveznostmi držav članic glede mednarodne zaščite in načela nevračanja. Zadevni dvostranski sporazumi za vzpostavitev navedenih skupnih mejnih prehodov se po potrebi ustrezno spremenijo."

10. **OKOLJE**

I. HORIZONTALNA ZAKONODAJA

1. 32003 L 0087: Direktiva 2003/87/ES Evropskega parlamenta in Sveta z dne 13. oktobra 2003 o vzpostavitvi sistema za trgovanje s pravicami do emisije toplogrednih plinov v Skupnosti in o spremembri Direktive Sveta 96/61/ES (UL L 275, 25.10.2003, str. 32).
  - (a) Kar zadeva vse lete med dvema letališčema na ozemlju Hrvaške in vse leta med letališčem na ozemlju Hrvaške in letališčem v državi zunaj območja EGP (tako imenovane "dodatne letalske dejavnosti"), se uporabljajo naslednje določbe:
    - (i) Z odstopanjem od člena 3c(2) se obdobje iz člena 13(1) s pričetkom 1. januarja 2013 za dodatne letalske dejavnosti začne 1. januarja 2014.

- (ii) Z odstopanjem od člena 3c(4) Komisija po postopku iz iste določbe v šestih mesecih po pristopu sprejme odločitev o zgodovinskih emisijah iz letalstva za dodatne letalske dejavnosti.
- (iii) Z odstopanjem od člena 3d(2) s 1. januarjem 2014 velja, da je odstotek pravic, ki se dajo na dražbo, za dodatne letalske dejavnosti tisti delež pravic, ki preostane po izračunu števila pravic, ki se v skladu s točko (d) člena 3e(3) dodelijo brezplačno, in števila pravic, ki se v skladu s členom 3f izločijo v posebno rezervo.
- (iv) Z odstopanjem od člena 3d(3) Komisija sprejme odločitev o dodeljenih emisijah iz letalstva v okviru dodatnih letalskih dejavnosti za referenčno leto 2010 na podlagi najboljših razpoložljivih podatkov. Število pravic, ki jih bodo dale na dražbo države članice, katerih skupne dodeljene emisije iz letalstva vključujejo emisije iz letov, ki prihajajo iz hrvaškega letališča, se od 1. julija 2013 naprej prilagodi, tako da se pravice za prodajo na dražbi v zvezi s temi emisijami prenesejo na Hrvaško.
- (v) Z odstopanjem od člena 3e(1) je leto spremljanja za dodatne letalske dejavnosti leto 2012, vse vloge za dodelitev pravic pa je treba vložiti pri pristojnem hrvaškem organu do 31. marca 2013.
- (vi) Z odstopanjem od člena 3e(2) Hrvaška Komisiji predloži vloge v zvezi z dodatnimi letalskimi dejavnostmi do 1. julija 2013.
- (vii) Z odstopanjem od člena 3e(3) Komisija sprejme odločitev o zadevah iz točk (a) do (e) tega člena, ki se nanašajo na dodatne letalske dejavnosti, do 30. septembra 2013.

(viii) Z odstopanjem od točke (d) člena 3e(3) se število pravic, ki se brezplačno dodelijo za dodatne letalske dejavnosti, izračuna tako, da se referenčno merilo iz točke (e) pomnoži z vsoto tonskih kilometrov iz vlog, predloženih Komisiji v skladu s členom 3e(2), ki je prilagojena tako, da upošteva povprečne spremembe tonskih kilometrov iz letalskih dejavnosti, zajetih v EU ETS, glede na ravni iz leta 2010. Komisija lahko referenčno merilo po potrebi prilagodi, tako da uporabi enotni korekcijski faktor.

(ix) Z odstopanjem od člena 3e(3) je referenčno merilo iz točke (e) tega člena v primeru dodatnih letalskih dejavnosti enako referenčnemu merilu, izračunanimu za letalske dejavnosti, zajete v EU ETS od 1. januarja 2012.

(x) Z odstopanjem od člena 3e(5) je datum izdaje pravic za dodatne letalske dejavnosti 28. februar 2014.

(xi) Z odstopanjem od člena 3f se glede dodatnih letalskih dejavnosti vsak sklic na drugo koledarsko leto obdobja, ki se začne leta 2013, razume kot sklic na leto 2014, sklic na tretje koledarsko leto tega obdobja pa kot sklic na leto 2015.

(xii) Z odstopanjem od člena 14(3) je datum iz tega člena za dodatne letalske dejavnosti 1. julij 2013.

(xiii) Z odstopanjem od člena 18a(1) se prenos pristojnosti za upravljanje letalskih operaterjev na Hrvaško opravi v letu 2014, potem ko operater izpolni svoje obveznosti iz leta 2013, razen če se prejšnji organ upravljanja in Hrvaška na podlagi zahteve letalskega operaterja dogovorita za drug datum v šestih mesecih po tem, ko Komisija objavi posodobljen seznam operaterjev, v katerem je upoštevan pristop Hrvaške. V tem primeru se prenos v zvezi z obdobjem trgovanja, ki se prične leta 2021, opravi najpozneje leta 2020.

(xiv) Z odstopanjem od člena 6 Priloge I se dodatne letalske dejavnosti vključijo od 1. januarja 2014.

- (b) Brez poseganja v zgornja odstopanja Hrvaška sprejme zakone in druge predpise, ki so potrebni, da bo na dan pristopa lahko usklajena z direktivo za celotno leto 2013.
2. 32010 R 0920: Uredba Komisije (EU) št. 920/2010 z dne 7. oktobra 2010 o standardiziranem in zaščitenem sistemu registrov v skladu z Direktivo 2003/87/ES Evropskega parlamenta in Sveta ter Odločbo št. 280/2004/ES Evropskega parlamenta in Sveta (UL L 270, 14.10.2010, str. 1).

Členi 16, 29, 41, 46 in 54 ter Priloga VIII se v zvezi z letalskimi dejavnostmi za Hrvaško uporabljajo od 1. januarja 2014.

## II. KAKOVOST ZRAKA

32008 L 0050: Direktiva 2008/50/ES Evropskega parlamenta in Sveta z dne 21. maja 2008 o kakovosti zunanjega zraka in čistejšem zraku za Evropo (UL L 152, 11.6.2008, str.1).

- (a) Z odstopanjem od Priloge XIV je referenčno leto prvega odstavka točke A drugo leto po koncu leta, v katerem bo Hrvaška pristopila. Kazalnik povprečne izpostavljenosti za to referenčno leto je srednja vrednost koncentracije v letu pristopa ter v prvem in drugem letu po letu pristopu.
- (b) Z odstopanjem od točke B Priloge XIV se ciljno zmanjšanje izpostavljenosti izračuna glede na kazalnik povprečne izpostavljenosti za referenčno leto, ki je drugo leto po koncu leta, v katerem bo Hrvaška pristopila.

### III. RAVNANJE Z ODPADKI

31999 L 0031: Direktiva Sveta 1999/31/ES z dne 26. aprila 1999 o odlaganju odpadkov na odlagališčih (UL L 182, 16.7.1999, str. 1).

- (a) Z odstopanjem od točk (a), (b) in (c) prvega pododstavka člena 5(2) zahteva za zmanjšanje količine biorazgradljivih komunalnih odpadkov, ki se odlagajo na odlagališčih, na 75 %, 50 % oziroma 35 % skupne količine (po teži) biorazgradljivih komunalnih odpadkov, proizvedenih leta 1997, za Hrvaško velja v skladu s spodaj navedenimi roki.

Hrvaška zagotovi postopno zmanjšanje količine biorazgradljivih komunalnih odpadkov, ki se odlagajo na odlagališčih, v skladu z naslednjim časovnim načrtom:

- (i) do 31. decembra 2013 se delež biorazgradljivih komunalnih odpadkov, ki se odlagajo na odlagališčih, zmanjša na 75 % skupne količine (po teži) biorazgradljivih komunalnih odpadkov, proizvedenih leta 1997;
- (ii) do 31. decembra 2016 se delež biorazgradljivih komunalnih odpadkov, ki se odlagajo na odlagališčih, zmanjša na 50 % skupne količine (po teži) biorazgradljivih komunalnih odpadkov, proizvedenih leta 1997;
- (iii) do 31. decembra 2020 se delež biorazgradljivih komunalnih odpadkov, ki se odlagajo na odlagališčih, zmanjša na 35 % skupne količine (po teži) biorazgradljivih komunalnih odpadkov, proizvedenih leta 1997.
- (b) Z odstopanjem od člena 14(c) vsa obstoječa odlagališča na Hrvaškem do 31. decembra 2018 izpolnjujejo zahteve iz Direktive, razen zahtev iz točke 1 Priloge I.

Hrvaška zagotovi postopno zmanjšanje odpadkov, ki se odlagajo na obstoječih odlagališčih, ki ne izpolnjujejo zahtev, v skladu z naslednjimi največjimi letnimi količinami:

- do 31. decembra 2013: 1.710.000 ton.
- do 31. decembra 2014: 1.410.000 ton.
- do 31. decembra 2015: 1.210.000 ton.
- do 31. decembra 2016: 1.010.000 ton.
- do 31. decembra 2017: 800 000 ton.

Hrvaška Komisiji do 31. decembra vsako leto, začenši z letom pristopa, predloži poročilo o postopnem izvajanju direktive in izpolnjevanju vmesnih ciljev.

#### IV. KAKOVOST VODE

1. 31991 L 0271: Direktiva Sveta 91/271/EGS z dne 21. maja 1991 o čiščenju komunalne odpadne vode (UL L 135, 30.5.1991, str. 40).

Z odstopanjem od členov 3, 4, 5, 6 in 7 se zahteve za sisteme zbiranja in čiščenja komunalne odpadne vode na Hrvaškem uporabljajo od 1. januarja 2024 v skladu z naslednjimi vmesnimi cilji:

- (a) Do 31. decembra 2018 se skladnost z Direktivo doseže v aglomeracijah s populacijskim ekvivalentom več kot 15 000, razen v naslednjih obalnih aglomeracijah:

Bibinje - Sukošan,  
Biograd,  
Jelsa - Vrboska,  
Makarska,  
Mali Lošinj,  
Malinska - Njivice,  
Nin,  
Pirovac - Tisno - Jezera,  
Pula - sjever,  
Vela Luka,  
Vir.

- (b) Do 31. decembra 2020 se skladnost z Direktivo doseže v aglomeracijah s populacijskim ekvivalentom več kot 10 000, katerih odpadna voda se izpušča v občutljiva območja, ter pri čistilnih napravah, ki se nahajajo v zadevnih zbiralnih področjih Donave in drugih občutljivih območij in ki prispevajo k onesnaževanju teh območij, ter v 11 obalnih aglomeracijah iz točke (a).
- (c) Do 31. decembra 2023 se skladnost z Direktivo doseže v aglomeracijah s populacijskim ekvivalentom več kot 2 000.

2. 31998 L 0083: Direktiva Sveta 98/83/ES z dne 3. novembra 1998 o kakovosti vode, namenjene za prehrano ljudi (UL L 330, 5.12.1998, str. 32).

Kot izjema se mikrobiološki parametri iz dela A Priloge I oziroma indikatorski parametri iz dela C Priloge I na naslednjih območjih za oskrbo z vodo na Hrvaškem uporabljajo od 1. januarja 2019:

Območje za oskrbo z vodo	Številka območja	Prebivalstvo	Koda NUTS
DA BJELOVAR	107	51 921	HR02
DA DARUVAR	125	25 608	HR02
DA ĐURĐEVAC	204	30 079	HR01
DA GORSKI KOTAR	306	26 430	HR03
DA HRVATSKO ZAGORJE	101	143 093	HR01
DA ISTOČNA SLAVONIJA - SLAVONSKI BROD	129	124 349	HR02
DA ISTRA	301	97 046	HR03
DA JASTREBARSKO-KLINČA SELA	114	23 213	HR01
DA KARLOVAC-DUGA RESA	116	91 511	HR02
DA KNIN	404	17 187	HR03
DA KOPRIVNICA	203	58 050	HR01
DA KRIŽEVCI	103	36 338	HR01
DA LAPAC	311	1 880	HR03
DA LIČKA JESENICA	118	13 893	HR02
DA NAŠICE	210	37 109	HR02
DA NERETVA-PELJEŠAC-KORČULA-LASTOVO-MLJET	407	58 246	HR03
DA OGULIN	117	25 192	HR02
DA OPATIJA-RIJEKA-KRK	304	238 088	HR03
DA OTOČAC	309	15 434	HR03
DA OZALJ	113	11 458	HR02
DA PETRINJA-SISAK	121	84 528	HR02
DA PISAROVINA	115	3 910	HR01
DA PITOMAČA	205	10 465	HR02

DA POŽEŠTINE	128	70 302	HR02
DA SVETI IVAN ZELINA	102	17 790	HR01
DA UDBINA-KORENICA	310	6 747	HR03
DA VARAŽDIN	201	184 769	HR01
DA VELIKA GORICA	503	75 506	HR01
DA ZAGREB	501	831 047	HR01
DA ZAPREŠIĆ	502	50 379	HR01
DA ZRMANJA-ZADAR	401	158 122	HR03
DA ŽRNOVNICA	307	20 160	HR03

## V. CELOVITO PREPREČEVANJE IN NADZOROVANJE ONESNAŽEVANJA

1. 31999 L 0013: Direktiva Sveta 1999/13/ES z dne 11. marca 1999 o omejevanju emisij hlapnih organskih spojin zaradi uporabe organskih topil v nekaterih dejavnostih in obratih (UL L 85, 29.3.1999, str. 1).
  - (a) Z odstopanjem od člena 5 ter prilog IIA in IIB se mejne vrednosti emisij hlapnih organskih spojin zaradi uporabe organskih topil v nekaterih dejavnostih in obratih za naslednje obrate na Hrvaškem uporabljajo šele od navedenih datumov:
    - (i) Od 1. januarja 2014:
      1. ČATEKS, dioničko društvo za proizvodnju tkanine, umjetne kože, kućanskog rublja i proizvoda za šport i rekreaciju (ČATEKS d.d.), Čakovec, Ulica Zrinsko-Frankopanska 25
      2. Drvna industrija KLANA d.d. (DI KLANA d.d.), Klana, Klana 264.

(ii) Od 1. januarja 2015:

1. HEMPEL društvo s ograničenom odgovornošću Prerađivačka kemijska industrija (HEMPEL d.o.o.), Umag, Novigradska ulica 32
2. ALUFLEXPACK, proizvodno, trgovačko, export-import društvo s ograničenom odgovornošću (ALUFLEXPACK, d.o.o.), Zadar, Murvica bb - pogon Zadar (Zadar facility, location: Zadar, Murvica bb)
3. ALUFLEXPACK, proizvodno, trgovačko, export-import društvo s ograničenom odgovornošću (ALUFLEXPACK, d.o.o.), Zadar, Murvica bb - pogon Umag (Umag facility, location: Umag, Ungarija bb).

(iii) Od 1. januarja 2016:

1. PALMA društvo s ograničenom odgovornošću za proizvodnju pogrebnih potrepština (PALMA d.o.o.), Jastrebarsko, Donja Reka 24
2. FERRO-PREIS društvo s ograničenom odgovornošću za proizvodnju ljevanih, kovanih i prešanih metalnih proizvoda (FERRO-PREIS d.o.o.), Čakovec, Dr. Tome Bratkovića 2
3. AD PLASTIK dioničko društvo za proizvodnju dijelova i pribora za motorna vozila i proizvoda iz plastičnih masa (AD PLASTIK d.d.), Solin, Matoševa ulica 8 - location: Zagreb, Jankomir 5
4. REMONT ŽELJEZNIČKIH VOZILA BJELOVAR društvo s ograničenom odgovornošću (RŽV d.o.o.), Bjelovar, Trg Kralja Tomislava 2
5. FEROKOTAO d.o.o. za proizvodnju transformatorskih kotlova i ostalih metalnih konstrukcija (FEROKOTAO d.o.o.), Kolodvorska bb, Donji Kraljevec
6. SAME DEUTZ-FAHR Žetelice, društvo s ograničenom odgovornošću za proizvodnju i usluge (SAME DEUTZ-FAHR Žetelice d.o.o.), Županja, Industrijska 5
7. CMC Sisak d.o.o. za proizvodnju i usluge (CMC Sisak d.o.o.), Sisak, Braće Kavurića 12
8. METALSKA INDUSTRIJA VARAŽDIN dioničko društvo (MIV d.d.), Varaždin, Fabijanska ulica 33

9. CHROMOS BOJE I LAKOVI, dioničko društvo za proizvodnju boja i lakova (CHROMOS BOJE I LAKOVI, d.d.), Zagreb, Radnička cesta 173/d
10. CHROMOS-SVJETLOST, Tvornica boja i lakova, društvo s ograničenom odgovornošću (CHROMOS-SVJETLOST d.o.o.), Lužani, Mijata Stojanovića 13
11. MURAPLAST društvo s ograničenom odgovornošću za proizvodnju i preradu plastičnih masa (MURAPLAST d.o.o.), Kotoriba, Industrijska zona bb
12. ISTRAPLASTIKA dioničko društvo za proizvodnju ambalaže (ISTRAPLASTIKA d.d.), Pazin, Dubravica 2/a
13. GRUDINA društvo s ograničenom odgovornošću za proizvodnju i usluge (GRUDINA d.o.o.), Županja, Aleja Matice Hrvatske 21
14. SLAVICA - KEMIJSKA ČISTIONICA, vlasnik Slavica Hinek, Beli Manastir, J. J. Strossmayera 17
15. MIDA d.o.o. za usluge i ugostiteljstvo (MIDA d.o.o.), Osijek, Ivana Gundulića 206
16. EXPRESS KEMIJSKA ČISTIONA, vlasnik Ivanka Drčec, Križevci, Ulica Petra Preradovića 14
17. Kemijska čistionica "BISER", vlasnik Gojko Miletić, Dubrovnik, Nikole Tesle 20
18. Kemijska čistionica "ELEGANT", vlasnik Frane Miletić, Dubrovnik, Andrije Hebranga 106
19. KOLAR obrt za kemijsko čišćenje odjeće, vlasnik Svjetlana Kolar, Žakanje, Kamanje 70/a
20. MM d.o.o. za trgovinu i usluge (MM d.o.o.), Draganić, Lug 112
21. KEMIJSKA ČISTIONA "AGATA", vlasnik Branko Szabo, Virovitica, S. Radića 66
22. Obrt za kemijsko čišćenje odjeća "KEKY", vlasnik Jovita Malek-Milovanović, Pula, Dubrovačke bratovštine 29
23. LORNA d.o.o. za pranje i kemijsko čišćenje tekstila i krznenih proizvoda (LORNA d.o.o.), Pula, Valdebečki put 3
24. KEMIJSKA ČISTIONICA I KOPIRANJE KLJUČEVA "ŠUPER", vlasnik Ivan Šuper, Virovitica, J.J. Strossmayera 5
25. KEMIJSKO ČIŠĆENJE ŠTEFANEC kemijsko čišćenje tekstila i krznenih proizvoda, vlasnik Nadica Štefanec, Koprivnica, Ledinska 1a
26. ARIES društvo s ograničenom odgovornošću za proizvodnju glazbala i usluge (ARIES d.o.o.), Varaždin, Creska 3

27. OBRT ZA PRANJE I ČIŠĆENJE TEKSTILA I ODJEĆE ĐORĐEVIĆ, vlasnik Javorka Đorđević, Makarska, Ante Starčevića 2
  28. OBRT ZA USLUGE PRANJA I KEMIJSKOG ČIŠĆENJA "KORDIĆ", vlasnik Pero Kordić, Makarska, Kipara Rendića 2
  29. Kemijsko čišćenje tekstila i krvnenih proizvoda ČISTIONICA GALEB, vlasnik Stipan Radović, Zadar, Varoška 6
  30. KEMIJSKA ČISTIONICA, vlasnik Krešimir Borovec, Varaždin, Juraja Habdelića 2
  31. KEMIJSKA ČISTIONICA "VBM", vlasnik Biserka Posavec, Maruševec, Biljevec 47
  32. OBRT ZA KEMIJSKO ČIŠĆENJE I PRANJE RUBLJA "PLITVICE", vlasnik Momirka Ninić, Pula, Rizzijeva 34
  33. "ANA" KEMIJSKA ČISTIONA, vlasnik Saša Dadić, Pula, Zagrebačka 18
  34. Kemijska čistionica, vlasnik Gordana Bralić, Trogir, Put Demunta 16
  35. "ECONOMATIC" - PRAONICA RUBLJA, vlasnik Marino Bassanese, Umag, Savudrijska cesta 9
  36. SERVIS ZA ČIŠĆENJE "SJAJ", vlasnik Danijela Brković, Virovitica, Golo Brdo 2A.
- (b) Z odstopanjem od člena 5(3)(b) obveznost upravljavca, da pristojnemu organu prepričljivo dokaže, da se uporablja najboljši razpoložljivi postopek za nanašanje zaščitnih prevlek v ladjedelništvu, za naslednje obrate na Hrvaškem velja od 1. januarja 2016:
1. BRODOTROGIR d.d., Trogir, Put Brodograditelja 16
  2. NCP-NAUTIČKI CENTAR PRGIN-REMONTNO BRODOGRADILIŠTE ŠIBENIK d.o.o. za remont i proizvodnju brodova (NCP - REMONTNO BRODOGRADILIŠTE ŠIBENIK d.o.o.), Šibenik, Obala Jerka Šižgorića 1
  3. BRODOGRADILIŠTE VIKTOR LENAC dioničko društvo (BRODOGRADILIŠTE VIKTOR LENAC d.d.), Rijeka, Martinšćica bb
  4. 3. MAJ BRODOGRADILIŠTE d.d., Rijeka, Liburnijska 3
  5. BRODOSPLIT-BRODOGRADILIŠTE društvo s ograničenom odgovornošću (BRODOSPLIT-BRODOGRADILIŠTE d.o.o.), Split, Put Supavlja 21
  6. ULJANIK Brodogradilište, d.d., Pula, Flaciusova 1.

2. 32001 L 0080: Direktiva 2001/80/ES Evropskega parlamenta in Sveta z dne 23. oktobra 2001 o omejevanju emisij nekaterih onesnaževal v zrak iz velikih kuričnih naprav (UL L 309, 27.11.2001, str. 1).
  - (a) Z odstopanjem od člena 4(1) in (3) se mejne vrednosti emisij žveplovega dioksida, dušikovih oksidov in prahu za naslednje naprave na Hrvaškem uporablja od 1. januarja 2018:
    1. BELIŠĆE d.d., Belišće: parni kotel K3 +K4 (240 MW)
    2. DIOKI d.d., Zagreb: parni kotel SG 6401C (86 MW)
    3. HEP-Proizvodnja d.o.o., Zagreb, TE Plomin 1: parni kotel (338 MW)
    4. TE PLOMIN d.o.o., Plomin, TE Plomin 2: parni kotel (544 MW)
    5. HEP-Proizvodnja d.o.o., Zagreb, TE Rijeka: parni kotel (800 MW)
    6. HEP-Proizvodnja d.o.o., Zagreb, TE Sisak - blok 1: parna kotla 1A+1B (548 MW)
    7. HEP-Proizvodnja d.o.o., Zagreb, TE Sisak - blok 2: parna kotla 2A+2B (548 MW)
    8. HEP-Proizvodnja d.o.o., Zagreb, TE-TO Zagreb: sestavljena iz parnega kotla K3 bloka C, vročevodnih kotlov VK 3, VK 4, VK 5, VK 6 in parnega kotla PK 3 (skupaj: 828 MW)
    9. HEP-Proizvodnja d.o.o., Zagreb, EL-TO Zagreb: sestavljena iz bloka 30 MW s parnima kotloma K4 (K8) in K5 (K9), bloka 12 MW s parnim kotlom K3 (K6), vročevodnih kotlov WK 1 in WK 3 in parnega kotla K2 (K7) (skupaj: 510 MW)
    10. HEP-Proizvodnja d.o.o., Zagreb, TE-TO Osijek: parna kotla K1+K2 (skupaj: 196 MW).
3. 32008 L 0001: Direktiva 2008/1/ES Evropskega parlamenta in Sveta z dne 15. januarja 2008 o celovitem preprečevanju in nadzorovanju onesnaževanja (IPPC) (UL L 24, 29.1.2008, str. 8).

Z odstopanjem od člena 5(1) se zahteve za izdajanje dovoljenj obstoječim obratom za naslednje obrate na Hrvaškem uporabljajo šele od datuma, določenega za vsak obrat, kar zadeva obveznosti za obratovanje v skladu z mejnimi vrednostmi emisij, enakovrednimi parametri ali tehničnimi ukrepi, ki temeljijo na najboljši razpoložljivi tehnologiji v skladu s členom 2(12):

(a) Od 1. januarja 2014:

1. NAŠICECEMENT Tvornica cementa, dioničko društvo (NAŠICECEMENT d.d. Našice), Našice, Tajnovac 1, dejavnost IPPC 3.1.
2. LIPIK GLAS za proizvodnju stakla društvo s ograničenom odgovornošću (LIPIK GLAS d.o.o.), Lipik, Staklanska b.b., dejavnost IPPC 3.2.
3. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb – farma br. 18 (kmetija št.18, kraj: Čakovec, Totovec), dejavnost IPPC 6.6.a.
4. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 - farma Forkuševci (kmetija Forkuševci), dejavnost IPPC 6.6.c.
5. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 - farma V. Branjevina (kmetija V. Branjevina), dejavnost IPPC 6.6.c.
6. Drvna industrija KLANA d.d. (DI KLANA d.d.), Klana, Klana 264, dejavnost IPPC 6.7.
7. ČATEKS, dioničko društvo za proizvodnju tkanine, umjetne kože, kućanskog rublja i proizvoda za šport i rekreaciju (ČATEKS d.d.), Čakovec, Ulica Zrinsko-Frankopanska 25, dejavnost IPPC 6.7.

(b) Od 1. januarja 2015:

1. CIMOS LJEVAONICA ROČ d.o.o. proizvodnja aluminijskih odljevaka (CIMOS LJEVAONICA ROČ d.o.o.), Roč, Stanica Roč 21, dejavnost IPPC 2.5.b.
2. P. P. C. BUZET društvo s ograničenom odgovornošću za proizvodnju, trgovinu i usluge (P. P. C. BUZET d.o.o.), Buzet, Most 24, dejavnost IPPC 2.5.b.
3. Vetropack Straža tvornica stakla d.d. Hum na Sutli (Vetropack Straža d.d. Hum na Sutli), Hum na Sutli, Hum na Sutli 203, dejavnost IPPC 3.2.
4. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb - pogon mesa (mesni obrat), dejavnost IPPC 6.4.a.
5. SLADORANA TVORNICA ŠEĆERA dioničko društvo (SLADORANA d.d.), Županja, Šećerana 63, dejavnost IPPC 6.4.b.

6. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb – farma br. 19 (kmetija št. 19, kraj: Donji Martijanec, Vrbanovec), dejavnost IPPC 6.6.a.
7. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 - farma Slaščak (kmetija Slaščak), dejavnost IPPC 6.6.b.
8. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 - farma Magadenovac (kmetija Magadenovac), dejavnost IPPC 6.6.c.
9. ALUFLEXPACK, proizvodno, trgovačko, export-import društvo s ograničenom odgovornošću (ALUFLEXPACK, d.o.o.), Zadar, Murvica bb - pogon Umag (obrat Umag, kraj: Umag, Ungarija bb), dejavnost IPPC 6.7.
10. ALUFLEXPACK, proizvodno, trgovačko, export-import društvo s ograničenom odgovornošću (ALUFLEXPACK, d.o.o.), Zadar, Murvica bb - pogon Zadar (obrat Zadar, kraj: Zadar, Murvica bb), dejavnost IPPC 6.7.
11. HEMPEL društvo s ograničenom odgovornošću Prerađivačka kemijska industrija (HEMPEL d.o.o.), Umag, Novigradska ulica 32, dejavnost IPPC 6.7.
12. BELIŠĆE dioničko društvo za proizvodnju papira, kartonske ambalaže, strojeva, primarnu i finalnu preradu drva i suhu destilaciju drva (BELIŠĆE d.d.), Belišće, Trg Ante Starčevića 1 - razen parnih kotlova K3 in K4 (prehodno obdobje do 31. decembra 2017, glej spodaj), dejavnost IPPC 6.1.b.
13. MAZIVA-ZAGREB d.o.o. za proizvodnju i trgovinu mazivima i srodnim proizvodima (MAZIVA-ZAGREB d.o.o.), Zagreb, Radnička cesta 175, dejavnost IPPC 1.2.

(c) Od 1. julija 2015:

1. GAVRILOVIĆ Prva hrvatska tvornica salame, sušena mesa i masti M. Gavrilovića potomci, d.o.o. (GAVRILOVIĆ d.o.o.), Petrinja, Gavrilovićev trg 1 - pogon klaonice: papkari, rezanje i prerada mesa i proizvodnja prerađevina od peradi i papkara, te skladištenje mesa (obrat klavnice: parkljarji, rezanje in predelava mesa ter proizvodnja predelanih proizvodov iz perutnine in parkljarjev ter hramba mesa), dejavnost IPPC 6.4.a.

(d) Od 1. januarja 2016:

1. FERRO-PREIS društvo s ograničenom odgovornošću za proizvodnju ljevanih, kovanih i prešanih metalnih proizvoda (FERRO-PREIS d.o.o.), Čakovec, Dr. Tome Bratkovića 2, dejavnost IPPC 2.4.
2. CEMEX Hrvatska dioničko društvo za proizvodnju i prodaju cementa i drugih građevinskih materijala (CEMEX Hrvatska d.d.), Kaštel Sućurac, Cesta dr. Franje Tuđmana bb - pogon Sv. Kajo (obrat Sv. Kajo), dejavnost IPPC 3.1
3. CEMEX Hrvatska dioničko društvo za proizvodnju i prodaju cementa i drugih građevinskih materijala (CEMEX Hrvatska d.d.), Kaštel Sućurac, Cesta dr. Franje Tuđmana bb - pogon Sv. Juraj (obrat Sv. Juraj), dejavnost IPPC 3.1.
4. CEMEX Hrvatska dioničko društvo za proizvodnju i prodaju cementa i drugih građevinskih materijala (CEMEX Hrvatska d.d.), Kaštel Sućurac, Cesta dr. Franje Tuđmana bb - pogon 10. kolovoza (obrat 10. kolovoza), dejavnost IPPC 3.1.
5. KIO KERAMIKA d.o.o. za proizvodnju keramičkih pločica - "u stečaju" (KIO KERAMIKA d.o.o. - "u stečaju"), Orahovica, V. Nazora bb - pogon Orahovica (obrat Orahovica, kraj: Orahovica, V. Nazora bb), dejavnost IPPC 3.5.
6. KIO KERAMIKA d.o.o. za proizvodnju keramičkih pločica - "u stečaju" (KIO KERAMIKA d.o.o. - "u stečaju"), Orahovica, V. Nazora bb - pogon Rujevac (obrat Rujevac, kraj: Dvor, Rujevac bb), dejavnost IPPC 3.5.
7. PLIVA HRVATSKA d.o.o. za razvoj, proizvodnju i prodaju lijekova i farmaceutskih proizvoda (PLIVA HRVATSKA d.o.o.), Zagreb, Prilaz baruna Filipovića 25 - pogon Savski Marof (obrat Savski Marof, kraj: Prigorje Brdovečko, Prudnička 98), dejavnost IPPC 4.5.
8. PURIS, poljoprivredna, prehrambena, trgovачka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - mesna industrija (mesna industrija, kraj: Sv. Petar u Šumi), dejavnost IPPC 6.4 a in b.
9. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb – farma br. 20 (kmetija št. 20, kraj: Petrijanec-Nova Ves), dejavnost IPPC 6.6.a.

10. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Sv. Petar u Šumi 8 (kmetija Sv. Petar u Šumi 8, kraj: Sveti Petar u Šumi), dejavnost IPPC 6.6.a.
11. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Sv. Petar u Šumi 9 (kmetija Sv. Petar u Šumi 9, kraj: Sveti Petar u Šumi), dejavnost IPPC 6.6.a.
12. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Barban (kmetija Barban, kraj: Barban), dejavnost IPPC 6.6.a.
13. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Muntrilj (kmetija Muntrilj, kraj: Muntrilj), dejavnost IPPC 6.6.a.
14. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Šikuti (kmetija Šikuti, kraj: Svetvinčenat), dejavnost IPPC 6.6.a.
15. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Žminj 2 (kmetija Žminj 2, kraj: Žminj), dejavnost IPPC 6.6.a.
16. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Surani 2 (kmetija Surani 2, kraj: Tinjani, Surani), dejavnost IPPC 6.6.a.
17. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Pilati (kmetija Pilati, kraj: Lovrin, Pilati), dejavnost IPPC 6.6.a.
18. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Škropeti 2 (kmetija Škropeti 2, kraj: Škropeti), dejavnost IPPC 6.6.a.
19. PURIS, poljoprivredna, prehrambena, trgovacka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Katun 2 (kmetija Katun 2, kraj: Trviz, Katun Trviski), dejavnost IPPC 6.6.a.

20. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Srbinjak (kmetija Srbinjak, kraj: Jakovici, Srbinjak), dejavnost IPPC 6.6.a.
21. AD PLASTIK dioničko društvo za proizvodnju dijelova i pribora za motorna vozila i proizvoda iz plastičnih masa (AD PLASTIK d.d.), Solin, Matoševa ulica 8 - kraj: Zagreb, Jankomir 5, dejavnost IPPC 6.7.
22. BRODOSPLIT-BRODOGRADILIŠTE društvo s ograničenom odgovornošću (BRODOSPLIT-BRODOGRADILIŠTE d.o.o.), Split, Put Supavlja 21, dejavnost IPPC 6.7.
23. CHROMOS BOJE I LAKOVI, dioničko društvo za proizvodnju boja i lakova (CHROMOS BOJE I LAKOVI, d.d.), Zagreb, Radnička cesta 173/d, dejavnost IPPC 6.7.
24. MURAPLAST društvo s ograničenom odgovornošću za proizvodnju i preradu plastičnih masa (MURAPLAST d.o.o.), Kotoriba, Industrijska zona bb, dejavnost IPPC 6.7.
25. 3. MAJ BRODOGRADILIŠTE d.d., Rijeka, Liburnijska 3, dejavnost IPPC 6.7.
26. CHROMOS-SVJETLOST, Tvornica boja i lakova, društvo s ograničenom odgovornošću (CHROMOS-SVJETLOST d.o.o.), Lužani, Mijata Stojanovića 13, dejavnost IPPC 6.7.
27. BROTROTROGIR d.d., Trogir, Put Brodograditelja 16, dejavnost IPPC 6.7.
28. ULJANIK Brodogradilište, d.d., Pula, Flaciusova 1, dejavnost IPPC 6.7.

(e) Od 1. januarja 2017:

1. METALSKA INDUSTRIJA VARAŽDIN dioničko društvo (MIV d.d.), Varaždin, Fabijanska ulica 33, dejavnost IPPC 2.4.
2. KANDIT PREMIJER d.o.o. za proizvodnju, promet i usluge (KANDIT PREMIJER d.o.o.), Osijek, Frankopanska 99, dejavnost IPPC 6.4.b.
3. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb – farma br. 21 (kmetija št. 21, kraj: Čakovec, Totovec), dejavnost IPPC 6.6.a.
4. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 – farma Lužani (kmetija Lužani), dejavnost IPPC 6.6.b.

(f) Od 1. januarja 2018:

1. BELIŠĆE dioničko društvo za proizvodnju papira, kartonske ambalaže, strojeva, primarnu i finalnu preradu drva i suhu destilaciju drva (BELIŠĆE d.d.), Belišće, Trg Ante Starčevića 1 – parni kotao K3, parni kotao K4 (parni kotel K3, parni kotel K4), dejavnost IPPC 1.1 (nanaša se le na parne kotle K3 in K4).
2. HEP-Proizvodnja d.o.o. za proizvodnju električne i plinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 – KTE Jertovec (kombinirana elektrarna Jertovec, kraj: Konjščina, Jertovec, Jertovec 151), dejavnost IPPC 1.1.
3. HEP-Proizvodnja d.o.o. za proizvodnju električne i plinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE Plomin 1 (termoelektrarna Plomin 1, kraj: Plomin, Plomin bb), dejavnost IPPC 1.1.
4. TE PLOMIN društvo s ograničenom odgovornošću za proizvodnju električne energije (TE PLOMIN d.o.o.), Plomin, Plomin bb - TE Plomin 2 (termoelektrarna Plomin 2, kraj: Plomin, Plomin bb), dejavnost IPPC 1.1.
5. HEP-Proizvodnja d.o.o. za proizvodnju električne i plinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - EL-TO Zagreb (elektrarna Zagreb - topotna postaja, kraj: Zagreb, Zagorska 1), dejavnost IPPC 1.1.
6. HEP-Proizvodnja d.o.o. za proizvodnju električne i plinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE-TO Zagreb (termoelektrarna Zagreb - topotna postaja, kraj: Zagreb, Kuševačka 10 a), dejavnost IPPC 1.1.
7. HEP-Proizvodnja d.o.o. za proizvodnju električne i plinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE Sisak (termoelektrarna Sisak, kraj: Sisak, Čret bb), dejavnost IPPC 1.1.
8. HEP-Proizvodnja d.o.o. za proizvodnju električne i plinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE-TO Osijek (termoelektrarna Osijek - topotna postaja, kraj: Osijek, Martina Divalta 203), dejavnost IPPC 1.1.
9. HEP-Proizvodnja d.o.o. za proizvodnju električne i plinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE Rijeka (termoelektrarna Rijeka, kraj: Kostrena, Urinj bb), dejavnost IPPC 1.1.

10. DIOKI Organska petrokemija dioničko društvo (DIOKI d.d.), Zagreb, Čulinečka cesta 252, dejavnost IPPC 1.1.
11. INA-INDUSTRija NAFTE, d.d. (INA, d.d.), Zagreb, Avenija V. Holjevca 10 – Rafinerija nafte Rijeka - Urinj (rafinerija nafte Rijeka - Urinj, kraj: Kostrena, Urinj), dejavnost IPPC 1.2.
12. INA-INDUSTRija NAFTE, d.d. (INA, d.d.), Zagreb, Avenija V. Holjevca 10 – Rafinerija nafte Sisak (rafinerija nafte Sisak, kraj: Sisak, Ante Kovačića 1), dejavnost IPPC 1.2.
13. ŽELJEZARA SPLIT poduzeće za proizvodnju i preradu čelika d.d. "u stečaju" (ŽELJEZARA SPLIT d.d. "u stečaju"), Kaštel Sućurac, Cesta dr. F. Tuđmana bb, dejavnost IPPC 2.2.
14. PETROKEMIJA, d.d. tvornica gnojiva (PETROKEMIJA, d.d.), Kutina, Aleja Vukovar 4, dejavnost IPPC 4.2.b.

## VI. KEMIKALIJE

32006 R 1907: Uredba (ES) št. 1907/2006 Evropskega parlamenta in Sveta z dne 18. decembra 2006 o registraciji, evalvaciji, avtorizaciji in omejevanju kemikalij (REACH) ter o ustanovitvi Evropske agencije za kemikalije in o spremembi Direktive 1999/45/ES ter o razveljavitvi Uredbe Sveta (EGS) št. 793/93 in Uredbe Komisije (ES) št. 1488/94 ter Direktive Sveta 76/769/EGS in direktiv Komisije 91/155/EGS, 93/67/EGS, 93/105/ES in 2000/21/ES (UL L 396, 30.12.2006, str. 1).

- (a) Z odstopanjem od člena 23(1) in (2) ter člena 28, ki določata rok za registracijo in predregistracijo snovi iz teh členov, se proizvajalcem, uvoznikom in izdelovalcem izdelkov s sedežem na Hrvaškem odobri šestmesečno prilagoditveno obdobje od dneva pristopa za predregistracijo snovi v postopnem uvajanju. Datum prvega in drugega roka za registracijo iz člena 23(1) in (2) je 12 mesecev po datumu pristopa.

- (b) Členi 6, 7, 9, 17, 18 in 33 se za Hrvaško ne uporabljajo šest mesecev po datumu pristopa.
- (c) Z odstopanjem od prehodnih ureditev za vse snovi, ki so vključene v Prilogo XIV, v primeru če bi se rok za oddajo vlog iztekel pred dnevom pristopa ali prej kot v šestih mesecih po tem dnevu, se za prosilce s sedežem na Hrvaškem odobri prilagoditveno obdobje šestih mesecev od dneva pristopa, do izteka katerega morajo biti prejete vloge za avtorizacijo.
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*Dodatek k Prilogi V*

Seznam(\*), ki ga je v enem jeziku predložila Hrvaška, na katerem so zdravila, za katera ostanejo dovoljenja za promet, izdana na podlagi hrvaške zakonodaje pred datumom pristopa, v veljavi do podaljšanja veljavnosti v skladu s pravnim redom Unije oziroma do 30. junija 2017, če nastopi prej.

Uvrščenost na ta seznam ne pomeni, da zadevno zdravilo ima oziroma nima dovoljenja za promet v skladu s pravnim redom Unije.

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(\*) Glej UL C xxx [E], xx.xx.xxxx, str. xxx. [Besedilo, kakor je navedeno v dok. 30/11].

**PRILOGA VI**  
**Razvoj podeželja (iz člena 35(2) Akta o pristopu)**

**I. UKREP ZA RAZVOJ PODEŽELJA ZA HRVAŠKO**

32005 R 1698: Uredba Sveta (ES) št. 1698/2005 z dne 20. septembra 2005 o podpori za razvoj podeželja iz Evropskega kmetijskega sklada za razvoj podeželja (EKSRP) (UL L 277, 21.10.2005, str. 1 in UL L 286M, 4.11.2010, str. 26).

Uredba Sveta (ES) št. 1698/2005 se v celotnem programskem obdobju 2007–2013 za Hrvaško ne uporablja.

**II. ZAČASNI DODATNI UKREPI ZA RAZVOJ PODEŽELJA ZA HRVAŠKO**

**A. Podpora za delno samooskrbne kmetije v prestrukturiraju**

V zakonodajnjem okviru razvoja podeželja za programsko obdobje 2014–2020 se, kar zadeva Hrvaško, kmetom v skladu z načeli iz člena 34 Uredbe Sveta (ES) št. 1698/2005 dodeli posebna podpora za delno samooskrbna kmetijska gospodarstva, in sicer na podlagi vlog, odobrenih do 31. decembra 2017, če v novi uredbi o razvoju podeželja za programsko obdobje 2014–2020 ne bo predviden noben podoben ukrep in/ali podpora.

**B. Skupine proizvajalcev**

V zakonodajnjem okviru razvoja podeželja za programsko obdobje 2014–2020 se, kar zadeva Hrvaško, skupinam proizvajalcev, ki jih uradno priznava hrvaški pristojni organ, do 31. decembra 2017 v skladu z načeli iz člena 35 Uredbe Sveta (ES) št. 1698/2005 dodeli posebna podpora za lažje ustanavljanje in upravno delovanje skupin proizvajalcev, če v novi uredbi o razvoju podeželja za programsko obdobje 2014–2020 ne bo predviden noben podoben ukrep in/ali podpora.

## C. Leader

V zakonodajnem okviru razvoja podeželja za programsko obdobje 2014–2020 se – kar zadeva Hrvaško – najnižji prispevek EKSRP iz programa razvoja podeželja za LEADER določi v povprečju na ravni, ki je vsaj polovica odstotka proračuna, ki se bo uporabljal za ostale države članice, če se takšna zahteva določi.

## D. Dopolnila neposrednih plačil

1. Podpora se lahko dodeljuje kmetom, ki so upravičeni do dopolnilnih nacionalnih neposrednih plačil ali pomoči na podlagi člena 132 Uredbe Sveta (ES) št. 73/2009<sup>1</sup>.
2. Podpora, podeljena kmetu za leta 2014, 2015 in 2016, ne presega razlike med:
  - (a) ravnijo neposrednih plačil, ki se uporabljajo na Hrvaškem za zadevno leto v skladu s členom 121 Uredbe Sveta (ES) št. 73/2009, in
  - (b) 45 % ravni neposrednih plačil, ki se uporabljajo v Uniji v njeni sestavi na dan 30. aprila 2004 za zadevno leto.
3. Prispevek Unije k podpori, dodeljeni kmetu na podlagi pododdelka D na Hrvaškem za leta 2014, 2015 in 2016 ne presega 20 % njenih celotnih sredstev, dodeljenih za razvoj podeželja (EKSRP).
4. Višina prispevka Unije za dopolnila k neposrednim plačilom ne presega 80 %.

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<sup>1</sup> Uredba Sveta (ES) št. 73/2009 z dne 19. januarja 2009 o skupnih pravilih za sheme neposrednih podpor za kmete v okviru skupne kmetijske politike in o uvedbi nekaterih shem podpor za kmete, sprememb uredb (ES) št. 1290/2005, (ES) št. 247/2006, (ES) št. 378/2007 in razveljavitvi Uredbe (ES) št. 1782/2003 (UL L 30, 31.1.2009, str. 16).

## **E. Predpristopni instrument – razvoj podeželja**

1. Hrvaška lahko še naprej sklepa pogodbe ali sprejema obveznosti na podlagi programa IPARD v skladu z Uredbo Komisije (ES) št. 718/2007 z dne 12. junija 2007 o izvajanju Uredbe Sveta (ES) št. 1085/2006 o vzpostaviti instrumenta za predpristopno pomoč (IPA), dokler ne bo začela sklepati pogodbe ali sprejemati obveznosti na podlagi ustrezne uredbe o razvoju podeželja<sup>1</sup>. Hrvaška Komisijo obvesti o datumu, ko bo začela sklepati pogodbe ali sprejemati obveznosti na podlagi ustrezne uredbe o razvoju podeželja.
2. Komisija sprejme ukrepe, ki so potrebni v ta namen, po postopku iz člena 5 Uredbe (EU) št. 182/2011 Evropskega parlamenta in Sveta z dne 16. februarja 2011 o določitvi splošnih pravil in načel, na podlagi katerih države članice nadzirajo izvajanje izvedbenih pooblastil Komisije. V ta namen Komisiji pomaga Odbor IPA iz člena 14(1) Uredbe Sveta (ES) št. 1085/2006.

## **F. Naknadno vrednotenje programa IPARD**

V zakonodajnem okviru razvoja podeželja za programsko obdobje 2014–2020 se, kar zadeva izvajanje programa IPARD za Hrvaško, izdatki v zvezi z naknadnim vrednotenjem programa IPARD iz člena 191 Uredbe Komisije (ES) št. 718/2007 lahko štejejo za upravičene v okviru ukrepa tehnične pomoči.

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<sup>1</sup> UL L 170, 29.6.2007, str. 1.

## **G. Posodabljanje kmetijskih gospodarstev**

V zakonodajnem okviru razvoja podeželja za programsko obdobje 2014–2020 znaša, kar zadeva Hrvaško, največja intenzivnost pomoči za posodobitev kmetijskih gospodarstev 75 % zneska upravičene naložbe za izvajanje Direktive Sveta 91/676/EGS z dne 12. decembra 1991 o varstvu voda pred onesnaževanjem z nitrati iz kmetijskih virov v obdobju največ štirih let od dneva pristopa v skladu s členoma 3(2) in 5(1) navedene direktive<sup>1</sup>.

## **H. Izpolnjevanje standardov**

V zakonodajnem okviru razvoja podeželja za programsko obdobje 2014–2020 se, kar zadeva Hrvaško, izpolnjujejo predpisane zahteve ravnanja iz Priloge II k Uredbi Sveta (ES) št. 73/2009, ki se uporablja v navedenem programskem obdobju, v skladu z naslednjim časovnim razporedom: zahteve iz točke A Priloge II se uporablja od 1. januarja 2014; zahteve iz točke B Priloge II se uporablja od 1. januarja 2016 in zahteve iz točke C Priloge II se uporablja od 1. januarja 2018.

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<sup>1</sup> UL L 375, 31.12.1991, str. 1.

## PRILOGA VII

### **Posebne zaveze, ki jih je Republika Hrvaška prevzela v pristopnih pogajanjih (iz drugega pododstavka člena 36(1) Akta o pristopu)**

1. Nadaljnje zagotavljanje učinkovitega izvajanja strategije in akcijskega načrta za reformo pravosodja.
2. Nadaljnja krepitev neodvisnosti, odgovornosti, nepristranskosti in strokovnosti sodstva.
3. Nadaljnje izboljševanje učinkovitosti sodstva.
4. Nadaljnje izboljševanje obravnave domačih zadev, povezanih z vojnimi zločini.
5. Nadaljnje trajno doseganje opaznih rezultatov z uspešnimi, učinkovitimi in nepristranskimi preiskavami, pregonom in sodnimi odločbami v zadevah v zvezi z organiziranim kriminalom in korupcijo na vseh ravneh, tudi korupcijo na visoki ravni, in v izpostavljenih sektorjih, kot so javna naročila.
6. Nadaljnje izboljševanje rezultatov v okviru okrepljenih preprečevalnih ukrepov v boju proti korupciji in pri navzkrižju interesov.
7. Nadaljnja krepitev varstva manjšin, med drugim z učinkovitim izvajanjem ustavnega zakona o pravicah narodnostnih manjšin.
8. Nadaljnje reševanje nerešenih vprašanj v zvezi z vračanjem beguncev.
9. Nadaljnje izboljševanje varstva človekovih pravic.
10. Nadaljnje polno sodelovanje z Mednarodnim kazenskim sodiščem za nekdanjo Jugoslavijo.

## PRILOGA VIII

### **Zaveze, ki jih je Republika Hrvaška prevzela v zvezi s prestrukturiranjem hrvaške ladjedelniške industrije (iz tretjega pododstavka člena 36(1) Akta o pristopu)**

Ladjedelniška podjetja, ki bodo prestrukturirana (v nadalnjem besedilu: podjetja), so naslednja:

- Brodograđevna industrija 3 MAJ dioničko društvo, Rijeka (v nadalnjem besedilu: 3. MAJ)
- BRODOTROGIR d.d., Trogir (v nadalnjem besedilu: Brodotrogir)
- BRODOGRAĐEVNA INDUSTRIJA SPLIT, dioničko društvo, Split (v nadalnjem besedilu: Brodosplit)
- BRODOSPLIT-BRODOGRADILIŠTE SPECIJALNIH OBJEKATA društvo s ograničenom odgovornošću, Split (v nadalnjem besedilu: BSO)
- BRODOGRADILIŠTE KRALJEVICA dioničko društvo za izgradnju i popravak brodova, Kraljevica (v nadalnjem besedilu: Kraljevica).

Hrvaška soglaša, da se prestrukturiranje teh podjetij izvede s privatizacijo na podlagi konkurenčnega razpisnega postopka. Načrte prestrukturiranja teh podjetij, ki so jih predložili ponudniki, sta odobrili hrvaška agencija za konkurenco in Evropska komisija. Vključeni bodo v ustrezne privatizacijske pogodbe, ki jih bo Hrvaška sklenila s kupci podjetij.

Načrti prestrukturiranja, predloženi za posamezna podjetja, podrobno določajo naslednje ključne pogoje, ki jih je treba spoštovati v procesu prestrukturiranja:

- Vsa državna pomoč, ki so jo ta podjetja prejemala od 1. marca 2006, se mora šteti kot pomoč za prestrukturiranje. Podjetja za načrt prestrukturiranja zagotovijo prispevek iz lastnih sredstev, ki mora biti realen, ne sme vsebovati državne pomoči in znaša najmanj 40 % celotnih stroškov prestrukturiranja.

- Splošna proizvodna zmogljivost podjetij se v primerjavi z ravnimi z dne 1. junija 2011 zmanjša s 471 324 KBT na 372 346 KBT. Podjetja svojo proizvodno zmogljivost zmanjšajo najpozneje dvanajst mesecev po podpisu privatizacijske pogodbe. Zmanjšanje zmogljivosti se izvede s trajnim zaprtjem splavišč, z določitvijo splavišč za kraje izključne vojaške proizvodnje v smislu člena 346 PDEU in/ali z zmanjšanjem površine. Kompenzirana bruto tonaža (KBT) je enota za merjenje obsega proizvodnje, ki se izračunava skladno z ustreznimi pravili OECD.
- Skupna letna proizvodnja podjetij se omeji na 323 600 KBT za deset let z začetkom 1. januarja 2011. Obseg proizvodnje podjetij bo omejen na naslednjih ravneh<sup>1</sup>:
  - 3 MAJ: 109 570 KBT
  - Brodotrogir: 54 955 KBT
  - Brodosplit in BSO: 132 078 KBT
  - Kraljevica: 26 997 KBT

Ta podjetja utegnejo privoliti v revizijo njihovih individualnih proizvodnih omejitev. Na podlagi zavezujočih sporazumov lahko izrecno določijo, kateri del njihove individualne proizvodne kvote (izražene v KBT) si medsebojno odstopijo. Upošteva se splošna letna proizvodna omejitev v višini 323 600 KBT.

- V načrtih prestrukturiranja je določena tudi vrsta drugih ukrepov, ki jih bo izvedlo vsako podjetje, da bi se ponovno usposobilo za dolgoročno preživetje.

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<sup>1</sup> Letna proizvodnja danega podjetja se izračuna na naslednji način. Začetek proizvodnje ladje je načrtovani datum rezanja jekla, zaključek proizvodnje pa datum pričakovane dobave ladje, kot je določen v pogodbi s kupcem (ali predvideni datum dostave nedokončane ladje, kadar pri izgradnji ladje sodelujeta dve podjetji). Število KBT za posamezno ladjo se dodeli linearno glede na število koledarskih let v obdobju proizvodnje. Skupni obseg proizvodnje podjetja v danem letu se izračuna tako, da se doda število v tem letu proizведенih KBT.

Morebitne naknadne spremembe teh načrtov morajo biti skladne s ključnimi pogoji, ki jih je treba spoštovati v navedenem procesu prestrukturiranja, in se predložijo v odobritev Komisiji.

Podjetja najmanj deset let od datuma podpisa privatizacijske pogodbe ne prejmejo nikakršne nove pomoči za reševanje ali prestrukturiranje. Komisija od Hrvaški ob njenem pristopu zahteva vrnitev vsakršne pomoči za reševanje ali prestrukturiranje, ki ji je bila dodeljena v nasprotju s to določbo, skupaj z obrestnimi obrestmi.

Načrti prestrukturiranja, ki sta jih hrvaška agencija za konkurenco in Komisija odobrili, bodo vključeni v ustrezne privatizacijske pogodbe, ki jih bo Hrvaška sklenila s kupci podjetij.

Privatizacijske pogodbe se predložijo Komisiji v odobritev in se podpišejo pred pristopom Hrvaške.

Komisija pozorno spremlja izvajanje načrtov prestrukturiranja ter spoštovanje v tej prilogi določenih pogojev glede ravni državne pomoči, lastnega prispevka, zmanjšanj zmogljivosti, omejitve proizvodnje in ukrepov, sprejetih za ponovno usposobitev podjetij za preživetje.

To spremljanje se izvaja vsa leta obdobja prestrukturiranja. Hrvaška v celoti spoštuje vse ureditve za spremljanje. Zlasti naslednje:

- Hrvaška Komisiji do konca obdobja prestrukturiranja vsako leto najpozneje 15. januarja in 15. julija predloži šestmesečna poročila o prestrukturiranju upravičenih podjetij;
- poročila vsebujejo vse podatke, potrebne za spremljanje procesa prestrukturiranja, lastnega prispevka, zmanjšanja zmogljivosti, omejitve proizvodnje in ukrepov, sprejetih za ponovno usposobitev podjetij za preživetje;
- Hrvaška do konca leta 2020 vsako leto najpozneje 15. julija predloži poročila o letnem obsegu proizvodnje podjetij v postopku prestrukturiranja;

- Hrvaška od podjetij zahteva, da razkrijejo vse pomembne podatke, ki bi se jih v drugih okoliščinah lahko štelo za zaupne. Komisija zagotovi, da se zaupni podatki, ki zadevajo posamezna podjetja, ne razkrijejo.

Komisija se lahko kadar koli odloči za pooblastitev neodvisnega strokovnjaka, da ovrednoti rezultate spremeljanja, izvede vse potrebne raziskave in poroča Komisiji. Hrvaška polno sodeluje z neodvisnim strokovnjakom, ki ga imenuje Komisija, in mu zagotovi poln dostop do vseh podatkov, ki jih bo potreboval za opravljanje nalog, ki mu jih je zaupala Komisija.

Komisija od Hrvaške ob njenem pristopu zahteva vrnitev vse pomoči za reševanje ali prestrukturiranje, ki je bila določenemu podjetju dodeljena od 1. marca 2006, skupaj z obrestnimi obrestmi, če:

- privatizacijska pogodba za to podjetje še ni bila podpisana ali ne vključuje vseh pogojev, določenih v načrtu prestrukturiranja, ki sta ga odobrili hrvaška agencija za konkurenco in Komisija, ali
- podjetje iz lastnih sredstev ni zagotovilo takega prispevka v višini najmanj 40 % celotnih stroškov prestrukturiranja, ki bi bil realen in ne bi vseboval državne pomoči, ali
- zmanjšanje splošne proizvodne zmogljivosti ni bilo opravljeno v dvanajstih mesecih od podpisa privatizacijske pogodbe. V tem primeru se vračilo pomoči zahteva le od tistih podjetij, ki niso dosegla naslednjih individualnih zmanjšanj zmogljivosti:
  - 3 MAJ: za 46 543 KBT
  - Brodotrogir: za 15 101 KBT
  - Brodosplit in BSO: za 29 611 KBT
  - Kraljevica: za 9 636 KBT

- je bila v katerem koli posamičnem koledarskem letu v obdobju 2011–2020 presežena splošna proizvodna omejitev za ladnjedelnice (tj. 323 600 KBT). V tem primeru se vračilo pomoči zahteva od tistih podjetij, ki so presegla individualne proizvodne omejitve (kakor so bile spremenjene s pravno zavezujočim sporazumom z drugim ladnjedelniškim podjetjem, če je ustrezno).
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## PRILOGA IX

### **Zaveze, ki jih je Republika Hrvaška prevzela v zvezi s prestrukturiranjem jeklarskega sektorja (iz tretjega pododstavka člena 36(1) Akta o pristopu)**

Hrvaška je s pismom z dne 23. maja 2011 obvestila Komisijo, da je od proizvajalca jekla CMC Sisak d.o.o. prejela pripoznavo dolga, ki ustreza vsoti pomoči za prestrukturiranje, ki jo je to podjetje prejelo v obdobju od 1. marca 2002 do 28. februarja 2007, in obrestnih obresti<sup>1</sup>. Prejeta državna pomoč, brez obrestnih obresti, znaša 19 117 572,36 HRK.

Če CMC Sisak d.o.o. do datuma pristopa Hrvaške ne vrne skupnega zneska te pomoči skupaj z obrestnimi obrestmi, Komisija od Hrvaške zahteva vrnitev vsakršne pomoči za reševanje in prestrukturiranje, ki je bila temu podjetju dodeljena od 1. marca 2006, skupaj z obrestnimi obrestmi.

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<sup>1</sup> Izračuna se v skladu s členi 9–11 Uredbe Komisije (ES) št. 794/2004 z dne 21. aprila 2004 o izvajanju Uredbe Sveta (ES) št. 659/1999 z dne 22. marca 1999 o določitvi podrobnih pravil za uporabo člena 93 Pogodbe ES (UL L 140, 30.4.2004, str. 1), kakor je bila nazadnje spremenjena z Uredbo Komisije (ES) št. 1125/2009 z dne 23. novembra 2009.

## **PROTOKOL**

**Protokol o nekaterih dogovorih o morebitnem enkratnem prenosu enot dodeljenih količin, ki se izdajo v okviru Kjotskega protokola, Republiki Hrvaški ter o ustreznem nadomestilu**

VISOKE POGODBENICE SO SE,

OB UGOTOVITVI, da je bilo glede na posebne zgodovinske okoliščine, ki so zaznamovale Hrvaško, dogovorjeno, da se izrazi pripravljenost za pomoč Hrvaški z enkratnim prenosom enot dodeljenih količin, ki se izdajo v okviru Kjotskega protokola,

OB OPOZARJANJU, da bi šlo le za enkraten prenos, ki ne bi pomenil precedensa in bi odražal edinstveno in izjemno naravo položaja Hrvaške,

OB POUĐARJANJU, da bi morala Hrvaška takšen prenos nadomestiti s prilagoditvijo svojih obveznosti v skladu z Odločbo št. 406/2009/ES, da se zagotovi okoljska skladnost in prepreči povišanje skupne količine dovoljenih emisij Unije in Hrvaške do leta 2020 –

DOGOVORILE O NASLEDNJEM:

### **DEL I**

#### **PRENOS**

##### *Člen 1*

Ta del se uporablja za ukrepe v zvezi z morebitnim enkratnim prenosom enot dodeljenih količin Hrvaški, ki se izdajo v okviru Kjotskega protokola.

## *Člen 2*

Prenos se izvede samo, če Hrvaška v skladu z ustreznimi pravili in časovnimi omejitvami, ki veljajo za umik pritožb, umakne pritožbo zoper odločitev izvršilne veje odbora za zagotavljanje izpolnjevanja obveznosti iz Kjotskega protokola, in sicer pred začetkom konference UNFCCC, ki bo od 28. novembra do 9. decembra 2011 v Durbanu.

Prenos se izvede šele, ko skupina izvedencev UNFCCC za pregledovanje po obdobju prilagoditve ("true-up period") določi, da Hrvaška ni izpolnila svojih obveznosti iz člena 3 Kjotskega protokola.

Prenos se izvede samo, če si Hrvaška po najboljših močeh prizadeva za izpolnitev svojih obveznosti iz člena 3 Kjotskega protokola, vključno z dosledno uporabo enot odstranitve iz naslova rabe zemljišč, spremembe namembnosti zemljišč in gozdarstva.

## *Člen 3*

Sklep o prenosu enot dodeljenih količin (AAU) se sprejme v skladu s postopkom pregleda iz člena 5 Uredbe (EU) št. 182/2011<sup>1</sup>. Komisiji pomaga Odbor za podnebne spremembe, ustanovljen s členom 9 Odločbe št. 280/2004/ES<sup>2</sup>. Navedeni odbor je odbor v smislu Uredbe (EU) št. 182/2011. Če odbor mnenja ne da, se sklep ne sprejme.

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<sup>1</sup> Uredba (EU) št. 182/2011 Evropskega parlamenta in Sveta z dne 16. februarja 2011 o določitvi splošnih pravil in načel, na podlagi katerih države članice nadzirajo izvajanje izvedbenih pooblastil Komisije (UL L 55, 28.2.2011, str. 13).

<sup>2</sup> Odločba št. 280/2004/ES Evropskega parlamenta in Sveta z dne 11. februarja 2004 o mehanizmu za spremljanje emisij toplogrednih plinov v Skupnosti in o izvajanju Kjotskega protokola (UL L 49, 19.2.2004, str. 1).

AAU, ki se prenesejo, se vzamejo iz količine AAU iz člena 2 Sklepa Komisije 2006/944/ES<sup>1</sup>.

Prenos ne presega skupne količine 7 milijonov AAU.

## **DEL II** **NADOMESTILO**

### *Člen 4*

Ta del se uporablja za nadomestilo, ki ga mora Hrvaška zagotoviti v primeru prenosa AAU v skladu z določbami iz dela I.

### *Člen 5*

1. Hrvaška zagotovi nadomestilo za vse AAU, ki so bile nanjo prenesene, tako da v skladu s tem členom prilagodi svoje obveznosti, ki izhajajo iz Odločbe št. 406/2009/ES<sup>2</sup>.

Zlasti se enakovredna količina prenesenih AAU, izražena v tonah ekvivalenta ogljikovega dioksida, v skladu s tem členom odšteje od letnih emisij, dodeljenih Hrvaški, potem ko se letne količine določijo v skladu s členom 3(2) Odločbe št. 406/2009/ES.

2. Komisija objavi podatke za letne emisije, dodeljene Hrvaški, izračunane v skladu z odstavkom 1.

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<sup>1</sup> Odločba Komisije 2006/944/ES z dne 14. decembra 2006 o določitvi ravni emisij, ki se dodelijo Skupnosti in vsaki od njenih držav članic v okviru Kjotskega protokola v skladu z Odločbo Sveta 2002/358/ES (UL L 358, 16.12.2006, str. 87), kakor je bila spremenjena s Sklepom Komisije 2010/778/EU z dne 15. decembra 2010 (UL L 332, 16.12.2010, str. 41).

<sup>2</sup> Odločba št. 406/2009/ES Evropskega parlamenta in Sveta z dne 23. aprila 2009 o prizadevanju držav članic za zmanjšanje emisij toplogrednih plinov, da do leta 2020 izpolnijo zavezo Skupnosti za zmanjšanje emisij toplogrednih plinov (UL L 140, 5.6.2009, str. 136).

## **SKLEPNA LISTINA**

## I. BESEDILO SKLEPNE LISTINE

1. Pooblaščenci:

NJEGOVEGA VELIČANSTVA KRALJA BELGIJEV,

PREDSEDNIKA REPUBLIKE BOLGARIJE,

PREDSEDNIKA ČEŠKE REPUBLIKE,

NJENEGA VELIČANSTVA KRALJICE DANSKE,

PREDSEDNIKA ZVEZNE REPUBLIKE NEMČIJE,

PREDSEDNIKA REPUBLIKE ESTONIJE,

PREDSEDNICE IRSKE,

PREDSEDNIKA HELENSKE REPUBLIKE,

NJEGOVEGA VELIČANSTVA KRALJA ŠPANIJE,

PREDSEDNIKA FRANCOSKE REPUBLIKE,

[ENTRY FOR CROATIA TO BE INSERTED AT A LATER STAGE],

PREDSEDNIKA ITALIJANSKE REPUBLIKE,

PREDSEDNIKA REPUBLIKE CIPER,

PREDSEDNIKA REPUBLIKE LATVIJE,

PREDSEDNICE REPUBLIKE LITVE,

NJEGOVE KRALJEVE VISOKOSTI VELIKEGA VOJVODE LUKSEMBURŠKEGA,

PREDSEDNIKA REPUBLIKE MADŽARSKE,

PREDSEDNIKA MALTE,

NJENEGA VELIČANSTVA KRALJICE NIZOZEMSKE,

ZVEZNEGA PREDSEDNIKA REPUBLIKE AVSTRIJE,

PREDSEDNIKA REPUBLIKE POLJSKE,

PREDSEDNIKA PORTUGALSKIE REPUBLIKE,

PREDSEDNIKA ROMUNIJE,

PREDSEDNIKA REPUBLIKE SLOVENIJE,

PREDSEDNIKA SLOVAŠKE REPUBLIKE,

PREDSEDNICE REPUBLIKE FINSKE,

VLADE KRALJEVINE ŠVEDSKE,

NJENEGA VELIČANSTVA KRALJICE ZDRUŽENEGA KRALJESTVA VELIKA  
BRITANIJA IN SEVERNA IRSKA,

zbrani v/na [city to be inserted] [date to be inserted] ob podpisu Pogodbe med Kraljevino Belgijo, Republiko Bolgarijo, Češko republiko, Kraljevino Dansko, Zvezno republiko Nemčijo, Republiko Estonijo, Irsko, Helensko republiko, Kraljevino Španijo, Francosko republiko, Italijansko republiko, Republiko Ciper, Republiko Latvijo, Republiko Litvo, Velikim vojvodstvom Luksemburg, Republiko Madžarsko, Republiko Malto, Kraljevino Nizozemsko, Republiko Avstrijo, Republiko Poljsko, Portugalsko republiko, Romunijo, Republiko Slovenijo, Slovaško republiko, Republiko Finsko, Kraljevino Švedsko, Združenim kraljestvom Velika Britanija in Severna Irska (državami članicami Evropske unije) ter Republiko Hrvaško o pristopu Republike Hrvaške k Evropski uniji,

so ugotovili, da so bila na konferenci držav članic Evropske unije in Republike Hrvaške sestavljena in sprejeta naslednja besedila o pristopu Republike Hrvaške k Evropski uniji:

- I Pogodba med Kraljevino Belgijo, Republiko Bolgarijo, Češko republiko, Kraljevino Dansko, Zvezno republiko Nemčijo, Republiko Estonijo, Irsko, Helensko republiko, Kraljevino Španijo, Francosko republiko, Italijansko republiko, Republiko Ciper, Republiko Latvijo, Republiko Litvo, Velikim vojvodstvom Luksemburg, Republiko Madžarsko, Republiko Malto, Kraljevino Nizozemsko, Republiko Avstrijo, Republiko Poljsko, Portugalsko republiko, Romunijo, Republiko Slovenijo, Slovaško republiko, Republiko Finsko, Kraljevino Švedsko, Združenim kraljestvom Velika Britanija in Severna Irska (državami članicami Evropske unije) ter Republiko Hrvaško o pristopu Republike Hrvaške k Evropski uniji (v nadalnjem besedilu: Pristopna pogodba)
- II. Akt o pogojih pristopa Republike Hrvaške in o prilagoditvah Pogodbe o Evropski uniji, Pogodbe o delovanju Evropske unije in Pogodbe o ustanovitvi Evropske skupnosti za atomsko energijo (v nadalnjem besedilu: Akt o pristopu)

III. spodaj navedena besedila, ki so priložena Aktu o pristopu:

A. Priloga I: Seznam konvencij in protokolov, h katerim pristopi Republika Hrvaška ob pristopu (iz člena 3(4) Akta o pristopu)

Priloga II: Seznam določb schengenskega pravnega reda, kakor so vključene v okvir Evropske unije, in aktov, ki na njem temeljijo ali so z njim kako drugače povezani, ki so za Republiko Hrvaško zavezajoči in se v njej uporabljajo od pristopa (iz člena (4(1) Akta o pristopu)

Priloga III: Seznam iz člena 15 Akta o pristopu: prilagoditve aktov, ki so jih sprejele institucije

PRILOGA IV: Seznam iz člena 16 Akta o pristopu: druge trajne določbe

Priloga V: Seznam iz člena 18 Akta o pristopu: prehodni ukrepi

Priloga VI: Razvoj podeželja (iz člena 35(2) Akta o pristopu)

Priloga VII: Posebne zaveze, ki jih je Republika Hrvaška prevzela v pristopnih pogajanjih (iz drugega pododstavka člena 36(1) Akta o pristopu)

Priloga VIII: Zaveze, ki jih je Republika Hrvaška prevzela v zvezi s prestrukturiranjem hrvaške ladjedelniške industrije (iz tretjega pododstavka člena 36(1) Akta o pristopu)

Priloga IX: Zaveze, ki jih je Republika Hrvaška prevzela v zvezi s  
prestrukturiranjem jeklarskega sektorja (iz tretjega pododstavka  
člena 36(1) Akta o pristopu)

- B. Protokol o nekaterih dogovorih o morebitnem enkratnem prenosu enot dodeljenih količin, ki se izdajo v okviru Kjotskega protokola, Republiki Hrvaški ter o ustreznom nadomestilu
- C. Besedila Pogodbe o Evropski uniji, Pogodbe o delovanju Evropske unije in Pogodbe o ustanovitvi Evropske skupnosti za atomsko energijo ter pogodbe, ki jih spreminjajo ali dopolnjujejo, vključno s Pogodbo o pristopu Kraljevine Danske, Irske ter Združenega kraljestva Velika Britanija in Severna Irska, Pogodbo o pristopu Helenske republike, Pogodbo o pristopu Kraljevine Španije in Portugalske republike, Pogodbo o pristopu Republike Avstrije, Republike Finske in Kraljevine Švedske, Pogodbo o pristopu Češke republike, Republike Estonije, Republike Ciper, Republike Latvije, Republike Litve, Republike Madžarske, Republike Malte, Republike Poljske, Republike Slovenije in Slovaške republike ter Pogodbo o pristopu Republike Bolgarije in Romunije v hrvaškem jeziku.
2. Visoke pogodbalice so dosegle politični dogovor o nizu prilagoditev aktov institucij zaradi pristopa ter pozivajo Svet in Komisijo, naj sprejmeta te prilagoditve pred pristopom v skladu s členom 50 Akta o pristopu, kakor je navedeno v členu 3(4) Pristopne pogodbe; prilagoditve se po potrebi dopolnijo in posodobijo, da se upošteva razvoj prava Unije.

3. Visoke pogodbenice se obvezujejo, da bodo Komisiji in druga drugi posredovale vse informacije, potrebne za uporabo Akta o pristopu. Če je to potrebno, se te informacije zagotovijo dovolj časa pred dnem pristopa, da je z dnem pristopa mogoča polna uporaba Akta o pristopu, predvsem glede delovanja notranjega trga. V tej zvezi je nadvse pomembno čimprejšnje uradno obvestilo v skladu s členom 47 Akta o pristopu v zvezi z ukrepi, ki jih sprejme Republika Hrvaška. Komisija lahko obvesti Republiko Hrvaško o roku, ki se ji zdi primeren za prejem oziroma prenos določenih informacij. Do dne podpisa pogodbenice prejmejo seznam, ki opredeljuje obveznosti obveščanja na področju veterinarstva.
4. Pooblaščenci so se seznanili z naslednjimi sprejetimi izjavami, ki so priložene tej sklepni listini:

[A.] Skupna izjava sedanjih držav članic

[1.] Skupna izjava o polni uporabi določb schengenskega pravnega reda

[B.] Skupna izjava nekaterih sedanjih držav članic

[1.] Skupna izjava Zvezne republike Nemčije in  
Republike Avstrije o prostem gibanju delavcev: Hrvaška

[C.] Skupna izjava sedanjih držav članic in Republike Hrvaške

[1.] Skupna izjava o Evropskem razvojnem skladu

[D.]. Izjava Republike Hrvaške:

[1.] [Izjava Republike Hrvaške o prehodni ureditvi glede liberalizacije  
hrvaškega trga kmetijskih zemljišč

5. Pooblaščenci so se seznanili z izmenjavo pisem, priloženo tej sklepni listini, med Evropsko Unijo in Republiko Hrvaško o postopku obveščanja in posvetovanja za sprejetje nekaterih sklepov in drugih ukrepov, ki jih je treba sprejeti v obdobju pred pristopom.

[*"Done at....on"....:to be inserted in all the official languages, including Croatian]*

Pour Sa Majesté le Roi des Belges  
Voor Zijne Majesteit de Koning der Belgen  
Für Seine Majestät den König der Belgier

Cette signature engage également la Communauté française, la Communauté flamande, la Communauté germanophone, la Région wallonne, la Région flamande et la Région de Bruxelles-Capitale.

Deze handtekening verbindt eveneens de Vlaamse Gemeenschap, de Franse Gemeenschap, de Duitstalige Gemeenschap, het Vlaamse Gewest, het Waalse Gewest en het Brussels Hoofdstedelijk Gewest.

Diese Unterschrift bindet zugleich die Deutschsprachige Gemeinschaft, die Flämische Gemeinschaft, die Französische Gemeinschaft, die Wallonische Region, die Flämische Region und die Region Brüssel-Hauptstadt.

За Република България

Za prezidenta České republiky

For Hennes Majestæt Danmarks Dronning

Für den Präsidenten der Bundesrepublik Deutschland

Eesti Vabariigi Presidendi nimel

Thar ceann Uachtaráin na hÉireann

For the President of Ireland

Για τον Πρόεδρο της Ελληνικής Δημοκρατίας

Por Su Majestad el Rey de España

Pour le Président de la République française

[Insert translation into Croatian: Entry for Croatia to be inserted at a later stage]

Per il Presidente della Repubblica italiana

Για τον Πρόεδρο της Κυπριακής Δημοκρατίας

Latvijas Republikas Valsts prezidentas vārdā

Lietuvos Respublikos Prezidento vardu

Pour Son Altesse Royale le Grand-Duc de Luxembourg

A Magyar Köztársaság Elnöke részéről

Għall-President ta' Malta

Voor Hare Majesteit de Koningin der Nederlanden

Für den Bundespräsidenten der Republik Österreich

Za Prezydenta Rzeczypospolitej Polskiej

Pelo Presidente da República Portuguesa

Pentru Președintele României

Za predsednika Republike Slovenije

Za prezidenta Slovenskej republiky

Suomen Tasavallan Presidentin puolesta

För Republiken Finlands President

För Konungariket Sveriges regering

For Her Majesty the Queen of the United Kingdom of Great Britain and Northern Ireland

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## II. IZJAVE

### [A.] SKUPNA IZJAVA SEDANJIH DRŽAV ČLANIC

#### [1.] Skupna izjava o polni uporabi določb schengenskega pravnega reda

Razume se, da dogovorjeni postopki za prihodnjo polno uporabo vseh določb schengenskega pravnega reda na Hrvaškem, ki bodo navedeni v pogodbi o njenem pristopu k Uniji, ne posegajo v odločitev, ki jo bo Svet sprejel v zvezi s polno uporabo določb schengenskega pravnega reda v Bolgariji in Romuniji, niti nanjo ne vplivajo.

Odločitev Sveta v zvezi s polno uporabo določb schengenskega pravnega reda v Bolgariji in Romuniji se sprejme na podlagi postopka, ki je bil v tej zvezi določen v pogodbi o pristopu Bolgarije in Romunije k EU iz leta 2005, ter v skladu s sklepi Sveta z dne 9. junija 2011 o zaključku postopka evalvacije o pripravljenosti Bolgarije in Romunije na izvajanje vseh določb schengenskega pravnega reda.

Dogovorjeni postopki za prihodnjo polno uporabo vseh določb schengenskega pravnega reda na Hrvaškem, ki bodo vključene v pogodbo o njenem pristopu k Uniji, ne vzpostavljajo pravnih obveznosti v nobenem drugem kontekstu kot v kontekstu hrvaške pristopne pogodbe.

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**[1.] Skupna izjava Zvezne republike Nemčije in Republike Avstrije o prostem gibanju  
delavcev: Hrvaška**

Besedilo točke 12 prehodnih ukrepov o prostem gibanju delavcev iz Direktive 96/71/ES v Prilogi V k Aktu o pristopu si Zvezna republika Nemčija in Republika Avstrija v dogovoru s Komisijo razlagata tako, da lahko, kjer je to primerno, izraz "določene regije" vključuje tudi celotno nacionalno ozemlje.

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## [C.] SKUPNA IZJAVA SEDANJIH DRŽAV ČLANIC IN REPUBLIKE HRVAŠKE

### [1.] Skupna izjava o Evropskem razvojnem skladu

Republika Hrvaška bo pristopila k Evropskemu razvojnemu skladu (ERS) z začetkom veljavnosti novega večletnega finančnega okvira sodelovanja po pristopu k Uniji in bo k temu skladu prispevala od 1. januarja drugega koledarskega leta po datumu pristopa.

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[D.] IZJAVA REPUBLIKE HRVAŠKE

**[1.] Izjava Republike Hrvaške o prehodni ureditvi glede liberalizacije hrvaškega trga kmetijskih zemljišč**

*Ob upoštevanju prehodne ureditve glede nakupa kmetijskih zemljišč v Republiki Hrvaški s strani pravnih in fizičnih oseb iz EU/EGP, kakor jo določa Priloga V Akta o pristopu, in*

*ob upoštevanju določbe o tem, da Komisija na zaprosilo Republike Hrvaške odloči o podaljšanju sedemletnega prehodnega obdobja za dodatna tri leta, če obstajajo zadostni dokazi ta to, da bi po izteku sedemletnega prehodnega obdobja v Republiki Hrvaški prišlo do resnih motenj ali nevarnosti resnih motenj na trgu s kmetijskimi zemljišči,*

Republika Hrvaška izjavlja, da se bo v primeru odobrenega podaljšanja prehodnega obdobja trudila storiti vse potrebno za liberalizacijo nakupa kmetijskih zemljišč na zadevnih območjih še pred iztekom tega triletnega obdobja.

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### **III. IZMENJAVA PISEM**

#### **med Evropsko Unijo in Republiko Hrvaško o postopku obveščanja in posvetovanja za sprejetje nekaterih sklepov in drugih ukrepov v obdobju pred pristopom**

##### *Pismo št. 1*

Spoštovani,

v čast mi je sklicevati se na vprašanje v zvezi s postopkom obveščanja in posvetovanja za sprejetje nekaterih sklepov in drugih ukrepov v obdobju pred pristopom vaše države k Evropski uniji, ki je bilo sproženo v okviru pristopnih pogajanj.

Potrjujem, da Evropska unija lahko pristane na takšen postopek pod pogoji iz priloge k temu pismu; ta postopek bi se v zvezi z Republiko Hrvaško lahko začel uporabljati z datumom, ko pristopna konferenca izjavi, da so pristopna pogajanja dokončno zaključena.

Hvaležen bi vam bil, če bi lahko potrdili, da se vaša vlada strinja z vsebino tega pisma.

S spoštovanjem,

*Pismo št. 2*

Spoštovani,

v čast mi je potrditi prejem vašega pisma, ki se glasi:

"V čast mi je sklicevati se na vprašanje v zvezi s postopkom obveščanja in posvetovanja za sprejetje nekaterih sklepov in drugih ukrepov v obdobju pred pristopom vaše države k Evropski uniji, ki je bilo sproženo v okviru pristopnih pogajanj.

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Hvaležen bi vam bil, če bi lahko potrdili, da se vaša vlada strinja z vsebino tega pisma."

V čast mi je potrditi, da se moja vlada strinja z vsebino tega pisma.

S spoštovanjem,

*PRILOGA*

**Postopek obveščanja in posvetovanja za sprejetje nekaterih sklepov in drugih ukrepov  
v obdobju pred pristopom**

**I.**

1. Da se zagotovi ustrezna obveščenost Republike Hrvaške (v nadaljnjem besedilu: Hrvaška), se ta obvesti o vsakem predlogu, sporočilu, priporočilu ali pobudi, ki naj bi vodila do sprejetja pravnega akta Evropskega parlamenta in Sveta, Sveta ali Evropskega sveta, potem ko je poslana Svetu ali Evropskemu svetu.
2. Posvetovanja se opravijo na obrazloženo zaprosilo Hrvaške, ki v zaprosilu izrecno predstavi svoje interese kot bodoča članica Unije in navede svoje pripombe.
3. Upravne odločitve praviloma niso razlog za posvetovanje.
4. Posvetovanja potekajo v okviru začasnega odbora, ki ga sestavljajo predstavniki Unije in Hrvaške. Razen v primeru obrazloženega ugovora Unije ali Hrvaške lahko posvetovanja potekajo tudi v obliki izmenjave elektronskih sporočil, zlasti na področju skupne zunanje in varnostne politike.
5. Na strani Unije so člani začasnega odbora člani Odbora stalnih predstavnikov ali osebe, ki jih ti določijo v ta namen. Člani Odbora so v ustreznih primerih lahko tudi člani Političnega in varnostnega odbora. Komisija je ustrezno zastopana.
6. Začasnemu odboru pomaga sekretariat, ki je sekretariat konference in se ohrani v ta namen.

7. Posvetovanja se začnejo takoj, ko so v pripravljalnem delu, opravljenem na ravni Unije, za sprejetje aktov, navedenih v točki 1 zgoraj, oblikovane skupne smernice, na podlagi katerih je mogoča smiselna priprava teh posvetovanj.
8. Če po posvetovanjih resnejše težave še vedno niso odpravljene, se lahko zadeva na zaprosilo Hrvaške obravnava na ministrski ravni.
9. Zgornje določbe se smiselno uporabljajo tudi za odločitve sveta guvernerjev Evropske investicijske banke.
10. Postopek, določen v zgornjih odstavkih, se uporablja tudi za vse prihodnje odločitve Hrvaške, ki bi lahko vplivale na obveznosti, ki izhajajo iz njenega položaja bodoče članice Unije.

## II.

11. Unija in Hrvaška s sprejetjem potrebnih ukrepov zagotovita, da pristop Hrvaške k sporazumom ali konvencijam in protokolom iz členov 3(4), 6(2) in 6(5) Akta o pogojih pristopa Republike Hrvaške in o prilagoditvah Pogodb, na katerih temelji Evropska unija (v nadalnjem besedilu: Akt o pristopu), čim bolj sovpada z začetkom veljavnosti Pogodbe o pristopu.
12. V zvezi s pogajanji s sopogodbenicami protokolov iz drugega pododstavka člena 6(2) Akta o pristopu se predstavniki Hrvaške vključijo v delo kot opazovalci, skupaj s predstavniki sedanjih držav članic.

13. Nekateri nepreferencialni sporazumi, ki jih je sklenila Unija in ostanejo v veljavi tudi po dnevu pristopa, se lahko zaradi upoštevanja širitve Unije spremenijo ali prilagodijo. O teh spremembah ali prilagoditvah se bo pogajala Unija skupaj s predstavniki Hrvaške po postopku iz prejšnjega odstavka.

### III.

14. Institucije pravočasno sestavijo besedila iz člena 52 Akta o pristopu. V ta namen Hrvaška institucijam pravočasno zagotovi prevode teh besedil.
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**PRILOGA II**

**SVET  
EVROPSKE UNIJE**

**Bruselj, 13. september (14.09)  
(OR. en)**

**GENERALNI SEKRETARIAT**

**AC 30/11**

**LIMITE**

**KONČNO BESEDILO PRISTOPNE POGODBE, DOGOVORJENO MED EVROPSKO  
UNIJO IN DRŽAVO KANDIDATKO**

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Zadeva: Pristopna pogodba:  
Dodatek k Prilogi V  
Država kandidatka: Hrvaška

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1. Texts in square brackets [ ] are for information. These could include:
  - the reference text in English of the adaptation inserted in the relevant candidate country language, where necessary,
  - data which still needs to be confirmed,
  - reminders for a later date.
2. The draft provisions included in this text are those that are required in relation to the specific *acquis* screened and negotiated under this chapter, within the framework of the list of chapter headings defined by the EU at the beginning of the negotiations with Croatia.

NAME OF THE MEDICINAL PRODUCT	PHARMACEUTICAL FORM	MANUFACTURER	NATURE AND CONTENTS OF CONTAINER	Domestic	Imported	Proprietary	Generic UDMP	nCADREAC	CP	MRP	OTC	Herbal	Immunological	Blood	Orphan
1M potassium-chloride (7.45%) concentrate 50 mL	concentrate for intravenous after reconstitution	Hrvatski zavod za transfuzijsku medicinu, Petra 3, Zagreb, Republic of Croatia	50 mL of solution in a glass injection bottle with a chlorobutyl stopper protected with an aluminium cap (40 bottles per box)	YES			YES								
1M sodium hydrogencarbonate (8.4%) solution for intravenous infusion, 100 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petra 3, Zagreb, Republic of Croatia	100 mL of solution in a glass infusion bottle with rubber stopper protected by Al cap, 20 bottles with plastic holders in a box	YES			YES								
A.T. 10 solution	oral solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	15 mL of solution in an amber glass bottle with plastic dropper attachment, supplied in a box		YES	YES									
Abaktal 400 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 (1x10) tablets in a blister, supplied in a box		YES		YES								
Abaktal 400 mg/5 mL solution for injection	solution for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 ampoules each containing 5 mL of solution, supplied in a box		YES		YES								
Accupro 10 mg tablets	film coated tablets	Gödecke GmbH, dio Pfizer grupe, Karlsruhe, Germany	30 (3x10) tablets in a blister, supplied in a box		YES	YES									
Accupro 20 mg tablets	film coated tablets	Gödecke GmbH, dio Pfizer grupe, Karlsruhe, Germany	31 (3x10) tablets in a blister, supplied in a box		YES	YES									
Accupro 5 mg tablets	film coated tablets	Gödecke GmbH, dio Pfizer grupe, Karlsruhe, Germany	32 (3x10) tablets in a blister, supplied in a box		YES	YES									
Aclasta 5 mg solution for infusion	solution for infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	100 mL solution in a plastic bottle with rubber stopper, aluminium ring and plastic protective cap, 1 bottle in a box		YES	YES			YES						
Act HIB, vaccine against Haemophilus influenzae type B	lyophilisate and diluent for preparation of injection solution	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Bottle with 1 dose of lyophilised vaccine and 1 glass syringe with solvent for preparation for injection (0.5 mL), supplied in a box		YES								YES		
Actilyse lyophilisate for injection 50 mg	lyophilisate and diluent for preparation of solution for injection	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer Strasse 65, Biberach an der Riss, Germany	50 mg of lyophilisate in a bottle, 50 mL of solvent (water for injection) in a bottle and a transfer needle, supplied in a box		YES	YES									
Activelle	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 tablets in a plastic calendar dial pack (dispenser with marked days of the week), supplied in a box		YES	YES									
Actonel 30 mg tablets	film coated tablets	Procter & Gamble Pharmaceuticals Germany GmbH, Weiterstadt, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES									
Actonel 35 mg tablets	film coated tablets	Procter & Gamble Pharmaceuticals Germany GmbH, Weiterstadt, Germany	4 (1x4) tablets in a blister, supplied in a box		YES	YES									
Actonel 5 mg tablets	film coated tablets	Procter & Gamble Pharmaceuticals Germany GmbH, Weiterstadt, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES									

Actrapid HM 100	solution for injection (for s.c., i.m. and i.v. use)	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	10 mL of solution in a glass bottle, supplied in a box		YES	YES						
Actrapid Penfill	solution for subcutaneous injection	Novo Nordisk A/S, Novo Allé, Bagsvaerd, Denmark Novo Nordisk Production SAS, 45, Avenue d' Orleans, Chartres, France	5 glass cartridges with 3 mL of solution in a blister, supplied in a box		YES	YES						
Adartrel 0.25 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	12 (1x12) tablets in a PVC/PCTFE/AI blister, supplied in a box		YES	YES		YES	YES			
Adartrel 0.5 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (2x14) tablets in a PVC/PCTFE/AI blister, supplied in a box		YES	YES		YES	YES			
Adartrel 2 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (2x14) tablets in a PVC/PCTFE/AI blister, supplied in a box		YES	YES		YES	YES			
Adriblastina PFS 10 mg injection (2 mg/mL)	solution for injection	Pfizer Italia S.r.l., Milano, Italy	5 mL of solution for injection in a glass bottle, supplied in a box		YES	YES						
Adriblastina PFS 50 mg injection (2 mg/mL)	solution for injection	Pfizer Italia S.r.l., Milano, Italy	25 mL of solution for injection in a glass bottle, supplied in a box		YES	YES						
Advantan cream	cream	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	15 g of cream in an aluminum tube, supplied in a box		YES	YES						
Advantan ointment	ointment	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	15 g of cream in an aluminum tube, supplied in a box		YES	YES						
Aerius syrup of 0.5 mg/mL	syrup	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	60 mL of syrup in an amber glass bottle and a measuring spoon, supplied in a box		YES	YES						
Aerius 5 mg film coated tablets	film coated tablets	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	10 (1x10) tablets in a blister, supplied in a box		YES	YES						
Afloderm cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 grams of cream in an aluminum tube with a plastic cap, supplied in a box		YES		YES					
Afloderm cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	40 g of cream in an aluminium tube with a plastic stopper, supplied in a box		YES		YES					
Afloderm ointment	ointment	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 grams of ointment in an aluminum tube with a plastic cap, supplied in a box		YES		YES					
Afluria suspension for injection in pre-filled syringe, influenza vaccine (fragmented inactivated)	suspension for injections	CSL Limited, 45 Poplar Road, Parkville, Melbourne, Victoria 3052, Australia	Box with 1 pre-filled syringe (glass, type I) with a needle, with 1 dose of vaccine (0.5 mL of suspension)		YES							YES
Aggrastat concentrate of solution for infusion	concentrate of solution for infusion	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Netherlands	50 mL of solution concentrate in a glass bottle, supplied in a box		YES	YES			YES			
Aggrenox 200/25 mg modified release capsules	modified release capsules, hard	Boehringer Ingelheim Pharma GmbH&Co.KG, Biberach an der Riss, Germany	60 capsules in a white plastic (PP) container with a plastic (PE) temperature-evident stopper with a desiccant, supplied in a box		YES	YES						
Aglurab 1000	film coated tablets	Weifa AS, Oslo, Norway	60 tablets in a plastic (HDPE) bottle with a plastic stopper (there is a bag in a bottle or a capsule in a stopper containing silicagel to attenuate the tablet odor)		YES		YES					

Aglurab 850	film coated tablets	Weifa AS, Oslo, Norway	36 tablets in a plastic (HDPE) bottle with a desiccant		YES	YES						
Agrippal vaccine against influenza (surface antigen, inactivated)	suspension for intramuscular or subcutaneous administration	Chiron S.r.l, Siena, Italy	Pre-filled syringe with a needle (containing a single 0.5-mL vaccine dose in the form of suspension)		YES						YES	
Agrippal suspension for injections in pre-filled syringe, influenza vaccine (surface antigens), inactivated	suspension for injections in a pre-filled syringe	Novartis Vaccines & Diagnostics S.r.l., Siena, Italy	A pre-filled syringe (glass type I) containing 0.5 mL of suspension, equipped with a needle (23G, 1"; or 25G, 1"; or 25G, 5/8"); and a rubber plunger stopper, supplied in a box		YES						YES	
Akineton injection	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg, KG, Mondseestrasse 11, Unterach, Austria	5 ampoules with 1 mL of solution for injection, supplied in a carton box		YES	YES						
Akineton tablets	tablets	Laboratorio Farmaceutico S.I.T. Srl, Via Cavour 70, Mede (PV), Italy	50 tablets (5x10) in a PVC/AI blister, supplied in a box		YES	YES						
Aknet	dermal solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 mL of solution in an amber glass bottle with a dropper and a plastic stopper, supplied in a box	YES		YES						
Aktivin H capsule	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/PVDC/AI blister, supplied in a box	YES					YES	YES		
Aktivin H capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 capsules in a polypropylene bag, supplied in a box	YES					YES	YES		
Alamcin 250 mg/5 mL powder for oral suspension	powder for preparation of oral suspension	Alkaloid AD - Skopje, FYROM in cooperation with BILIM PHARMACEUTICALS A.S., Maslak Istanbul, Turkey	Amber glass bottle with powder for preparation of 100 mL of suspension with a polyethylene stopper and a plastic spoon, supplied in a box		YES	YES						
Albothyl solution	solution	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	25 mL of solution in an amber glass bottle with black plastic cap, supplied in a box		YES	YES						
Albothyl pessaries	pessaries	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	6 pessaries in a white non-transparent plastic foil (PVC/PE), supplied in a box		YES	YES						
Human albumin 20% solution for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 50 mL of solution, supplied in a box	YES							YES	
Human albumin 20% solution for i.v. use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 100 mL of solution, supplied in a box	YES							YES	
Human albumin 20% solution for intravenous use (Albumini humani solutio), 200g/l	solution for infusion	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 50 mL of solution, supplied in a box		YES						YES	
Human albumin 20% solution for intravenous use (Albumini humani solutio), 200g/l blood	solution for infusion	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 100 mL of solution, supplied in a box		YES						YES	
Albumin (human) 5% solution for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	One glass vial with 250 mL of solution, supplied in a box	YES							YES	
Aldactone 100 mg capsules	capsules	Roche Farma S.A., Madrid, Spain	20 (2x10) capsules in PVC/AI blister, supplied in a box		YES	YES						

Aldactone 25 mg coated tablets	coated tablets	Roche Farma S.A., Madrid, Spain	50 (5x10) coated tablets in a PVC/AI blister, supplied in a box		YES	YES						
Aldactone 50 mg coated tablets	coated tablets	Roche Farma S.A., Madrid, Spain	20 (2x10) coated tablets in PVC/AI blister, supplied in a box		YES	YES						
Aldizem 60 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	34 (3x10) tablets in a PVC/AI blister, supplied in a box		YES		YES					
Aldizem 90 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	35 (3x10) tablets in a PVC/AI blister, supplied in a box		YES		YES					
Aldurazyme 100 U/mL concentrate for solution for infusion	concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial with 5 mL of solution concentrate, supplied in a box		YES	YES		YES	YES			YES
Aledox 70 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	4 (1x4) tablets in a PA/AI/PVC//AI blister, supplied in a box	YES		YES						
Alendor 70	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	4 (1x4) tablets in a blister (PVC/PE/PVDC//AI), supplied in a box	YES		YES						
Alendor tablets 5 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister, supplied in a box	YES		YES						
Alendor tablets 10 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister, supplied in a box	YES		YES						
Alfuzosin Pliva tablets 10 mg	film coated tablets with prolonged-release	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	33 (3x10) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Alfuzosin Pliva tablets 5 mg	prolonged-release film-coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	23 (2x10) tablets in a blister (PVC/AI), supplied in a box	YES		YES						
Alimta 500 mg powder for infusion solution concentrate	powder for concentrate for infusion solution	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	Glass bottle, supplied in a box		YES	YES		YES				
Alkagin 2.5 g/5 mL solution for injection	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	50 (5x10) ampoules each with 5 mL of solution in a protective container, supplied in a box		YES		YES					
Alkagin 500 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (1x10) tablets in a PVC/AI blister, supplied in a box		YES		YES					
Almacin 500 mg capsules	capsules	Alkaloid AD - Skopje, Skopje, FYROM in cooperation with BILIM PHARMACEUTICALS A.S., Maslak Istanbul, Turkey	16 capsules in a A/PVC blister, supplied in a box		YES		YES					
Alomax 2% dermal solution	dermal solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 mL of solution in a white plastic bottle with a plastic stopper, a metering plastic pump and a spray attachment, in a protective bag, supplied in a box	YES		YES			YES			
Alomax 5% dermal solution	dermal solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 mL of solution in a white plastic bottle with a plastic stopper, a metering plastic pump and a spray attachment, in a protective bag, supplied in a box	YES		YES			YES			

Alomide 1 mg/mL eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of solution in a plastic bottle with a dropper, supplied in a carton box		YES	YES						
Alopurinol 100 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 tablets in a plastic bottle, supplied in a box	YES			YES					
Aloxi, solution for injection	solution for injection	Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Republic of Ireland	One glass vial with 5 mL of solution, supplied in a box		YES	YES			YES			
Alphagan eye drops	eye drops	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	5 mL of solution in a plastic bottle with a dropper, supplied in a box		YES	YES						
Alvesco 160 Inhaler	pressurized inhalant, solution	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	AI container with a metering valve, mouthpiece and stopper, 60 inhalations		YES	YES			YES			
Alvesco 40 Inhaler	pressurized inhalant, solution	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	AI container with a metering valve, mouthpiece and stopper, 60 inhalations		YES	YES			YES			
Alvesco 80 Inhaler	pressurized inhalant, solution	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	AI container with a metering valve, mouthpiece and stopper, 60 inhalations		YES	YES			YES			
Amaryl 1.0	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	30 (2x15) tablets in a blister, supplied in a box		YES	YES						
Amaryl 2.0	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	30 (2x15) tablets in a blister, supplied in a box		YES	YES						
Amaryl 3.0	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	30 (2x15) tablets in a blister, supplied in a box		YES	YES						
Amicor 10	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	41 (3x10) tablets in a PVC/AI blister, supplied in a box	YES			YES					
Amicor 20	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	42 (3x10) tablets in a PVC/AI blister, supplied in a box	YES			YES					
Amicor 5	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (1x20) tablets in a PVC/AI blister, supplied in a box	YES			YES					
Amicor H 10	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (1x20) tablets in a PVC/AI blister, supplied in a box	YES			YES					
Amicor H 10	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	43 (3x10) tablets in a PVC/AI blister, supplied in a box	YES			YES					
Amicor H 20	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	44 (3x10) tablets in a PVC/AI blister, supplied in a box	YES			YES					
Aminfluorid dental gel	dental gel	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Tube with 25 g of gel, supplied in a box	YES			YES			YES		
Aminfluorid dental solution	dental solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 mL of solution in a polyethylene bag with a dropper and a screw cap, supplied in a box	YES			YES			YES		

Aminomix 2 Novum	solution for infusion (for parenteral nutrition)	Fresenius Kabi Deutschland GmbH, Bad Homburg, Germany	One plastic bag with two compartments (for solutions A and B), peel seam and two attachments connected to the compartments (with solutions for drug delivery and infusion) in an external protective bag inserted with bag with agent	YES	YES							
Aminomix 2 Novum	solution for infusion (for parenteral nutrition)	Fresenius Kabi Deutschland GmbH, Bad Homburg, Germany	One plastic bag with two compartments (for solutions A and B), peel seam and two attachments connected to the compartments (with solutions for drug delivery and infusion) in an external protective bag inserted with bag with agent	YES	YES							
Aminophyllin Lek 100 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) tablets in a blister (PVC/AI), supplied in a carton box	YES	YES							
Aminophyllin Lek 250 mg/10 mL solution for injection	solution for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) ampoules with 10 mL of solution for injection, supplied in a box	YES	YES							
Aminophyllin Lek 350 mg prolonged-release tablets	prolonged-release tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister (PVC/AI), supplied in a carton box	YES	YES							
Aminoplasmal - 10% E	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a glass bottle, 10 bottles in a box	YES	YES							
Aminoplasmal - 5% E	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a glass bottle, 10 bottles in a box	YES	YES							
Aminoplasmal Hepa - 10%	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a glass bottle, 10 bottles in a box	YES	YES							
Aminoven 10%	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	One glass bottle for infusion with 500 mL of solution	YES	YES		YES					
Aminoven 5%	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	One glass bottle for infusion with 500 mL of solution	YES	YES		YES					
Aminoven Infant 10%	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass infusion bottles with 100 mL of solution, supplied in a carton box	YES	YES							
Aminoven Infant 10%	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass infusion bottles with 250 mL of solution, supplied in a carton box	YES	YES							
Amiodaron 200 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Box with 30 (2x15) tablets in a blister	YES	YES							
AmLodipin Cipla 10 mg	tablets	Cipla Ltd., Verna Industrial Estate, Verna Goa, India	30 (3x10) tablets in a brown PVC/AI blister, supplied in a box	YES	YES							
AmLodipin Cipla 5 mg	tablets	Cipla Ltd., Verna Industrial Estate, Verna Goa, India	30 (3x10) tablets in a brown PVC/AI blister, supplied in a box	YES	YES							
AmLopin 10 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box	YES	YES							

AmLopin 5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
AmLopin 5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES	YES						
Amoksicilin 375 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	12 capsules in a bottle, supplied in a box	YES		YES						
Amoksicilin 500 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	16 capsules in a blister, supplied in a box	YES		YES						
Amoksicilin powder for oral suspension 250 mg/5 mL	powder for oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Bottle with powder for preparation of 100 mL of suspension, supplied in a box	YES		YES						
Amonex 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES		YES						
Amonex 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES		YES						
Amoxil capsules 500 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	16 (2x8) tablets in a blister, supplied in a box	YES		YES						
Amoxil syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Amber glass bottle with powder, supplied in a box	YES		YES						
Amphocil 100 mg	powder for preparation of solution for infusion	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	Turbid glass bottle (with 100 mg of dry matter) with a cap and Al ring, supplied in a box		YES	YES						
Amphocil 50 mg	powder for preparation of solution for infusion	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	Turbid glass bottle (with 50 mg of dry matter) with a cap and Al ring, supplied in a box		YES	YES						
Amphotericin B, powder for preparation of injections	powder for preparation of injections	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	One glass vial with powder for injection preparation, supplied in a box	YES		YES						
Ampril HD tablets 5 mg/25 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES	YES	YES	YES	YES			
Ampril HL tablets 2.5 mg/12.5 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES	YES	YES	YES	YES			
Ampril 1.25 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	33 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES	YES	YES	YES	YES			
Ampril 10 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	34 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES	YES	YES	YES	YES			
Ampril 2.5 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	35 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES	YES	YES	YES	YES			
Ampril 5 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	36 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES	YES	YES	YES	YES			
Amyzol 10 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	100 (4X25) tablets in a blister, supplied in a box		YES	YES						

Amyzol 25 mg film coated tablets	film coated tablets	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3X10) tablets in a blister, supplied in a box		YES		YES					
ANAFRANIL coated tablets	coated tablets	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Novartis Pharma Services Inc., Basel, Switzerland	31 (3x10) coated tablets in a PVC/AI blister, supplied in a box	YES			YES					
Analgin injections	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 mL of solution for injection in an amber glass ampoule, 50 ampoules in a box	YES			YES					
Analgin tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in an orange blister (PVC/AI), supplied in a box	YES			YES					
Andol	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	23 (2x10 tablets in AI/PVC/PVDC blister, supplied in a box	YES			YES			YES		
Andol 100	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	24 (2x10 tablets in AI/PVC/PVDC blister, supplied in a box	YES			YES			YES		
Andol C	effervescent tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 tablets in a vial (cap with silicagel and protective ring)	YES			YES					
Androcur-10 tablets	tablets	Schering GmbH und Co. Produktions KG, Doeberinerstrasse 20, Weimar, Germany	45 (3x15) tablets in a blister, supplied in a box		YES	YES						
Androcur-50 tablets	tablets	Delpharm Lille S.A.S., Z.I. De Roubaix Est, Rue de Toufflers, Lys Lez Lannoy, France	50 (5x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Androgel 50 mg, gel in bags	gel	Besins International Belgique, Drogenbos, Belgium	5 g of gel in a bag (PET/AI/PE), 30 bags in a carton box		YES	YES			YES			
Anexate	solution for injection or infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 mL of solution in a glass ampoule, 10 ampoules in a box		YES	YES						
Angal lozenges	lozenges	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) lozenges in PVC/AI blister, supplied in a box		YES		YES			YES		
Angal S oral spray	oromucosal spray	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 mL of solution in an amber glass bottle with a screw cap and automatic sprayer/spraying attachment, supplied in a box		YES		YES			YES		
Angeliq film tablets	film coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	aluminum		YES	YES			YES			
Ansilan 10 mg capsules	capsules	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	25 capsules in a glass bottle, supplied in a box		YES		YES					
Ansilan mite 5 mg capsules	capsules	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3x10) capsules in a PVC/AI blister, supplied in a box		YES		YES					
Antithrombin III Immuno 1000 IU	Iyophilized powder and diluent for preparation of solution for injection or infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Vial with 1000 IU antithrombin III, vial with diluent, portable needle, filter needle, vent needle, disposable needle, infusion kit, disposable syringe, supplied in a box		YES							YES
Antithrombin III Immuno 500 IU	Iyophilized powder or diluent for preparation of solution for injection or infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Vial with 500 IU antithrombin III, vial with diluent, portable needle, filter needle, vent needle, disposable		YES							YES

			needle, infusion kit, disposable syringe, supplied in a box									
Antitoxin (equine) against European viper venom	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 bottle containing 10 mL of preparation (1 dose), with a sterile needle and a disposable syringe	YES							YES	
Apidra 100 IU/mL (10 mL glass vial)	solution for injection (for s.c. use)	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	One glass vial with 10 mL of solution, supplied in a box		YES	YES			YES			
Apidra 100 IU/mL (3mL glass cartridge for use with OptiClik injector)	solution for subcutaneous injection	Sanofi - Aventis Deutschland GmbH, Frankfurt am Main, Germany	5 glass cartridges (for OptiClik) with 3 mL of solution, supplied in a box		YES	YES			YES			
Apidra 100 IU/mL (3.0 mL glass cartridge)	solution for subcutaneous injection	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	5 glass cartridges with 3 mL of solution, supplied in a box		YES	YES			YES			
Apidra 100 IU/mL OptiSet (injector with glass cartridge of 3 mL)	solution for subcutaneous injection	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	5 pens (injectors) with a glass cartridge containing 3 mL of solution, supplied in a box		YES	YES			YES			
Aprovel 150 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	28 (2x14) tablets in a blister (PC/PVDC/AI), supplied in a box		YES	YES			YES			
Aprovel 300 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	28 (2x14) tablets in a blister (PC/PVDC/AI), supplied in a box		YES	YES			YES			
Aprovel 75 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	28 (2x14) tablets in a blister (PC/PVDC/AI), supplied in a box		YES	YES			YES			
Aqua pro injectione	diluent for preparation of parenteral solutions	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of water for injection in a glass infusion bottle	YES			YES					
Aqua pro injectione	solvent for preparation of parenteral solutions	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	1000 mL of Water for Injection in a glass infusion bottle	YES			YES					
Aqua pro injectione	solvent for preparation of parenteral solutions	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of Water for Injection in a glass infusion bottle	YES			YES					
Aranesp 10 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.4 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 100 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.5 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 100 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.5 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 15 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.375 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 150 mcg solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.3 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 150 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.3 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			

Aranesp 20 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.5 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 20 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.5 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 30 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.3 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 300 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.6 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 300 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.6 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 40 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.4 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 40 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.4 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 50 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.5 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 500 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 1.0 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 500 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 1.0 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 60 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.3 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 60 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.3 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 80 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.4 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES			
Aranesp 80 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.4 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES			
Arava 10 mg tablets	film coated tablets	Aventis Intercontinental, Route de Choisy au Bac, Compiegne, Cedex, France	Box with 30 tablets in a plastic bottle		YES	YES						

Arava 100 mg tablets	film coated tablets	Aventis Intercontinental, Route de Choisy au Bac, Compiegne, Cedex, France	3 tablets in an aluminum blister, supplied in a box		YES	YES						
Arava 20 mg tablets	film coated tablets	Aventis Intercontinental, Route de Choisy au Bac, Compiegne, Cedex, France	Box with 30 tablets in a plastic bottle		YES	YES						
Arcoxia 120 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	7 (1x7) film coated tablets in an Al/Al blister, supplied in a box		YES	YES		YES	YES			
Arcoxia 60 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	14 (2x7) film coated tablets in a A/AI blister, supplied in a box		YES	YES		YES	YES			
Arcoxia 90 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	14 (2x7) film coated tablets in a A/AI blister, supplied in a box		YES	YES		YES	YES			
Aredia 15 mg	powder and diluent for solution for infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	4 colourless glass bottles with powder and 4 ampoules with 5 mL of solvent (water for injection), supplied in a box		YES	YES						
Aredia 30 mg	powder and diluent for solution for infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	2 clear glass bottles containing powder and 2 ampoules with 10 mL of diluent (Water for Injection), supplied in a box		YES	YES						
Arfincin 150 mg capsules	capsules	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 capsules in a brown plastic bottle, supplied in a box	YES		YES						
Arfincin 150 mg capsules	capsules	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Plastic bottle with 100 capsules, supplied in a box	YES		YES						
Arfincin 300 mg capsules	capsules	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	16 capsules in a white plastic bottle, supplied in a box	YES		YES						
Arilin rapid	pessaries	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	2 pessaries in an Al/AI strip, supplied in a box		YES	YES						
Arimidex	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	28 (2x14) tablets in a blister (PVC/al), supplied in a box		YES	YES						
Arixtra 2.5 mg/0.5 mL solution for injection (pre-filled syringe)	solution for s.c. and i.v. Injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	10 glass syringes with 0.5 mL of solution, supplied in a box		YES	YES		YES	YES			
Arixtra 7.5 mg/0.6 mL solution for injection (pre-filled syringe)	solution for s.c. and i.v. Injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	10 pre-filled glass syringes with 0.6 mL of solution, supplied in a box		YES	YES		YES	YES			
Artein 20 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	21 (2x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Arvind 100 mg tablets	tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x10) tablets in a blister, supplied in a box	YES		YES						
Arvind 200 mg tablets	tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x10) tablets in a blister, supplied in a box	YES		YES						
Arvind 25 mg tablets	tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x10) tablets in a blister, supplied in a box	YES		YES						

Arvind 50 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x10) tablets in a blister, supplied in a box	YES		YES					
Asacol 400 mg gastric-resistant tablets	gastric-resistant tablets	Lek farmaceutska družba d.d., Ljubljana, Republic of Slovenia in cooperation with Tillotts Pharma AG, Ziefen, Switzerland	100 (10x10) gastro-resistant tablets PVC/AI blisters, supplied in a box	YES		YES					
Asacol 800 mg gastric-resistant tablets	gastric-resistant tablets	Lek farmaceutska družba d.d., Ljubljana, Republic of Slovenia in cooperation with Tillotts Pharma AG, Ziefen, Switzerland	50 (5x10) gastro-resistant tablets in a PVC/AI blister, supplied in a box	YES		YES					
Asentra 100 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister, supplied in a box	YES		YES					
Asentra 50 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister, supplied in a box	YES		YES					
Aspirin 100 mg tablets	tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 (2x10) tablets in a blister, supplied in a box	YES		YES		YES			
Aspirin 500 mg tablets	tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 (2x10) tablets in a blister, supplied in a box	YES		YES		YES			
Aspirin direct	chewing tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	10 (5x2) tablets in a strip, supplied in a box	YES		YES		YES			
Aspirin plus C	effervescent tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	10 (5x2) effervescent tablets in a strip, supplied in a box	YES		YES		YES			
Aspirin protect 100 mg gastric-resistant tablets	gastric-resistant tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 (3x10) tablets in a blister, supplied in a box	YES		YES					
Aspirin protect 300 mg gastric-resistant tablets	gastric-resistant tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 (3x10) tablets in a blister, supplied in a box	YES		YES					
Astax tablets 10 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/TE/PVDC/AI) blister, supplied in a box	YES		YES					
Astax tablets 20 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/TE/PVDC/AI) blister, supplied in a box	YES		YES					
Astax tablets 40 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/TE/PVDC/AI) blister, supplied in a box	YES		YES					
Atacand 16 mg tablets	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umeå, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//AI), supplied in a box	YES	YES			YES			
Atacand 32 mg tablets	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umeå, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//AI), supplied in a box	YES	YES			YES			
Atacand 4 mg tablets	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umeå, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//AI), supplied in a box	YES	YES			YES			
Atacand 8 mg tablets	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umeå, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//AI), supplied in a box	YES	YES			YES			

Atacand Plus	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umeå, Sweden and AstraZeneca GmbH, Frankfurt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES			YES			
ATenativ 1000 IU	lyophilisate and diluent for intravenous solution	Octapharma AB, Stockholm, Sweden	Glass bottle with 50 mL of lyophilisate and a bottle with 20 mL of solvent		YES							YES
ATenativ 1500 IU	lyophilisate and diluent for intravenous solution	Octapharma AB, Stockholm, Sweden	Glass bottle with 100 mL of lyophilisate and a bottle with 30 mL of solvent		YES							YES
ATenativ 500 IU	lyophilisate and diluent for intravenous solution	Octapharma AB, Stockholm, Sweden	Glass bottle with 50 mL of lyophilisate and a bottle with 10 mL of solvent		YES							YES
Atenolol Pliva 100 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES			YES					
Atenolol Pliva 50 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/PVdC/A1 blister, supplied in a box	YES			YES					
ATG-Fresenius	concentrate for infusion solution	Fresenius Biotech GmbH, Am Haag 6-7, Gräfelfing, Germany	One glass bottle with 5 mL of concentrate, supplied in a box		YES							YES
Athyrazol	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	34 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES					
Atoris tablets 10 mg	film coated tablets	Krka, d.d., Novo mesto, Republic of Slovenia ili Krka-Farma d.o.o., Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box	YES			YES					
Atoris 10 mg tablets	film coated tablets	Krka d.d., Novo Mesto, Republic of Slovenia; Krka Farma d.o.o., DPC Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES					
Atoris 20 mg tablets	film coated tablets	Krka d.d., Novo Mesto, Republic of Slovenia; Krka Farma d.o.o., DPC Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES					
Atoris tablets 20 mg	film coated tablets	Krka, d.d., Novo mesto, Republic of Slovenia ili Krka-Farma d.o.o., Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box	YES			YES					
Atoris tablets 40 mg	film coated tablets	Krka d.d., Novo mesto, Republic of Slovenia or KRKA - FARMA d.o.o., DPC Jastrebarsko, Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister (OPA/Al/PVC-Al), supplied in a box	YES			YES					
Atorvox tablets 10 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film coated tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES					
Atorvox tablets 20 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film coated tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES					
Atorvox tablets 40 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	31 (3x10) film coated tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES					
Atropini sulfas 0.5 mg/mL injection	solution for s.c., i.m. and i.v. Injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 colourless glass ampoules each with 1 mL of solution, supplied in a box	YES			YES					

Atropini sulfas 1 mg/mL injection	solution for s.c., i.m. and i.v. Injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 colourless glass ampoules each with 1 mL of solution, supplied in a box	YES			YES					
Atrovent 0.025% inhalation solution	inhalation solution	Instituto de Angeli S.r.l., Regello (Firenza), Italy	20 mL of solution in an amber glass bottle with a plastic (PE) dropper and a plastic (PP) cap, supplied in a box		YES	YES						
Atrovent N inhalation aerosol	aerosol	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	200 inhalation doses in a metal container with metering valve and plastic mouthpiece, supplied in a box		YES	YES						
Augmentin injection 1.2 g	powder for solution for injection or infusion	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	5 glass bottles each with a dose of drug, supplied in a box		YES	YES						
Augmentin injection 2.2 g	powder for solution for injection or infusion	SmithKline Beecham S.A., Heppignies, Belgium	One glass vial containing one dose of medicinal product, supplied in a box		YES	YES						
Augmentin syrup 457mg/5 mL	powder for preparation of oral suspension	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	Powder for preparation of 70 mL of suspension (by the addition of 64 mL of water) in a glass bottle (with aluminium stopper), supplied in a box		YES	YES						
Augmentin tablets 1 g	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	14 (2x7) film coated tablets in a PVC/PVDC//Al blister inserted in a protective aluminum bags (with desiccant), supplied in a box		YES	YES						
Aulin 100 mg granules	granules	Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Republic of Ireland	6 bags each with 2 g of granules for preparation of oral suspension, supplied in a box		YES	YES						
Aulin 100 mg tablets	tablets	Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Republic of Ireland	6 (1x6) tablets in a blister (white non-transparent PVC/Al), supplied in a box		YES	YES						
Auropan film coated tablets 3 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 film coated tablets in an amber glass bottle, supplied in a box		YES		YES					
Aurorix	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	38 (3x10) tablets in a PVC/Al blister, supplied in a box		YES	YES						
Avandamet 2 mg/1000 mg tablets	film coated tablets	GlaxoWellcome S.A., Avenida de Extremadura 3, 9400 Aranda de Duero, Burgos, Spain	56 (4x14) film coated tablets in a PVC/PVDC//Al blister, supplied in a carton box		YES	YES		YES	YES			
Avandamet 4 mg/1000 mg tablets	film coated tablets	GlaxoWellcome S.A., Avenida de Extremadura 3, 9400 Aranda de Duero, Burgos, Spain	56 (4x14) film coated tablets in a PVC/PVDC//Al blister, supplied in a carton box		YES	YES		YES	YES			
Avandia 2 mg film-tablets	film coated tablets	Glaxo Wellcome Production, Mayenne, France	56 (4x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
Avandia 4 mg film-tablets	film coated tablets	Glaxo Wellcome Production, Mayenne, France	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
Avandia 8 mg film-tablets	film coated tablets	Glaxo Wellcome Production, Mayenne, France	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
Avastin 25 mg/mL concentrate for infusion solution	concentrate of solution for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	16 mL of infusion solution concentrate in a glass bottle, supplied in a box		YES	YES		YES	YES			
Avastin 25 mg/mL concentrate for infusion solution	concentrate for infusion solution	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	4 mL of concentrate for solution for infusion in a glass bottle, supplied in a box		YES	YES		YES	YES			

Avelox 400 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	5 (1x5) film coated tablets in a blister (PP/AI), supplied in a box		YES	YES			YES		
Avelox 400 mg/250 mL solution for infusion	solution for infusion	Bayer HealthCare AG, 51368 Leverkusen, Germany	One glass bottle with 250 mL of infusion solution, supplied in a box		YES	YES					
AVODART 0.5 mg soft capsules	soft capsules	RP Scherer S.A., Beinheim, France (for GlaxoSmithKline)	30 (3x10) capsules in a blister (PVC/PVdC/AI), supplied in a box		YES	YES			YES		
AVONEX 30 µg powder and diluent for injection	powder and diluent for solution for injection	BIOGEN Idec BV, 2132 WX Hoofddorp, the Netherlands	Box with 4 bottles with BIO SET reconstitution kit, 4 syringes with solvent and 4 needles (BIO SET kit)		YES	YES			YES		
Azilect 1 mg tablets	tablets	Teva Pharmaceuticals Europe B.V., the Netherlands	7 (1x7) tablets in a blister (AI/AI), supplied in a box		YES	YES		YES	YES		
Azilect 1 mg tablets	tablets	Teva Pharmaceuticals Europe B.V., the Netherlands	30 tablets in a plastic (HDPE) bottle (desiccant in a plastic PP stopper), supplied in a box		YES	YES		YES	YES		
AZIMED capsules 250 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 (1x6) capsules in a PVC/PVDC/AI blister, supplied in a box	YES			YES				
AZIMED tablets 500 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	3 (1x3) tablets in a PVC/AI blister, supplied in a box	YES			YES				
Azitromicin Lek 250 mg film coated tablets	film coated tablets	Sandoz S.R.L., TG. Mures, Mures District, Rumunjska	6 (1x6) film coated tablets in a blister (PVC/PVDC/AI), supplied in a box		YES		YES				
Azitromicin Lek 500 mg film coated tablets	film coated tablets	Sandoz S.R.L., TG. Mures, Mures District, Rumunjska	3 (1x3) film-coated tablets in a blister (PVC/PVDC/AI), supplied in a box		YES		YES				
Azopt eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	Box with 5 mL of suspension in a plastic bottle with a dropper		YES	YES					
Baclofen 10 mg	tablets	Polpharma S.A., Poland	50 tablets in a polypropylene bottle, supplied in a box		YES		YES				
Baclofen 25 mg	tablets	Polpharma S.A., Poland	50 tablets in a polypropylene bottle, supplied in a box		YES		YES				
Balance 1.5 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES		YES		
Balance 1.5 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES		YES		
Balance 1.5% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES		YES		
Balance 1.5% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES		YES		

Balance 2.3 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES	YES		YES			
Balance 2.3 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES	YES		YES			
Balance 2.3% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES	YES		YES			
Balance 2.3% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES	YES		YES			
Balance 4.25 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES	YES		YES			
Balance 4.25 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES	YES		YES			
Balance 4.25% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES	YES		YES			
Balance 4.25% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES	YES		YES			
Baralgin M	film tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	20 (2x10) tablets in a blister, supplied in a box		YES	YES					
Bazetham capsules 0.4 mg	modified release capsules, hard	Piiva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) capsules in an orange blister (PVC/PE/PVDC/AI), supplied in a box	YES		YES					
BCG VACCINE SSI, vaccine against tuberculosis - BCG SSI, 0.75 mg	lyophilisate and solvent for preparation of suspension for injection	Statens Serum Institut, Artillerivej, Copenhagen S, Denmark	Box with 10 glass bottles each with 10 doses of lyophilised vaccine (0.75 mg) and a box with 10 glass bottles each with 1 mL of solvent Sauton SSI		YES					YES	
BCG VACCINE SSI, tuberculosis vaccine - BCG SSI, 1.5 mg	lyophilisate and solvent for preparation of suspension for injection	Statens Serum Institut, Artillerivej, Copenhagen S, Denmark	Box with 10 glass bottles each containing 20 doses of lyophilised vaccine (1.5 mg) and a box with 10 glass bottles each containing 2 mL of solvent Sauton SSI		YES					YES	
B-COMPLEX granules	granules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	70 g of granules in a (PEPT/AI/PE) bag		YES	YES		YES			
B-COMPLEX coated tablets	coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (2x15) capsules in a PVC- AI blister, supplied in a box		YES	YES		YES			

Bekunis herbal tea	herbal tea	Roha Arzneimittel GmbH, Bremen, Germany	80 g of tea in a round carton box closed with aluminium foil and a plastic lid		YES				YES	YES		
Bekunis coated tablets	coated tablets	Roha Arzneimittel GmbH, Bremen, Germany	45 coated tablets in a plastic tube with a plastic stopper, supplied in a box		YES				YES	YES		
Belara	film coated tablets	Grünenthal GmbH, Stolberg, Germany	21 (1x21) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES			YES			
Bellune 35	coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	63 (3x21) tablets in a transparent blister (PVC/Al) calendar dial pack, supplied in a box	YES		YES						
Beloderm cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 g of cream in a tube, supplied in a box	YES			YES					
Beloderm ointment	ointment	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 g of cream in a tube, supplied in a box	YES			YES					
Belodin	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Box with 7 tablets (blister)	YES			YES					
Belodin 10mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Box with 10 tablets (blister)	YES			YES					
Belogent cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 g of cream in a tube, supplied in a box	YES			YES					
Belogent ointment	ointment	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 g of cream in a tube, supplied in a box	YES			YES					
Belomet 200 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a blister, supplied in a box	YES			YES			YES		
Belomet 200 mg/2 mL injection	solution for injection for intramuscular and intravenous use	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) ampoules each containing 2 mL of solution for injection, supplied in a box	YES			YES					
Belosalic lotion	lotion	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 mL of lotion in a plastic bottle, supplied in a box	YES			YES					
Belosalic ointment	ointment	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 g of ointment in a tube, supplied in a box	YES			YES					
Belozept solution	oromucosal solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	200 mL of solution in an amber glass bottle with aluminum cap and a 10 mL graduated plastic cup, supplied in a box	YES			YES			YES		
Benil 0.5 % nasal drops	nasal drops	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10-mL of solution in a glass bottle with plastic dropper attachment, supplied in a box		YES		YES			YES		
Benil nasal drops 1.0 %	nasal drops	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10-mL of solution in a glass bottle with plastic dropper attachment, supplied in a box		YES		YES			YES		
Benzyl benzoate, Jadran	skin emulsion	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	150 mL of emulsion in an amber glass bottle with a plastic cap, supplied in a box	YES			YES					

Beriate P 500	lyophilized preparation and diluent	Aventis Boehringer GmbH, Emil-von-Behring Strasse 76, Marburg, Germany	Bottle with a lyophilized drug and a bottle with water for injection in a carton box also containing a leaflet, dissolution kit, and a filter needle		YES							YES
Betadine 1 % solution	gargling solution	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	100 mL of solution in a brown plastic bottle, supplied in a box		YES		YES		YES			
Betadine 10 % ointment	ointment	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	20 grams of cream in an aluminum tube, supplied in a box		YES		YES					
Betadine 10 % solution	solution	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	100 mL of solution in a brown plastic bottle, supplied in a box		YES		YES		YES			
Betadine 200 mg pessaries	pessaries	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	14 (2x7) pessaries in a PVC/PE foil, supplied in a box		YES		YES					
Betadine 7.5 % solution	solution for cleansing and disinfection of skin	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	1000 mL of solution in a white polyethylene bottle		YES		YES		YES			
Betaferon	lyophilisate and diluent for preparation of solution for injection	Boehringer Ingelheim Pharma KG, Biberach an der Riss, Germany and Chiron Corporation, Emeryville, US for Schering AG, Berlin, Germany	15 3-mL bottles with lyophilisate and 15 3-mL bottles with 2 mL of diluent		YES	YES			YES			
Betaferon injection	lyophilisate and diluent for preparation of solution for injection	Boehringer Ingelheim Pharma KG, Biberach, Germany and Chiron Corporation, Emeryville, US for Schering AG, Berlin, Germany	15 lyophilisate bottles and 15 syringes with 1.2 mL of diluent (0.54% sodium chloride solution)		YES	YES			YES			
Betaglid 1 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	32 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box	YES		YES						
Betaglid 2 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	33 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box	YES		YES						
Betaglid 3 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	34 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box	YES		YES						
Betaklav duo tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (5x2) tablets in a AL/PE//AL strip, supplied in a box		YES		YES					
Betaklav powder for solution for infusion 2.2	powder for solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100-mL glass bottle containing 2.2 g of powder for solution for infusion, supplied in a box		YES		YES					
Betaklav powder for solution for injection 1.2	powder for solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20-mL glass bottle containing 1.2 g of powder for solution for injection, supplied in a box		YES		YES					
Betaserc 16 mg	tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands i Solvay Pharmaceuticals, Lieu dit Maillard, Chatillon sur Chalaronne, France	60 (3x20) tablets in a PVC/PVdC/Al blister, supplied in a box		YES	YES						
Betaserc 24 mg	tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands i Solvay Pharmaceuticals, Lieu dit Maillard, Chatillon sur Chalaronne, France	20 (1x20) tablets in a PVC/PVdC blister, supplied in a box		YES	YES						

Betaserc 8 mg	tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands i Solvay Pharmaceuticals, Lieu dit Maillard, Chatillon sur Chalaronne, France	100 (4x25) tablets in a PVC/PVDC/AI blister, supplied in a box		YES	YES						
Betazon cream	cream	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of cream in an aluminium tube, supplied in a box	YES		YES						
Betazon ointment	ointment	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of cream in an aluminium tube, supplied in a box	YES		YES						
Betoptic 0.5 % eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of solution in a plastic bottle, supplied in a box		YES	YES						
Betrion	ointment	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Aluminium tube	YES		YES						
BiCNU injection 100 mg	powder and diluent for preparation of solution for infusion	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	Vial with powder and vial with 3 mL of diluent, supplied in a box		YES	YES						
Bilobil forte capsules 80 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) capsules in a blister (PVC-AI), supplied in a box		YES				YES	YES		
Bilobil capsules	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) capsules in a blister, supplied in a box		YES				YES	YES		
Bisobel 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-AI), supplied in a box	YES		YES						
Bisobel 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-AI), supplied in a box	YES		YES						
Bisolex F tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in an orange blister (PVC/AI), supplied in a box	YES		YES			YES			
Bisolex solution	oral drops, solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 mL of solution in an amber glass bottle with a dropper and a plastic 6 mL measuring cup, supplied in a box	YES		YES			YES			
Bisolex syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of solution in an amber glass bottle with an aluminum cap and a 5 mL plastic measuring spoon, supplied in a box	YES		YES			YES			
Bisolex tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in an orange blister (PVC/AI), supplied in a box	YES		YES			YES			
Bisolvon 2 mg/mL solution	oral and inhalation solution	Instituto de Angeli, Regello (FI), Italy	40 mL of solution in an amber glass bottle with a plastic dropper and a measuring graduated (1-6 mL) cup, supplied in a box		YES	YES			YES			
Bisolvon syrup 4 mg/5 mL	syrup	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	250-mL of syrup in an amber glass bottle, a plastic dispenser glass with 2.5 and 5 mL printed graduation lines or plastic dispenser spoon with 2.5 and 5 mL graduation marks, supplied in a box		YES	YES			YES			

Bisolvon 8 mg tablets	tablets	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	20 (2x10) tablets in a white blister (PVC/PVDC//AI), supplied in a box		YES		YES		YES		
Bisopromerck 10	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	30 (3x10) tablets in a PVC/AI blister, supplied in a box		YES		YES				
Bisopromerck 5	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	30 (3x10) tablets in a PVC/AI blister, supplied in a box		YES		YES				
Bivacyn eye and nasal drops	eye and nasal drops	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	One amber glass bottle with powder, one glass bottle with 10 ml of diluent, and a plastic dropper attachment (in a protective package), supplied in a box		YES		YES				
Bivacyn ointment	ointment	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 g of ointment in an aluminium tube, supplied in a box		YES		YES				
Bivacyn eye ointment	eye ointment	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	3.5 g of ointment in an aluminum tube, supplied in a box		YES		YES				
Bivacyn dermal powder	dermal powder	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	5 g of powder in a plastic bottle, supplied in a box		YES		YES				
Bivacyn dermatological spray, powder	dermatological spray, powder	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	150 mL of spray (in a Powder form) in an aluminum container with nebulizer, supplied in a box		YES		YES				
BLEOCIN - S	powder for solution for injection	Euro Nippon Kayaku GmbH, Frankfurt am Main, Germany	10-mL clear glass bottle containing powder, supplied in a box		YES	YES					
Bloxan 100 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
Bondronat 2 mg concentrate for solution for infusion	concentrate for infusion solution	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim, Germany	One glass vial with 2-mL of concentrate, supplied in a box		YES	YES		YES	YES		
Bondronat 50 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	28 (4x7) tablets in a blister (A1/AI), supplied in a box		YES	YES		YES	YES		
Bondronat 6 mg concentrate for solution for infusion	concentrate for solution for infusion	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim, Germany	One glass vial with 6 mL of concentrate, supplied in a box		YES	YES		YES	YES		
Bonefos 400 mg capsules	capsules	Schering Oy, Turku, Finland	100 capsules in a plastic (HDPE) bottle, supplied in a box		YES	YES					
Bonefos 60 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Schering Oy, Turku, Finland	5 glass ampoules with 5 mL of solution concentrate, supplied in a box		YES	YES					
Bonefos 60 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Schering Oy, Turku, Finland	5 glass ampoules with 5 mL of solution concentrate, supplied in a box		YES	YES					
Bonefos 800 mg tablets	film coated tablets	Schering Oy, Turku, Finland	60 tablets in a PVC/AI blister, supplied in a box		YES	YES					
Bonna 35 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	4 (1x4) tablets in a blister (PVC/PE/PVDC//AI), supplied in a box	YES		YES					

Bonna 5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (1x28) tablets in a PVC/PE/PVDC//Al blister, supplied in a box	YES			YES					
Bonviva 150 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One film coated tablet in a blister (Al/Al), supplied in a box	YES	YES		YES	YES				
Bonviva 3 mg solution for injection in a pre-filled syringe	solution for injection (in pre-filled syringe)	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim, Germany	Pre-filled syringe containing 3 mL of solution, supplied in a box	YES	YES		YES	YES				
Botox	lyophilisate for preparation of injection for intramuscular use	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	Glass bottle of 10 mL containing 1.4 mg of lyophilisate, supplied in a box	YES	YES							
Brinerdin coated tablets	coated tablets	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Novartis Pharma Ltd., Switzerland	50 (5x10) tablets in a blister, supplied in a box	YES		YES						
Brivuzost	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	7 tablets in a blister (PVC/Al), supplied in a carton box	YES	YES				YES			
Bromergon 2.5 mg tablets	tablets	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 tablets in an amber glass bottle, supplied in a box	YES		YES						
Brufen 400 film coated tablets	film coated tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	30 (3x10) tablets in a PVC/Al or PVC/PVDC/Al blister, supplied in a box	YES	YES							
Brufen 600 film coated tablets	film coated tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	30 (3x10) tablets in a PVC/Al or PVC/PVDC/Al blister, supplied in a box	YES	YES							
Bubil shampoo	shampoo	AD JAKA 80 Radoviš, Radoviš, FYROM	60 mL of shampoo in an amber glass bottle with an aluminium stopper, supplied in a box	YES		YES				YES		
Buscol dragee	sugar-coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 20 (2x10) sugar-coated tablets in a blister	YES		YES						
Buscopan 10 mg coated tablets	coated tablets	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	20 (1x20) tablets in PVC/Al blister, supplied in a box	YES		YES			YES			
Byol 10 mg film coated tablets	film coated tablets	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), in an aluminium bag, supplied in a carton box	YES		YES						
Byol 10 mg film coated tablets	film coated tablets	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3X10) tablets in a blister, in an aluminium bag, supplied in a box	YES		YES						
Byol 5 mg film coated tablets	film coated tablets	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), in an aluminium bag, supplied in a carton box	YES		YES						
Byol 5 mg film coated tablets	film coated tablets	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3X10) tablets in a blister, in an aluminium bag, supplied in a box	YES		YES						
Ca-C 500 Sandoz	effervescent tablets	Krka d.d., Novo Mesto, Republic of Slovenia for Novartis Consumer Health S.A., Nyon, Switzerland	10 effervescent tablets in an Al-foil in a vial, supplied in a box	YES		YES				YES		
Caduet 10 mg/10 mg tablets	film coated tablets	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldalde 1, Freiburg, Germany	30 (3x10) film coated tablets in a blister (polyamide/aluminum/PVC), supplied in a carton box	YES	YES		YES	YES				

Caduet 5 mg/10 mg tablets	film coated tablets	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldalde 1, Freiburg, Germany	31 (3x10) film coated tablets in a blister (polyamide/aluminum/PVC), supplied in a carton box		YES	YES		YES	YES			
Caffetin Cold	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (1x10) tablets in a PVC/TE/PVdc-Al blister, supplied in a box		YES	YES			YES			
Caffetin tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	12 (2x6) tablets in Al/PE strip, supplied in a box		YES	YES			YES			
"Droga" herbal laxative	herbal laxative tea	Droga Kolinska d.d., Ljubljana, Republic of Slovenia	1.8 g of herbal tea in a filter bag wrapped in paper envelope, 20 filter bags in a box		YES				YES	YES		
Calcium Sandoz 10 % injection	solution for injection for intramuscular and intravenous use	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	10 mL of solution in a glass ampoule, 5 ampoules in a carton box		YES	YES						
Calciumvita C effervescent tablets	effervescent tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 effervescent tablets wrapped in an Al-foil in a vial, supplied in a box		YES	YES			YES			
Calgel gum gel	gum gel	GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Poland	10 g of gel in aluminum tube, supplied in a box		YES	YES			YES			
Calixta 15 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES		YES						
Calixta 30 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES		YES						
Calixta 45 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES		YES						
CAMPTO 100 mg/5 mL	concentrate for preparation of solution for infusion	Aventis Pharma Dagenham, Dagenham, Essex, Great Britain	Amber glass bottle containing 5 mL of solution, supplied in a box		YES	YES						
CAMPTO 40 mg/2 mL	concentrate for preparation of solution for infusion	Aventis Pharma Dagenham, Dagenham, Essex, Great Britain	Amber glass bottle containing 2 mL of solution, supplied in a box		YES	YES						
CANCIDAS 50 mg powder for concentrate for infusion solution	powder for concentrate for infusion solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Netherlands	10-mL glass bottle with powder, supplied in a box		YES	YES			YES			
CANCIDAS 70 mg powder for concentrate for infusion solution	powder for concentrate for infusion solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Netherlands	10-mL glass bottle with powder supplied in a box		YES	YES			YES			
Canesten 1 vaginal tablet 0.5 g	vaginal tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	One vaginal tablet in a PA/Al/PVC/Al blister pack and one applicator, supplied in a box		YES	YES						
Canesten 1 vaginal tablet 0.5 g/Canesten cream	vaginal tablets and cream	Bayer HealthCare AG, 51368 Leverkusen, Germany	One vaginal tablet in a PA/Al/PVC/Al blister pack, 20 g of cream in an aluminum tube and applicator, supplied in a box		YES	YES						
Canesten 3 vaginal cream	vaginal cream	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 grams of cream and 3 applicators, supplied in a box		YES	YES						
Canesten 3 vaginal tablets 0.2 g	vaginal tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	3 (1x3) vaginal tablets in a blister (PA/Al/PVC/Al) and one applicator, supplied in a box		YES	YES						

Canesten 3 vaginal tablets 0.2 g / Canesten cream	vaginal tablet and cream	Bayer HealthCare AG, 51368 Leverkusen, Germany	3 vaginal tablets in a blister (PA/Al/PVC/Al), 20 g cream in aluminum tube and an applicator, supplied in a box		YES	YES						
Canesten cream	cream	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 grams of cream in an aluminum tube, supplied in a box		YES	YES						
Canesten solution	solution (for external use)	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 mL of solution in a plastic bottle with dropper attachment, supplied in a box		YES	YES						
Canesten dermal powder	dermal powder	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 g of powder in a plastic bottle, supplied in a box		YES	YES						
Canesten dermatological spray, solution	dermatological spray, solution	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 mL of solution in a plastic bottle with a spray attachment, supplied in a box		YES	YES						
Canifug 1% solution	dermal solution	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	30 mL of solution in an amber glass bottle with a spray applicator supplied in a box		YES	YES						
CAPD/DPCA 17 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box		YES	YES						
CAPD/DPCA 17 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2500 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES	YES						
CAPD/DPCA 17 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box		YES	YES			YES			
CAPD/DPCA 17 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES	YES						
CAPD/DPCA 17 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2500 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box		YES	YES			YES			
CAPD/DPCA 18 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box		YES	YES						
CAPD/DPCA 18 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2500 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES	YES						

CAPD/DPCA 18 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")	YES	YES							
CAPD/DPCA 18 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2500 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box	YES	YES			YES				
CAPD/DPCA 18 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box	YES	YES			YES				
CAPD/DPCA 19 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box	YES	YES							
CAPD/DPCA 19 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box	YES	YES			YES				
CAPD/DPCA 19 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2500 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box	YES	YES			YES				
CAPD/DPCA 19 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with casing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")	YES	YES							
CAPD/DPCA 19 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2500 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")	YES	YES							
CAPD/DPCA 2 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box	YES	YES							
CAPD/DPCA 2 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution, inserted in a protective plastic bag, supplied in a box	YES	YES							
CAPD/DPCA 2 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")	YES	YES							

CAPD/DPCA 3 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box"		YES	YES						
CAPD/DPCA 3 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES	YES						
CAPD/DPCA 3 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution, inserted in a protective plastic bag, supplied in a box		YES	YES						
CAPD/DPCA 4 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box"		YES	YES						
CAPD/DPCA 4 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution, inserted in a protective plastic bag		YES	YES						
CAPD/DPCA 4 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES	YES						
Carbomed granules	granules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	50 g of granules in an amber glass bottle, supplied in a box	YES		YES		YES				
Carbomed tablets	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 (3x10) tablets in a PVC/Al blister, supplied in a box	YES		YES		YES		YES		
CARBOPLATIN EBEWE 150 mg/15 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	15 mL of solution concentrate in an amber glass bottle (with rubber stopper), supplied in a box		YES	YES						
CARBOPLATIN EBEWE 50 mg/5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution concentrate in an amber glass bottle (with a rubber stopper), supplied in a box		YES	YES						
Carboplatin Pliva 150	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	15 mL of concentrate in a glass bottle (amber or clear, with rubber stopper and aluminum cap with plastic lid), supplied in a box	YES		YES						
Carboplatin Pliva 50	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 mL of concentrate in a glass bottle (amber or colourless, with a rubber stopper and an Al cap with a plastic lid), supplied in a box	YES		YES						
Cardioprin 100 mg gastric-resistant tablets	gastric-resistant tablets	Lannacher Heilmittel GmbH, Lannach, Austria	30 (3x10) tablets in a blister, supplied in a box		YES	YES						

Cardiopirin 50 mg gastric-resistant tablets	gastric-resistant tablets	Lannacher Heilmittel GmbH, Lannach, Austria	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
CARMOL drops	drops, solutiojn	Dr. A.&L. Schmidgall, Vienna, Austria	40 mL of solution in a glass bottle with a plastic dropper and a plastic stopper, supplied in a box		YES		YES		YES		
Carvelol 12.5 mg tablets	tablets	Belupo, lijekovi i kozmetika, d.d., Koprivnica in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	28 tablets in a blister, supplied in a box	YES			YES				
Carvelol 25 mg tablets	tablets	Belupo, lijekovi i kozmetika, d.d., Koprivnica in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	28 tablets in a blister, supplied in a box	YES			YES				
Carvelol 3.125 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in transparent PVC/PVDC/AI blister, supplied in a box		YES		YES				
Carvelol 6.25 mg tablets	tablets	Belupo, lijekovi i kozmetika, d.d., Koprivnica in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	28 tablets in a blister, supplied in a box	YES			YES				
CARVETREND tablets 12.5 mg	each tablet contains 12.5 mg of carvedilolum	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC/AI blister, supplied in a box	YES			YES				
CARVETREND tablets 25 mg	each tablet contains 25 mg of carvedilolum	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (1x28) tablets in a PVC/PVDC/AI blister, supplied in a box	YES			YES				
CARVETREND tablets 3.125 mg	each tablet contains 3.125 mg of carvedilolum	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC/AI blister, supplied in a box	YES			YES				
CARVETREND tablets 6.25 mg	each tablet contains 6.25 mg of carvedilolum	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC/AI blister, supplied in a box	YES			YES				
Casodex tablets 150 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany and AstraZeneca UK Limited, Macclesfield, Cheshire, Great Britain	28 (2x14) tablets in a blister (PVC/AI), supplied in a box		YES	YES					
Casodex tablets 50 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Cheshire, Great Britain	28 (2x14) tablets in a blister (PVC/Alu foil), supplied in a carton box		YES	YES					
Cedax capsules 400 mg	capsules	SIFI S.p.A., Aci S. Antonio, Catania, Italy	5 capsules in a strip, supplied in a box		YES	YES					
Cedax powder for preparation of oral suspension 180 mg/5 mL	powder for preparation of oral suspension	SIFI S.p.A., Aci S. Antonio, Catania, Italy	15 grams of powder for preparation of 60 mL oral suspension		YES	YES					
Cefalexin 500 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	16 (1x16) capsules in a PVC/AI blister, supplied in a box	YES			YES				
Cefalexin 250 mg/5 mL powder for oral suspension	powder for preparation of oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Amber glass bottle with an aluminium screw cap	YES			YES				
Cefalexin Alkaloid 250 mg /5 mL powder for oral suspension	powder for preparation of oral suspension	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	Amber glass bottle with powder for preparation of 100 mL of suspension with an aluminium stopper and a plastic measuring spoon, supplied in a box		YES		YES				

Cefalexin Alkaloid 500 mg capsules	capsules	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	16 (2x8) capsules in a PVC/AI blister, supplied in a carton box		YES	YES						
Cefalin capsules 500 mg	capsules	Pliva Krakow, Krakow, Poland	16 capsules (2x8) in a PVC/AI blister, supplied in a box		YES	YES						
Cefalin syrup 250 mg/5 mL	powder for preparation of oral suspension	Pliva Krakow, Krakow, Poland	Amber glass bottle of 100 mL with a plastic stopper and ROPP cap		YES	YES						
Cefalin tablets 1 g	film coated tablets	Pliva Krakow, Krakow, Poland	16 tablets (2x8) in a PVC/AI blister, supplied in a box		YES	YES						
Cefixim suspension	powder for preparation of oral suspension	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	53 g of powder for preparation of 100 mL of suspension in an amber glass bottle, supplied in a box		YES	YES						
Cefixim tablets	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 tablets in an amber glass bottle, supplied in a box		YES	YES						
Cefotaksim injection 1 g	powder for preparation of injection solution	Farmal d.d., Ludbreg, Branitelja domovinskog rata 8, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Verovškova 57, Republic of Slovenia	One glass vial with 1.0 g of powder, supplied in a box	YES		YES						
Cefotaksim injection 2 g	powder for preparation of solution for injection	Farmal d.d., Ludbreg, Branitelja domovinskog rata 8, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Verovškova 57, Republic of Slovenia	One glass vial with 2.0 g of powder, supplied in a box	YES		YES						
Cefzil 250 mg/5 mL powder for oral suspension	powder for preparation of oral suspension	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Ceraso, Anagni, Italy	30 g of powder for oral suspension in a 60 mL plastic (HDPE) bottle with a plastic measuring spoon, supplied in a box	YES		YES						
Cefzil 500 mg film-tablets	film coated tablets	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Ceraso, Anagni, Italy	10 (2x5) film coated tablets in a PVC/PVDC//AI blister, supplied in a box	YES		YES						
Celebrex capsules 200 mg	capsules	Pharmacia Limited, Whalton Road, Morpeth, Northumberland NE61 3YA, Great Britain	10 capsules in a blister, supplied in a box		YES	YES						
CellCept 250 mg capsules	capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 (10x10) capsules in a PVC/AI blister, supplied in a box		YES	YES		YES	YES			
CellCept 500 mg tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	50 (5x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES		YES	YES			
Cerezyme 200 U powder for concentrate for solution for infusion	powder for concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial with powder for infusion solution concentrate supplied, in a carton box		YES	YES			YES			YES
Cerezyme 400 U powder for concentrate for solution for infusion	powder for concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial with powder for infusion solution concentrate supplied, in a carton box		YES	YES			YES			YES
Cerson 5 mg tablets	tablets	Belupo, Ijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Certican 0.1 mg tablets for oral suspension	tablets for oral susension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/AI/PVC/AI), supplied in a box		YES	YES			YES			

Certican 0.25 mg tablets	tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/AI/PVC//AI), supplied in a box		YES	YES			YES		
Certican 0.25 mg tablets for oral suspension	tablets for oral susension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/AI/PVC//AI), supplied in a box		YES	YES			YES		
Certican 0.5 mg tablets	tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/AI/PVC//AI), supplied in a box		YES	YES			YES		
Certican 0.75 mg tablets	tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/AI/PVC//AI), supplied in a box		YES	YES			YES		
Certican 1.0 mg tablets	tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/AI/PVC//AI), supplied in a box		YES	YES			YES		
CETROTIDE 0.25 mg	powder and diluent for solution for injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Vial with powder and syringe with diluent, supplied in a box		YES	YES					
CETROTIDE 3 mg	powder and diluent for solution for injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Vial with powder and syringe with diluent, supplied in a box		YES	YES					
Champix tablets 0.5 mg/1 mg	film coated tablets	Heinrich Mack Nachf. GmbH & Co., Illertissen, Germany	Eleven 0.5 mL tablets in a blister (Aclar/PVC//AI) + fourteen 1-mg tablets in a blister (Aclar/PVC//AI), supplied in a carton box		YES	YES		YES	YES		
Champix tablets 1 mg	film coated tablets	Heinrich Mack Nachf. GmbH & Co., Illertissen, Germany	28 (2x14) tablets in a blister (Aclar/PVC//AI) in a carton wrapping		YES	YES		YES	YES		
Chirocaine 2.5 mg/mL solution for injection	solution for injection/concentrate for preparation of infusion solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	10 polypropylene ampoules each containing 10 mL of solution for injection, supplied in a box		YES	YES					
Chirocaine 5 mg/mL solution for injection	solution for injection/concentrate for preparation of infusion solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	10 polypropylene ampoules each containing 10 mL of solution for injection, supplied in a box		YES	YES					
Chirocaine 7.5 mg/mL solution for injection	solution for injection/concentrate for preparation of infusion solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	10 polypropylene ampoules Each containing 10 mL of solution for injection, supplied in a box		YES	YES					
Chloramphenicol Krka eye ointment	eye ointment	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 g of ointment in a tube, supplied in a box		YES		YES				
Cialis 10 mg tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	4 tablets in a blister (PVC/PE/Aclar/AI), supplied in a carton box		YES	YES			YES		
Cialis 20 mg tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	2 tablets in a blister (PVC/PE/Aclar/AI), supplied in a carton box		YES	YES			YES		
Cialis 20 mg tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	4 tablets in a blister (PVC/PE/Aclar/AI), supplied in a carton box		YES	YES			YES		
Ciflox 250 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a box	YES			YES				
Ciflox 500 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a box	YES			YES				

Ciflox 750 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a box	YES			YES					
Cilazil 2.5mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film tablets in a blister, supplied in a box	YES			YES					
Cilazil 5mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film tablets in a blister, supplied in a box	YES			YES					
Cilazil plus	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film coated tablets in a blister (OPA/AI/PVC//AI), supplied in a box	YES			YES					
Cilazil tablets 1 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film tablets in a blister, supplied in a box	YES			YES					
Cilest tablets	tablets	Cilag AG, Schaffhausen, Switzerland	21 (1x21) tablets in a blister (PVC/A1), supplied in a box		YES	YES						
CIMOLAN capsules	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) capsules in a blister (PVC/AI), supplied in a box	YES			YES			YES		
CIMOLAN P syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of syrup in an amber glass bottle with aluminum cap and a 5-mL plastic measuring spoon, supplied in a box	YES			YES			YES		
CIMOLAN syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of syrup in an amber glass bottle with aluminum cap and a 5-mL plastic measuring spoon, supplied in a box	YES			YES			YES		
Cinarizin forte 75mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	Box with 50 tablets (blister, 5x10 tablets)		YES		YES					
CINNABIN	tablets	Deutsche Homöopathie - Union, DHU - Arzneimittel GmbH & Co.KG, Karlsruhe, Germany	100 (5x20) tablets in PVC/AI blister, supplied in a box		YES					YES	YES	
Cipralex 10 mg film-tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Cipralex 5 mg film-tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Cipralex, 10mg film-tablets	film tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	Box with 28 tablets (blister, 2x14 tbl.)		YES	YES						
Cipralex, 5mg film-tablets	film tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	Box with 28 tablets (blister, 2x14 tbl.)		YES	YES						
Ciprinol film coated tablets 250 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) tablets in a PVC/PVDC//AI blister, supplied in a box		YES		YES					
Ciprinol film coated tablets 500 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) tablets in a PVC/PVDC//AI blister, supplied in a box		YES		YES					
Ciprinol 100 mg/10 mL solution concentrate for infusion	solution concentrate for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 mL of infusion solution concentrate in a glass ampoule, 5 ampoules on a plastic tray, supplied in a box		YES		YES					

Ciprinol solution for infusion 100 mg/50 mL	solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	50 mL of solution for infusion in a glass bottle (with a rubber stopper, aluminium ring and a plastic flip off stopper), supplied in a carton box		YES	YES						
Ciprinol 200 mg/100 mL solution for infusion	solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 mL of infusion solution in a glass bottle (with rubber stopper and aluminum ring), supplied in a carton box		YES	YES						
Ciprinol solution for infusion 400 mg/200 mL	solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	200 mL of solution for infusion in a glass bottle (with rubber stopper, aluminum ring and plastic cap/flip off), supplied in a carton box		YES	YES						
Ciprobay 200 mg/100 mL solution for infusion	solution for infusion	Bayer HealthCare AG, 51368 Leverkusen, Germany	100 mL of infusion solution in a plastic bottle, supplied in a box		YES	YES						
Ciprobay 250 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	10 (1x10) film coated tablets in a PP/AI blister, supplied in a box		YES	YES						
Ciprobay 400 mg/200 mL solution for infusion	solution for infusion	Bayer HealthCare AG, 51368 Leverkusen, Germany	200 mL of solution for infusion in a glass bottle, supplied in a box		YES	YES						
Ciprobay 500 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	10 (1x10) film coated tablets in a PP/AI blister, supplied in a box		YES	YES						
Cipromed tablets 250mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES		YES						
Cipromed tablets 500 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES		YES						
Cipromed tablets 750mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES		YES						
Cisplatin Pliva 10	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Amber glass bottle with 20 mL of concentrate (with a rubber stopper, and an aluminium cap with a plastic lid), 10 bottles in a box	YES		YES						
Cisplatin Pliva 10	solution concentrate for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 amber glass vials each containing 20 mL of solution, supplied in a box	YES		YES						
Cisplatin Pliva 50	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of solution in an amber glass bottle, supplied in a box	YES		YES						
Cisplatin Pliva 50	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Amber glass bottle with 100 mL of concentrate (with a rubber stopper, and aluminium cap with a plastic lid), supplied in a box	YES		YES						
Citalon 10 mg film coated tablets	film coated tablets	Sandoz Pharmaceuticals GmbH, Carl-Zeiss-Ring 3, Ismaning, Germany	28 (2x14) tablets in a PVC/PVDC/Alu blister, supplied in a carton box		YES	YES			YES			
Citalon 20 mg film coated tablets	film coated tablets	Sandoz Pharmaceuticals GmbH, Carl-Zeiss-Ring 3, Ismaning, Germany	28 (2x14) tablets in a PVC/PVDC/Alu blister, supplied in a carton box		YES	YES			YES			
Citalon 40 mg film coated tablets	film coated tablets	Sandoz Pharmaceuticals GmbH, Carl-Zeiss-Ring 3, Ismaning, Germany	28 (2x14) tablets in a PVC/PVDC/Alu blister, supplied in a carton box		YES	YES			YES			

Citeral 100 mg/10 mL concentrate for solution for infusion	concentrate for infusion solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	5 ampoules with 10 mL of solution, supplied in a carton box		YES	YES						
Citeral 250 mg film coated tablets	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 tablets in an amber glass bottle, supplied in a carton box		YES	YES						
Citeral 500 mg film coated tablets	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 tablets in an amber glass bottle, supplied in a carton box		YES	YES						
Absorbed diphtheria and tetanus vaccine for children (above the age of 7) and adults, 1 dose	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass ampoule containing 1 dose of vaccine (0.5 mL of suspension)	YES							YES	
Absorbed diphtheria and tetanus vaccine for children (above the age of 7) and adults, 10 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 10 doses of vaccine (5 mL of suspension)	YES							YES	
Absorbed diphtheria and tetanus vaccine for children (above the age of 7) and adults, 20 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 20 doses of vaccine (10 mL of suspension)	YES							YES	
Absorbed diphtheria and tetanus vaccine, 1 dose	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass ampoule containing 1 dose of vaccine (0.5 mL of suspension)	YES							YES	
Absorbed diphtheria and tetanus vaccine 10 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 10 doses of vaccine (5 mL of suspension)	YES							YES	
Absorbed diphtheria, tetanus and pertussis vaccine, 10 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of vaccine (5 mL of suspension)	YES							YES	
Absorbed diphtheria, tetanus and pertussis vaccine, 1 dose	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass ampoule containing 1 dose of vaccine (0.5 mL of suspension)	YES							YES	
Absorbed diphtheria, tetanus and pertussis vaccine, 20 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 20 doses of vaccine (10 mL of suspension)	YES							YES	
Meningococcal group A and group C polysaccharide vaccine, lyophilized, 1 dose	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Amber glass lyophilisation bottle, volume of 3.5 mL with 0.5 mL of lyophilisate for one dose of vaccine + ampoule with the volume of 2 mL with 0.5 mL of solvent for one dose of vaccine	YES							YES	
Meningococcal A and C polysaccharide vaccine, lyophilized, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Amber glass lyophilisation bottle, volume of 5.5 mL with 0.5 mL of lyophilisate for ten doses of vaccine + ampoule with 5 mL of solvent for ten doses of vaccine	YES							YES	
Live, lyophilized morbilli and rubella vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS, 1 dose	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle with 1 dose of lyophilised vaccine (for 0.5 mL of reconstituted vaccine) + 1 ampoule with 0.5 mL of solvent for vaccine against measles and rubella, sterile water for injection	YES							YES	
Live, lyophilized morbilli and rubella vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine (for 5 mL of reconstituted vaccine) + 50 ampoules with 5 mL of solvent for vaccine against measles and rubella, sterile water for injection	YES							YES	
Live, lyophilized morbilli and rubella vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS, 5 doza	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine (for 2.5 mL of reconstituted vaccine) + 50 ampoules with 2.5 mL of solvent for	YES							YES	

			vaccine against measles and rubella, sterile water for injection										
Live, lyophilized vaccine against morbilli, rubella, parotitis, Edmonston-Zagreb, HDS, RA 27/3, HDS I L-Zagreb, PF, 1 doza	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 1 dose of lyophilised vaccine (for 0.5 mL of reconstituted vaccine) and 1 ampoule with 0.5 mL of solvent for vaccine against measles, rubella and parotitis, sterile water for injection	YES								YES	
Live, lyophilized morbilli, rubella and parotitis vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS; L-Zagreb, PF, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine (for 5 mL of reconstituted vaccine) + 50 ampoules with 5 mL of solvent for vaccine against measles, rubella and parotitis, sterile water for injection	YES								YES	
Live, lyophilized morbilli, rubella and parotitis vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS; L-Zagreb, PF, 5 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 5 doses of lyophilised vaccine (for 2.5 mL of reconstituted vaccine) + 50 ampoules with 2.5 mL of solvent for vaccine against measles, rubella and parotitis, sterile water for injection	YES								YES	
Live, lyophilized morbilli vaccine, Edmonston-Zagreb, HDS 1 dose	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	One glass vial with single dose of lyophilised vaccine (for 0.5 mL of reconstituted vaccine) and one ampoule with 0.5 mL of diluent, sterile Water for Injection, supplied in a carton box	YES								YES	
Live, lyophilized morbilli vaccine, Edmonston-Zagreb, HDS, 5 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	50 glass bottles with 5 doses of lyophilised vaccine (for 2.5 mL of reconstituted vaccine), supplied in a carton box, and 50 ampoules with 2.5 mL of solvent, sterile water for injection, supplied in a carton box	YES								YES	
Live, lyophilized morbilli vaccine, Edmonston-Zagreb, HDS, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	50 glass bottles with 10 doses of lyophilised vaccine (for 5 mL of reconstituted solvent), supplied in a carton box, and 50 ampoules with 5 mL of solvent, sterile water for injection, supplied in a carton box	YES								YES	
Live, lyophilized parotitis vaccine, L-Zagreb, PF, 1 doza	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with a glass bottle with 1 dose of lyophilised vaccine against parotitis (for 0.5 mL of reconstituted vaccine) + 1 ampoule with 0.5 mL of solvent for vaccine against parotitis, sterile water for injection	YES								YES	
Live, lyophilized parotitis vaccine, L-Zagreb, PF, 10 doza	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine against parotitis (for 5 mL of reconstituted vaccine) + 50 ampoules with 5 mL of solvent for vaccine against parotitis, sterile water for injection	YES								YES	
Live, lyophilized rubella vaccine RA 27/3, HDS, 1 dose	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 1 dose of lyophilised vaccine against rubella (for 0.5 mL of reconstituted vaccine) + 1 ampoule with 0.5 mL of solvent for vaccine against rubella, sterile water for injection	YES								YES	
Live, lyophilized rubella vaccine, RA 27/3, HDS, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine against rubella (for 5 mL of reconstituted vaccine) + 50 ampoules with 5 mL of solvent for vaccine against rubella, sterile water for injection	YES								YES	

Live, lyophilized rubella vaccine, RA 27/3, HDS, 5 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 5 doses of lyophilised vaccine against rubella (for 2.5 mL of reconstituted vaccine) + 50 ampoules with 2.5 mL of solvent for vaccine against rubella, sterile water for injection	YES									YES	
Anti-tetanus vaccine, absorbed, 1 dose	suspension for injections	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass ampoule containing 1 dose of tetanus vaccine (0.5 mL of suspension)	YES									YES	
Anti-tetanus vaccine, absorbed, 1 dose	suspension for injections	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 10 doses of tetanus vaccine (5 mL of suspension)	YES									YES	
Absorbed tetanus vaccine, 20 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle with 20 doses of tetanus vaccine (5 mL of suspension)	YES									YES	
Claccium Folinat Ebewe 100 mg/10 mL	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 amber glass ampoules with 10 mL of solution, supplied in a box		YES		YES							
Claccium Folinat Ebewe 30 mg/3 mL	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 amber glass ampoules with 3 mL of solution, supplied in a box		YES		YES							
Claccium Folinat Ebewe 50 mg/5 mL	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 amber glass ampoules with 5 mL of solution, supplied in a box		YES		YES							
Clarexid tablets 250 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 tablets in PVC/Al blister, supplied in a box	YES			YES							
Clarexid tablets 500 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 tablets in PVC/Al blister, supplied in a box	YES			YES							
Clarinase 5 mg/120 mg prolonged-release tablets	prolonged release tablets	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	10 tablets in a PVC/PE/PCTFE/Al or PVC/PCTFE//Al blister, supplied in a box		YES	YES							YES	
Claritine syrup 1mg/mL	syrup	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	120 mL of solution in an amber glass bottle, supplied in a box		YES	YES								
Claritine tablets 10 mg	tablets	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	10 (1x10) tablets in a PVC/PVDC//Al OR PVC/PCTFE//Al blister, supplied in a box		YES	YES							YES	
Clarosip 125 mg	granules for oral suspension	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	White polypropylene tube with granules for oral suspension, closed with propylene cap on the top and regulator (porous structure) for the control of suspension flow at the bottom, in protective aluminum bag		YES	YES							YES	
Clarosip 187.5 mg	granules for oral suspension	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	White polypropylene tube with granules for oral suspension, closed with propylene cap on the top and regulator (porous structure) for the control of suspension flow at the bottom, in protective aluminum bag		YES	YES							YES	
Clarosip 250 mg	granules for oral suspension	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	White polypropylene tube with granules for oral suspension, closed with propylene cap on the top and regulator (porous structure) for the control of suspension flow at the bottom, in protective aluminum bag		YES	YES							YES	

Clexane 10.000 IU anti-Xa/1.0 mL injections	solution for injection (for s.c. and i.v. use in haemodialysis)	Aventis Intercontinental, France i Aventis Pharma Le Trait, France	2 glass syringes with needles (each containing 1.0 mL of solution) in a blister, supplied in a box		YES	YES							
Clexane 2000 IU anti-xa/0.2 mL injection	solution for injection (for s.c. and i.v. use in haemodialysis)	Aventis Intercontinental, Maisons Alfort, France; Aventis Pharma Le Trait, Le Trait, France	2 glass syringes with needles (each containing 0.2 mL of solution) in a blister, supplied in a box		YES	YES							
Clexane 4000 IU anti-xa/0.4 mL injection	solution for injection (for s.c. and i.v. use in haemodialysis)	Aventis Intercontinental, Maisons Alfort, France; Aventis Pharma Le Trait, Le Trait, France	2 glass syringes with needles (each containing 0.4 mL of solution) in a blister, supplied in a box		YES	YES							
Clexane 6000 IU anti-Xa/0.6 mL injection	solution for injection (for s.c. and i.v. use in haemodialysis)	Aventis Intercontinental, France i Aventis Pharma Le Trait, France	2 glass syringes with needles (each containing 0.6 mL of solution) in a blister, supplied in a box		YES	YES							
Clexane 8000 IU anti-Xa/0.8 mL injection	solution for injection (for s.c. and i.v. use in haemodialysis)	Aventis Intercontinental, France i Aventis Pharma Le Trait, France	2 glass syringes with needles (each containing 0.8 mL of solution) in a blister, supplied in a box		YES	YES							
Climen	coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	Coated tablets		YES	YES							
Clivarin 1432	solution for subcutaneous injection	Abbott GmbH & Co. KG, Ludwigshafen, Germany	10 (2x5) glass syringes (with needle) each containing 0.25 mL of solution, in a protective container, supplied in a carton box		YES	YES							
Clivarin 1750	solution for subcutaneous injection	Abbott GmbH & Co. KG, Ludwigshafen, Germany	10 (5x2) syringes with needles each containing 0.25 mL of solution in a blister, supplied in a box		YES	YES							
Clivarin 3436	solution for subcutaneous injection	Abbott GmbH & Co. KG, Ludwigshafen, Germany	10 (2x5) glass syringes (with needle) each containing 0.6 mL of solution, in a protective container, supplied in a carton box		YES	YES							
Clivarin 5153	solution for injection (for s.c. use)	Abbott GmbH & Co. KG, Ludwigshafen, Germany	10 (2x5) glass syringes (with needle) each containing 0.9 mL of solution, in a protective container, supplied in a box		YES	YES							
Clopixol acuphase 50 mg/mL solution for injection	solution for intramuscular injection	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	5 ampoules each with 1 mL of solution, supplied in a box		YES	YES							
Clopixol depot 200 mg/mL solution for injection	solution for injection for intramuscular use	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	10 ampoules each containing 1 mL of solution, supplied in a box		YES	YES							
Clopixol 10 mg tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	50 tablets in a polypropylene container with a specially designed stopper with a leaflet		YES	YES							
Clopixol 25 mg tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	50 tablets in a polypropylene container with a specially designed stopper with a leaflet		YES	YES							
Coaprovel 150 mg/12.5 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambarès, France	28 (2x14) tablets in a blister (PVC/PVDC/Al), supplied in a box		YES	YES							
Coaprovel 300 mg/12.5 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambarès, France	28 (2x14) tablets in a blister (PVC/PVDC/Al), supplied in a box		YES	YES							
Coaxil	coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France	30 (1x30) tablets in a PVC/Alu blister, supplied in a carton box		YES	YES							
Coaxil	coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France	60 (2x30) tablets in a blister (PVC/Al), supplied in a box		YES	YES							

Codeini phosphatis Alkaloid	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (1x10) tablets in a Al/PE//PE/Al strip, supplied in a box		YES		YES					
CO-Diovan film-tablets 160/12.5 mg	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
CO-Diovan film-tablets 160/25 mg	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
CO-Diovan film-tablets 80/12.5 mg	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
Coldrex HotRem Blackcurrant	powder for preparation of oral solution	SmithKline Beecham S.A., Madrid, Spain	5 bags with 5 g of powder, supplied in a box		YES	YES				YES		
Coldrex Junior	film coated tablets	Famar S.A., Atena, Greece	16 (2x8) tablets in a blister, supplied in a box		YES	YES				YES		
COLDREX JUNIOR syrup	oral solution	Wrafton Laboratories Ltd., Wrafton, Braunton, North Devon, Great Britain	160 mL of oral solution in an amber glass bottle with a plastic (PP) temper-proof closure and 20-ml measuring glass, supplied in a box		YES	YES				YES		
Coldrex MaxGrip Lemon	powder for preparation of oral solution	SmithKline Beecham S.A., Madrid, Spain	5 bags with 6.4 g of powder, supplied in a box		YES	YES				YES		
Coldrex tablets	tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 tablets in a blister, supplied in a box		YES	YES				YES		
Combivir tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain i GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	60 (6x10) film coated tablets in a blister (PVC/AI), supplied in a box		YES	YES						
COMTAN 200 mg film-tablets	film coated tablets	Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, Great Britain	30 film coated tablets in an amber glass bottle with a plastic (HDPP) stopper, supplied in a box		YES	YES						
Concerta 18 mg	prolonged-release tablets	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES	YES			
Concerta 36 mg	prolonged-release tablets	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES	YES			
Concerta 54 mg	prolonged-release tablets	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES	YES			
Concor 10	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Concor 5	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Concor Cor 1.25 mg	film tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	Box with 20 tablets (blister, 2x10 tbl.)		YES	YES						
Concor Cor 2.5 mg	film tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	Box with 30 tablets (blister, 3x10 tbl.)		YES	YES						

Contractubex gel	gel	Merz Pharma GmbH & Co KGaA, Frankfurt am Main, Germany	10 g of gel in aluminum tube, supplied in a box		YES		YES		YES		
Contral	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 10 tablets (blister)	YES			YES				
Controloc 20 mg tablets	gastric-resistant tablets	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	28 (2X14) gastric-resistant tablets in a blister (OPA/Al/PE//Al), supplied in a box		YES	YES					
Controloc 40 mg tablets	gastric-resistant tablets	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	14 (1x14) gastric-resistant tablets in a blister (OPA/Al/PE//Al), supplied in a box		YES	YES					
Controloc intravenous	powder for solution for injection	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	One glasss vial with lyophilisate, supplied in a box		YES	YES					
Copaxone 20 mg, powder and diluent for solution for injection	powder and diluent for solution for injection	Teva Pharmaceutical Industries Ltd., Kfar Saba, Israel	28 (4x7) amber glass bottles with powder and 28 (4x7) ampoules with diluent for solution for injection, supplied in a box		YES	YES		YES	YES		
Copaxone 20 mg/mL solution for injection	solution for injection, pre-filled syringe	Teva Pharmaceuticals Europe B.V., Mijdrecht, The Nederlands	Pre-filled syringe with 1 mL of solution for injection with a needle, in a blister, 28 (4x7) pre-filled syringes supplied in a box		YES	YES					
Copegus 200 mg	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	42 film coated tablets in a polyethylene bag, supplied in a box		YES	YES		YES	YES		
Cordarone 150 mg/3 mL injection	solution for injection	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambarès, France	6 ampoules each with 3 mL of solution for injection, supplied in a box		YES	YES					
Cordarone 200 mg tablets	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambarès, France	30 (3x10) tablets in a blister (PVC/Alu-foil) supplied in a box		YES	YES					
Cordipin XL tablets 40 mg	modified release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10 tablets in PVC/PVD/Al blister, supplied in a box		YES		YES				
Cordipin XL tablets 40 mg	modified release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in a PVC/PVD/Al blister, supplied in a box		YES		YES				
Corlentor 5 mg film coated tablets	film coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France; Servier (Republic of Ireland) Industries Ltd., Gorey Road, Arklow, Co. Wicklow, Republic of Ireland; Przedsiębiorstwo Farmaceutyczne Anpharm S.A., Ul. Annopol 603-236, Warszawa, Poland	28 (2x14) film coated tablets in a PVC/Al blister, supplied in a carton box		YES	YES		YES	YES		
Corlentor 7.5 mg film coated tablets	film coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France; Servier (Republic of Ireland) Industries Ltd., Gorey Road, Arklow, Co. Wicklow, Republic of Ireland; Przedsiębiorstwo Farmaceutyczne Anpharm S.A., Ul. Annopol 603-236, Warszawa, Poland	28 (2x14) film coated tablets in a PVC/Al blister, supplied in a carton box		YES	YES		YES	YES		

CORTEF tablets 10 mg	tablets	Pantheon YM Inc., Toronto, Canada i Pfizer Manufacturing Belgium, Puurs, Belgium	100 tablets in an amber glass bottle, supplied in a box		YES	YES					
Coryol tablets 12.5 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/AI/PVC//AI blister, supplied in a box		YES		YES				
Coryol tablets 25 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/AI/PVC//AI blister, supplied in a box		YES		YES				
Coryol tablets 3.125 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/AI/PVC//AI blister, supplied in a box		YES		YES				
Coryol tablets 6.25 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/AI/PVC//AI blister, supplied in a box		YES		YES				
Cosopt eye drops	eye drops, solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Netherlands	5 mL of solution in a plastic container OCUMETER PLUS, supplied in a box		YES	YES					
Cozaar 100 mg filmom oblo ete tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Cozaar 50 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Crestor 10 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	28 (2x14) film coated tablets in a blister of aluminum laminate and aluminum foil, supplied in a carton box		YES	YES		YES	YES		
Crestor 20 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	29 (2x14) film coated tablets in a blister of aluminum laminate and aluminum foil, supplied in a carton box		YES	YES		YES	YES		
Crestor 40 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	28 (4x7) film coated tablets of aluminum laminate and aluminum foil, supplied in a carton box		YES	YES		YES	YES		
Crestor 5 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	30 (2x14) film coated tablets in a blister of aluminum laminate and aluminum foil, supplied in a carton box		YES	YES		YES	YES		
CRINONE 8% vaginal gel	vaginal gel	M.Y. Healthcare Packaging Limited, Bedfordshire, Great Britain	1.45 g of gel in an applicator for single use, inserted in a protective bag (paper/AI/PE), 15 bags in a box		YES	YES					
CRIXIVAN 100 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	180 capsules in a polyethylene (HDPE) container		YES	YES		YES			
Crixivan 200 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	360 capsules in a polyethylene (HDPE) container		YES	YES		YES			
CRIXIVAN 333 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	135 capsules in a polyethylene (HDPE) container		YES	YES		YES			
Crixivan 400 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	180 capsules in a polyethylene (HDPE) container		YES	YES		YES			

Crystacillin	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 bottles with powder, supplied in a box	YES			YES					
Cymbalta 30 mg hard gastric-resistant capsules	gastric-resistant capsules, hard	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain	28 (2x14) capsules in a blister (PVC/PE/PCTFE//Al), supplied in a box		YES	YES			YES			
Cymbalta 60 mg hard gastric-resistant capsules	gastric-resistant capsules, hard	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain	28 (2x14) capsules in a blister (PVC/PE/PCTFE//Al), supplied in a box		YES	YES			YES			
Cymevene powder for solution for infusion	powder for solution for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10-mL glass vial with powder (for multiple use) supplied in a box		YES	YES						
Dabronston 10 mg tablets	film coated tablets	Belupo, Ijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES					
DACARBAZINE PLIVA 100	lyophilisate for preparation of solution for injection or infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Lyophilisate in an amber glass bottle (with a rubber stopper and an aluminium cap with a plastic lid), 10 bottles in a box	YES			YES					
DACARBAZINE PLIVA 200	lyophilisate for preparation of solution for injection or infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Lyophilisate in an amber glass bottle (with a rubber stopper and an aluminium cap with a plastic lid), 10 bottles in a box	YES			YES					
Daktarin cream	cream	Krka d.d., Novo Mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 g of cream in a tube, supplied in a box		YES		YES					
Daktarin oral gel	oral gel	Krka d.d., Novo Mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	40 g of gel in a tube with a measuring spoon, supplied in a box		YES		YES					
DALERON C granules for oral solution	granules for oral solution	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 bags each containing 5 g of granules, supplied in a box		YES		YES			YES		
DALERON C JUNIOR granules for oral solution	granules for oral solution	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 bags each containing 5 g of granules, supplied in a box		YES		YES			YES		
Dalsy syrup	syrup	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	Brown polyethylene bottle with 100 mL of syrup, supplied in a box		YES	YES						
Dalsy syrup	syrup	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	Brown polyethylene bottle with 200 mL of syrup, supplied in a box		YES	YES						
Danoptin 100 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/Aclar/Al blister, supplied in a box	YES			YES					
Danoptin 25 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/Aclar/Al blister, supplied in a box	YES			YES					
Danoptin tablets 50 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	31 (3x10) tablets in a PVC/Aclar/Al blister, supplied in a box	YES			YES					
Danoptin tablets for oral suspension 5 mg	tablets for oral solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	32 (3x10) tablets in a PVC/Aclar/Al blister, supplied in a box	YES			YES					
Danova capsules 100 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 capsules in a brown plastic bottle with aluminum cap, supplied in a carton box		YES		YES					

Darob	tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) tablets in a blister, supplied in a box		YES	YES					
Darob mite	tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) tablets in a blister, supplied in a box		YES	YES					
Dartelin 400 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
DaTscan 74 MBq/mL solution for injection	solution for injection	Amersham Health BV, Den Dolech 2, Eindhoven, NL 5612 AZ, the Netherlands	10-mL glass vial with 5.0 mL of solution, supplied in a box		YES	YES		YES			
DaTscan 74 MBq/mL solution for injection	solution for injection	Amersham Health BV, Den Dolech 2, Eindhoven, NL 5612 AZ, the Netherlands	10-mL glass vial with 2.5 mL of solution, supplied in a box		YES	YES		YES			
Decapeptyl 0.1 mg	solution for subcutaneous injection	Ferring GmbH, Wittland 1, Kiel, Germany; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	7 syringes each with 1 mL of solution for injection in a blister, supplied in a box		YES	YES					
Decapeptyl CR	micro-capsules for preparation of suspension for subcutaneous or intramuscular injection	Ferring GmbH, Wittland 1, Kiel, Germany; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	One syringe with 172 mg microcapsules, one syringe with 1 mL of suspending agent, one adapter and one needle, supplied in a box		YES	YES					
Decortin 20	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 (1x10) tablets in a PVC/AI blister, supplied in a box		YES		YES				
Decortin 5	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	24 (2x10) tablets in a blister (PVC/AI), supplied in a box		YES		YES				
Deep Freeze Cold gel	gel	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	35 g of gel in an aluminum tube with a plastic (HDPE) stopper, supplied in a box		YES		YES		YES		
Deep Freeze spray	spray, solution	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	200 mL (135 g) of spray solution in a metal container (with PE tube and PP atmizer) with plastic (PP) cap		YES		YES		YES		
Deep heat rub cream	cream	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	15 g of cream in an aluminum tube with plastic (HDPE) cap, supplied in a box		YES		YES		YES		
Deep Heat spray	spray, solution	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	150 mL of spray solution in a metal container (with PE tube and PP nebulizer) with plastic (HDPE) cap		YES		YES		YES		
Deep relief gel	gel	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	100 grams of gel in an aluminum tube, supplied in a box		YES		YES		YES		
Dentinox N	drops, oromucosal solution	Dentinox Gesellschaft für pharmazeutische Präparate Lenk & Schuppan, Berlin, Germany	10 g of solution in an amber glass bottle with plastic dropper and cap, supplied in a box		YES				YES		
Depakine Chrono 300 mg	film coated modified-release tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	100 tablets (two plastic containers with 50 tablets each) supplied in a box		YES	YES					
Depakine Chrono 500 mg	modified release film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	30 tablets in a plastic container, supplied in a box		YES	YES					

DEPAKINE CHRONOSPHERE 100 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES						
DEPAKINE CHRONOSPHERE 1000 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES						
DEPAKINE CHRONOSPHERE 250 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES						
DEPAKINE CHRONOSPHERE 500 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES						
DEPAKINE CHRONOSPHERE 750 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES						
Deprozel tablets 20 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 30 tablets (blister, 3x10 tbl.)	YES		YES						
Deprozel tablets 30 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 30 tablets (blister, 3x10 tbl.)	YES		YES						
Dercome Clear	suspension for topical application to the skin	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	100 grams of suspension in a plastic tube, supplied in a box		YES	YES						
Detralex	film coated tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	30 (2x15) film coated tablets in a PVC/AI blister, supplied in a box		YES	YES						
Detrunorm coated tablets 15 mg	coated tablets	Apogepha Arzneimittel GmbH, Germany	30 (3x10) coated tablets in a PVC/A1 blister, supplied in a box		YES	YES						
Dexamethason Krka solution for injection	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	25 ampoules (5x5) each containing 1 mL of solution in a blister, supplied in a box		YES	YES						
Dexamethason Krka tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 tablets in a blister, supplied in a box		YES	YES						
Diane-35 sugar-coated tablets	sugar-coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	63 (3x21) tablets in a PVC/AI blister, supplied in a box		YES	YES						
Dianeal PD1 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution and 5x1 empty bags (for draining of liquid), in a protective plastic bag; supplied in a carton box		YES	YES						
Dianeal PD1 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution and 5x1 empty bags (for draining of liquid), in a protective plastic bag; supplied in a carton box		YES	YES						
Dianeal PD1 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution and 5x1 empty bags (for draining of liquid), in a protective plastic bag; supplied in a carton box		YES	YES						
Dianeal PD4 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	2x1 plastic bags containing 5000 mL of solution in a protective plastic bag, supplied in a box		YES	YES						
Dianeal PD4 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag; supplied in a box		YES	YES						

Dianeal PD4 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	4x1 plastic bags with 2500 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag, supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution in a protective plastic bag, supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag; supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution in a protective plastic bag, supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	2x1 plastic bags containing 5000 mL of solution in a protective plastic bag, supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	4x1 plastic bags with 2500 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag, supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution in a protective plastic bag, supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	4x1 plastic bags with 2500 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag, supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	2x1 plastic bags containing 5000 mL of solution in a protective plastic bag, supplied in a box		YES	YES							
Dianeal PD4 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag; supplied in a box		YES	YES							
Diaprel	tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France	60 (3x20) tablets in a blister, supplied in a box		YES	YES							
Diaprel MR	modified release tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	60 (2x30) tablets in a blister (PVC/AI), supplied in a box		YES	YES							
Diazepam Alkaloid 10 mg/2 mL solution for injection	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 amber glass ampoules each containing 2 mL of solution, supplied in a box		YES	YES							
Diazepam Alkaloid 2 mg coated tablets	coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 coated tablets in a 15 mL amber glass bottle, supplied in a box		YES	YES							
Diazepam Alkaloid 5 mg coated tablets	coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 coated tablets in a 15 mL amber glass bottle, supplied in a box		YES	YES							
Diazepam Desitin 10 mg rectal solution	rectal solution	Desitin Arzneimittel GmbH, Hamburg, Germany	5 (5x1) plastic containers each with 2.5 mL of solution (with applicator for rectal administration) in a protective bag, supplied in a box		YES	YES							

Diazepam Desitin 5 mg rectal solution	rectal solution	Desitin Arzneimittel GmbH, Hamburg, Germany	5 (5x1) plastic containers each with 2.5 mL of solution (with applicator for rectal administration) in a protective bag, supplied in a box		YES		YES					
Diazepam Jadran 10 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES		YES						
Diazepam Jadran 2 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES		YES						
Diazepam Jadran 5 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 30 (3x10) tablets in a blister	YES		YES						
Diclo Duo capsules 75 mg	modified release capsules, hard	TemmLer Werke GmbH, München, Germany	20 (2x10) capsules in a blister (PVC/PVDC/AI), supplied in a box		YES		YES					
Diclo Duo spray 4%	dermatological spray, solution	Pharbil Waltrop GmbH, Im Wirrigen 25, D-45731 Waltrop, Germany	15-mL amber glass bottle containing 12.5 g solution, with metering pump/ spraying attachment and protective cap, supplied in a carton box		YES		YES	YES	YES	YES	YES	
DICLORAPID 75 mg	gastric-resistant capsules, hard	Astellas Pharma GmbH, München, Germany	10 (1x10) capsules in a PVC/PVdC/AI blister, supplied in a box		YES		YES	YES	YES	YES		
Diclorapid 75 mg	gastric-resistant capsules, hard	Astellas Pharma GmbH, München, Germany	20 (2x10) capsules in a PVC/PVDC/AI blister, supplied in a box		YES		YES	YES	YES	YES		
Dicynone 250 mg/2 mL injection	solution for injection for intramuscular use and intravenous infusion	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 (2x5) ampoules each containing 2 mL of solution in a blister, supplied in a box		YES		YES					
DIFETOIN	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 (10x10) tablets in OPA/AI/PVC//AI blister, supplied in a box	YES		YES						
DIFLUCAN 100 mg capsules	capsules	Pfizer PGM, Poce-sur-Cisse, France	7 (1x7) capsules in (PVC/AI) blister, supplied in a box		YES	YES						
DIFLUCAN 150 mg capsules	capsules	Pfizer PGM, Poce-sur-Cisse, France	One (1x1) capsule in a blister (PVC/AI) supplied in a box		YES	YES						
DIFLUCAN 50 mg capsules	capsules	Pfizer PGM, Poce-sur-Cisse, France	7 (1x7) capsules in (PVC/AI) blister, supplied in a box		YES	YES						
DIFLUCAN solution for infusion	solution for infusion	Pfizer PGM, Poce-sur-Cisse, France	100 mL of solution in a glass bottle for infusion, supplied in a box		YES	YES						
DIFLUCAN powder for suspension 50 mg/7 mL	powder for oral suspension	Pfizer PGM, Poce-sur-Cisse, France	Plastic (HDPE) bottle of 60 mL (with a plastic, temper-evident stopper) with powder for preparation of 35 mL of suspension and a plastic measuring spoon (of 5 mL), supplied in a box		YES	YES						
Diphtheria antitoxin (equine) 10000 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 bottle containing 10000 IU of preparation	YES						YES		
Diphtheria antitoxin (equine) 10000 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 bottles with 10000 IU of preparation	YES						YES		

Digical tablets 80 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in a blister, supplied in a box	YES			YES					
Dihalar tablets	tablets	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Novartis Pharma Ltd., Switzerland	30 (2x15) tablets in a blister, supplied in a box		YES		YES					
Diklofenak retard 100 mg tablets	prolonged-release tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES					
Diklonat P gel	gel	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 g of gel in an aluminium tube, supplied in a box	YES			YES			YES		
Diltiazem Pliva 60 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/AI blister, supplied in a carton box	YES			YES					
Diltiazem Pliva 90 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/AI blister, supplied in a carton box	YES			YES					
Dimidril tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	32 (3x10) tablets in a PVC/AI blister, supplied in a box	YES			YES					
Dinamico tablets 100 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One (1x1) tablet in a blister supplied in a box	YES			YES					
Dinamico tablets 25 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One (1x1) tablet in a blister supplied in a box	YES			YES					
Dinamico tablets 50 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One (1x1) tablet in a blister supplied in a box	YES			YES					
Diovan 160 mg film-tablets	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
Diovan 320 mg film-tablets	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister (PVC/PVDC//AI), supplied in a box		YES	YES		YES	YES			
Diovan 40 mg film-tablets	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
Diovan 80 mg film-tablets	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES			
Diprogenta cream	cream	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES						
Diprogenta ointment	ointment	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	Aluminium tube with 15 g of ointment, supplied in a box		YES	YES						
Diprosalic losion	lotion	Schering-Plough Labo N.V., Heist-op-den-Berg, Belgium; Schering-Plough France, Herouville-Saint-Clair, France	30 mL of lotion in a plastic bottle, supplied in a box		YES	YES						
Diprosalic ointment	ointment	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES						

Disoprivan 1% propofolum	emulsion for infusion	Fresenius Kabi AB, Stockholm, Sweden and AstraZeneca SpA, Caponago, Italy for AstraZeneca UK Ltd., Macclesfield, Cheshire, Great Britain	Box with 5 ampoules containing 20 mL of emulsion		YES	YES						
Disopyramide JADRAN	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	50 capsules in an amber glass bottle, supplied in a box	YES		YES						
Diuver 10 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES		YES						
Diuver 5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES		YES						
Dobutamin Admeda 250	solution for infusion	Wuelfing Pharma GmbH, Gronau, Germany	50 mL of solution for infusion in a glass ampoule, 1 ampoule in a box		YES	YES						
DOKSICIKLIN 100 mg capsules	capsules, hard	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	6 capsules in a white plastic (PP) bottle of 50 mL, bag with a temperature-evident (PP/PE) stopper, supplied in a box	YES		YES						
Dolokain gel	gel	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of gel in an aluminum tube with plastic cap (in a protective bag), supplied in a carton box	YES		YES						
Dopamin Admeda 200	concentrate of solution for infusion	Wuelfing Pharma GmbH	5 glass ampoules each with 10.3 mL of solution for infusion concentrate, supplied in a box		YES	YES						
Dopamin Admeda 50	concentrate of solution for infusion	Wuelfing Pharma GmbH	5 glass ampoules each with 5.3 mL of solution for infusion concentrate, supplied in a box		YES	YES						
Dormicum 15 mg tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 (1x10) tablets in a blister, supplied in a box		YES	YES						
Dormicum 15 mg/3 mL injection	solution for injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules with 3 mL of solution, supplied in a box		YES	YES						
Dormicum 5 mg/1 mL injection	solution for injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 ampoules each containing 1 mL of solution, supplied in a box		YES	YES						
Dormicum 7.5 mg tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 (1x10) tablets in a blister, supplied in a box		YES	YES						
Dotarem 0.5 mmol/mL	solution for injection	Guerbet, Roissy CdG Cedex, France	20 mL of solution in a glass bottle with rubber stopper, supplied in a box		YES	YES			YES			
Dotarem 0.5 mmol/mL	solution for injection	Guerbet, Roissy CdG Cedex, France	15 mL of solution in a glass bottle with rubber stopper, supplied in a box		YES	YES			YES			
Doxazin 2 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES		YES						
Doxazin 4 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES		YES						
DOXORUBICIN EBEWE 10 mg/5 mg	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution concentrate in an amber glass bottle (with a rubber stopper), supplied in a box		YES	YES						

DOXORUBICIN EBEWE 50 mg/25 mg	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	25 mL of solution concentrate in an amber glass bottle (with rubber stopper), supplied in a box		YES		YES					
Doxorubicin Pliva injection 10 mg	powder for solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	5-mL bottle containing 10 mg of powder, with bromobutyl stopper and aluminium cap and ring, supplied in a box		YES		YES					
Doxorubicin Pliva injection 50 mg	powder for solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	25-mL bottle containing 50 mg of powder, with bromobutyl stopper and aluminium cap and ring, supplied in a box		YES		YES					
Doxorubicin-Teva 2 mg/mL	solution for injection	Pharmachemie B.V., Haarlem, the Netherlands	Colourless glass bottle (glass type I) with a rubber stopper (chlorobutyl) coated with fluoropolymer film, aluminium ring and polypropylene lid containing 5 mL of solution, supplied in a box		YES		YES	YES	YES			
Doxorubicin-Teva 2 mg/mL	solution for injection	Pharmachemie B.V., Haarlem, the Netherlands	Colourless glass bottle (glass type I) with a rubber stopper (chlorobutyl) coated with fluoropolymer film, aluminium ring and polypropylene lid containing 25 mL of solution, supplied in a box		YES		YES	YES	YES			
Dr. Theiss Mucoplant eucalyptus balm against cold	ointment	Dr. Theiss Naturwaren GmbH, Homburg, Germany	50 g of ointment in an amber glass bottle with a wide neck, supplied in a box		YES					YES	YES	
Dramina	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 tablets in a A/PVC blister, supplied in a carton box	YES			YES			YES		
Driptane	tablets	Laboratories Fournier S.A., Fontaine les Dijon, France	60 (2x30) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Dulcolax suppositories	suppositories	Boehringer Ingelheim Italia S.p.A., Firenca, Italy	6 suppositories in aluminium foil, supplied in a box		YES		YES			YES		
Dulcolax coated tablets	coated tablets	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	30 (3x10) coated tablets in a PVC/PVDC-AI blister, supplied in a box		YES		YES			YES		
Duodopa intestinal gel	intestinal gel	Solvay Pharmaceuticals GmbH, Justus-von-Liebig-Strasse 33, Neustadt, Germany	100 mL of intestinal gel in a PVC bag with a plastic tube and pump attachment, inside a hard plastic cassette, carton with 7 cassettes		YES	YES		YES	YES			
Duphaston	film coated tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands	42 (3x14) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Duphaston	film coated tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands	20 (1x20) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
DURACEF 250 mg capsules	capsules	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	12 capsules (2x6) in PVC/PVDC/AI blister, supplied in a box	YES			YES					
DURACEF 500 mg capsules	capsules	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	12 capsules (2x6) in PVC/PVDC/AI blister, supplied in a box	YES			YES					

Duracef powder for oral suspension 250 mg/5 mL	powder for preparation of oral suspension	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	35 g of powder for oral suspension in a 60 mL plastic (HDPE) bottle with a plastic measuring spoon, supplied in a box	YES		YES							
Duracef 1 g dispersible tablets	dispersible tablets	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	10 (2x5) tablets in blisters, supplied in a box	YES		YES							
Durogesic transdermal patch 100 ug/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES							
Durogesic transdermal patch 12 µg/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES							
Durogesic transdermal patch 12 microg/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES							
Durogesic transdermal patch 25 ug/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES							
Durogesic transdermal patch 50 ug/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES							
Durogesic transdermal patch 75 µg/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES							
Nitric oxidul	medical gas	SOL SpA, Cremona, Italy i SOL SpA, Marcianise, Italy	10 or 40 l of nitrogen oxide in stainless steel bottles under pressure of 50 bars		YES	YES							
Nitric oxidul	medical gas	Messer Croatia Plin d.o.o., Zaprešić, Industrijska 1, Republic of Croatia	11 or 40 l of nitrogen oxide in stainless steel bottles under pressure of 50 bars	YES		YES							
Dysport	lyophilisate for solution for injection	IPSEN BIOPHARM LIMITED, Wrexham, Great Britain	2 glass bottles of lyophilisate for preparation of injection, supplied in a box		YES								YES
Dysport	lyophilisate for preparation of solution for injections	IPSEN BIOPHARM LIMITED, Wrexham, Great Britain	Glass vial with lyophilisate for preparation of injection, supplied in a box		YES								YES
Ebixa 10 mg tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (2x14) tablets in a blister, supplied in a box		YES	YES							
Ebixa 10 mg/g oral drops	solution for oral drops	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	50 g of solution in an amber glass bottle with a dropper and a plastic stopper, supplied in a box		YES	YES							
Ebrantil 25 iv.	solution for injection	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	5 ampoules each with 5 mL of solution, supplied in a box		YES	YES							
Ebrantil 30 capsules	prolonged release capsules	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	50 prolonged release capsules in a plastic bottle with a desiccant, supplied in a box		YES	YES							
Ebrantil 50 iv.	solution for injection	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	5 ampoules each with 10 mL of solution, supplied in a box		YES	YES							
Ebrantil 60 capsules	prolonged release capsules	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	50 prolonged release capsules in a plastic bottle with a desiccant, supplied in a box		YES	YES							

Ebrantil 90 capsules	prolonged release capsules	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	50 prolonged release capsules in a plastic bottle with a desiccant, supplied in a box		YES	YES						
Edemid forte 500 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 tablets in an amber glass bottle, supplied in a carton box		YES		YES					
Edemid forte 250mg/10mL injection	solution for infusion (concentrate)	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	5 ampoules with 10 mL of solution in a plastic container, supplied in a box		YES		YES					
Edicin 0.5 g injection for intravenous infusion	powder for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	One glass vial with powder for injection, supplied in a box		YES		YES					
Edicin 1.0 g injection for intravenous infusion	powder for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	One glass vial with powder for injection, supplied in a box		YES		YES					
EDRONAX tablets 4 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	60 (3x20) tablets in a blister, supplied in a box		YES	YES						
Efectin ER capsules 150 mg	prolonged release capsules	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland	Box with 28 capsules (blister, 2x14 capsules)		YES	YES						
Efectin ER capsules 37.5 mg	prolonged-release capsules	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
Efectin ER capsules 75 mg	prolonged release capsules	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland	Box with 28 capsules (blister, 2x14 capsules)		YES	YES						
Efferalgan 1 g effervescent tablets	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	8 effervescent tablets in a plastic tube, supplied in a box		YES		YES			YES		
Efferalgan 150 mg suppositories	suppositories	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	10 (2x5) suppositories in a PVC/PE strip, supplied in a box		YES		YES			YES		
Efferalgan 300 mg suppositories	suppositories	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	10 (2x5) suppositories in a PVC/PE strip, supplied in a box		YES		YES			YES		
EFFERALGAN 500 mg, effervescent tablets	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France i Bristol-Myers Squibb, 979 Avenue des Pyrénés, Le Passage, France	16 (4x4) effervescent tablets in a strip (Al/PE), supplied in a box		YES		YES			YES		
Efferalgan 80 mg suppositories	suppositories	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	10 (2x5) suppositories in a PVC/PE strip, supplied in a box		YES		YES			YES		
Efferalgan solution for children	solution for oral use	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	90 mL of solution in a brown plastic bottle with a temper-evident stopper, supplied in a box		YES		YES			YES		
EFFERALGAN plus vitamin C, effervescent tablets	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	10 effervescent tablets in a polypropylene tube, supplied in a box		YES		YES			YES		
Efflumidex Liquifilm eye drops	eye drops, suspension	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	5 mL of suspension in a plastic bottle with a dropper, supplied in a box		YES	YES						

EFOX tablets 250 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	10 (1x10) tablets in a Al/Al blister, supplied in a box	YES		YES						
Efox tablets 500 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	10 (1x10) tablets in a Al/Al blister, supplied in a box	YES		YES						
Eglonyl 100 mg/2 mL solution for injection	solution for injection	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Sanofi-Aventis, France	30 colourless glass ampoules each containing 2 mL of solution, supplied in a box		YES	YES						
Eglonyl 25 mg/5 mL oral solution	oral solution	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Sanofi-Aventis, France	120 mL of solution in an amber glass bottle with dispenser, supplied in a box		YES	YES						
Eglonyl 50 mg capsules	capsules	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 capsules in an amber glass bottle, supplied in a box		YES	YES						
Eglonyl forte tablets	tablets	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Sanofi-Aventis, France	12 tablets in an amber glass bottle, supplied in a box		YES	YES						
Elaprase 2 mg/mL concentrate for infusion solution	concentrate for infusion solution	Shire Human Genetic Therapies AB, Danderyd, Sweden	5-mL glass bottle with 3-mL of concentrate supplied in a box		YES	YES		YES	YES			
Elaprase 2 mg/mL concentrate for infusion solution	concentrate for solution for infusion	Shire Human Genetic Therapies AB, Danderyd, Sweden	10 5-mL glass bottles with 3 mL of concentrate, supplied in a box		YES	YES		YES	YES			
Elaprase 2 mg/mL concentrate for solution for infusion	concentrate for solution for infusion	Shire Human Genetic Therapies AB, Danderyd, Sweden	4 glass bottles (à 5 mL) with 3 mL of concentrate, supplied in a box		YES	YES		YES	YES			
ELEVIT PRONATAL film coated tablets	film coated tablets	Rottendorf Pharma GmbH, Enningerloch, Germany	30 (3x10) film coated tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES				YES		
Elidel 1 % cream 15 g	cream	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	15 g of cream in an aluminum tube, supplied in a box		YES	YES						
Elocom cream	cream	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES						
Elocom lotion	lotion	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	20 mL of lotion in a plastic bottle with dropper attachment, supplied in a box		YES	YES						
Elocom ointment	ointment	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES						
Emadine eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	Bottle-dropper with 5 mL of sterile solution, supplied in a box		YES	YES						
Emend 125 mg hard capsules	capsules, hard	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Netherlands	One (1x1) capsule in a blister back (Al/Al) supplied in a carton box		YES	YES		YES	YES			
Emend 125 mg hard capsules / Emend 80 mg hard capsules	hard capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	One 125-mg capsule in a blister (Al/Al) and two 80-mg capsules in a blister (A/Al), supplied in a box		YES	YES		YES	YES			
Emend 40 mg hard capsules	capsules, hard	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	One capsule in a blister (Al/Al), supplied in a box		YES	YES		YES	YES			
Emend 80 mg hard capsules	capsules, hard	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	2 (1x2) capsules in a blister (Al/Al), supplied in a box		YES	YES		YES	YES			

Eminens 0.25 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	210 tablets in a white plastic (HDPE) bottle with temper-proof closure and desiccant, supplied in a box	YES			YES						
Eminens 0.5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	21 tablets in a white (HDPE) plastic bottle with temper-proof closure and desiccant, supplied in a box	YES			YES						
Eminens 1 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	21 tablets in a white (HDPE) plastic bottle with temper-proof closure and desiccant, supplied in a box	YES			YES						
Eminens 2 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	21 tablets in a white (HDPE) plastic bottle with temper-proof closure and desiccant, supplied in a box	YES			YES						
Eminens 5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	21 tablets in a white (HDPE) plastic bottle with temper-proof closure and desiccant, supplied in a box	YES			YES						
Emselex 15 mg	prolonged-release tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES			YES				
Emselex 7.5 mg	prolonged-release tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES			YES				
Enap -H tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES						
Enap HL tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES						
Enap tablets 10 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES						
Enap tablets 20 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES						
Enap tablets 5 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES						
Enap-HL 20 tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 (6x10) tablets in a blister, supplied in a box		YES		YES						
Enap-HL 20 tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES						
Enazil 10	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES						
Enazil 20	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES						
ENAZIL 5	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES						
Enrel 25 mg powder and diluent for solution for injection	powder and diluent for solution for injection	Wyeth Pharmaceuticals, New Lane, Havant, Hampshire P092NG, Great Britain	Box with 4 glass bottles containing 25 mg of lyophilised powder, 4 syringes with needle filled with solvent (water for injection), 4 needles with protection, 3 bottle adapters and 8 alcohol impregnated pads		YES	YES							

Enbrel 25 mg powder and diluent for solution for injection	powder and diluent for solution for injection	Wyeth Pharmaceuticals, New Lane, Havant, Hampshire P092NG, Great Britain	Box with 4 glass bottles containing 25 mg of lyophilised powder, 4 syringes with needle filled with solvent (water for injection) and 8 alcohol impregnated pads		YES	YES								
Enbrel 25 mg powder for solution for injection	powder for solution for injection	Wyeth Pharmaceuticals, New Lane, Havant, Hampshire P092NG, Great Britain	Box with 4 glass bottles containing 25 mg of lyophilised powder and 8 alcohol impregnated pads		YES	YES								
ENCEPUR for children, vaccine against viral Middle-European tick-borne meningoencephalitis (inactivated, absorbed)	intramuscular suspension	Chiron Behring GmbH & Co, Marburg, Germany	Box with 1 pre-filled syringe with a needle with 1 dose of vaccine (0.25 mL of suspension)		YES							YES		
ENCEPUR Adult, inactivated absorbed vaccine against viral Central European tick-born meningoencephalitis	intramuscular suspension	Chiron Behring GmbH & Co, Marburg, Germany	Box with 1 pre-filled syringe with a needle with 1 dose of vaccine (0.5 mL of suspension)		YES							YES		
Endoxan coated tablets 50 mg	coated tablets	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	50 (5x10) coated tablets in a blister (PVC/PVDC/AI), supplied in a box		YES	YES								
Endoxan 1 g powder for solution for injection	powder for injection solution (for intravenous use)	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Powder for solution for injection in a glass bottle, supplied in a box		YES	YES								
Endoxan 200 mg powder for solution for injection	powder for solution for intravenous injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Powder for solution for injection in a glass bottle, supplied in a box		YES	YES								
Endoxan powder for injection solution 500 mg	powder for solution for intravenous injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Powder for solution for injection in a glass bottle, supplied in a box		YES	YES								
Engerix-B Dosis Adulta; recombinant hepatitis B vaccine for adults	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with one pre-filled syringe with 1 mL of vaccine, needle and needle protection		YES							YES		
Engerix-B Dosis Adulta; recombinant hepatitis B vaccine for adults	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with 25 glass bottles with 1 mL of vaccine		YES							YES		
Engerix-B Dosis Paediatrica; recombinant hepatitis B vaccine for children	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with 25 glass bottles with 0.5 mL of vaccine		YES							YES		
Engerix-B Dosis Paediatrica; recombinant hepatitis B vaccine for children	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with one pre-filled syringe with 0.5 mL of vaccine, needle and needle protection		YES							YES		
Epiramat tablets 100 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/AI/PVC//AI blister, supplied in a box	YES		YES								
Epiramat tablets 200 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/AI/PVC//AI blister, supplied in a box	YES		YES								
Epiramat tablets 25 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/AI/PVC//AI blister, supplied in a box	YES		YES								
Epiramat tablets 50 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/AI/PVC//AI blister, supplied in a box	YES		YES								
Epirubicin Ebewe 10 mg/5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution for infusion concentrate in a glass bottle (with a rubber stopper), supplied in a box		YES	YES								

Epirubicin Ebewe 100 mg/50 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	50 mL of solution for infusion concentrate in a glass bottle (with a rubber stopper), supplied in a box		YES		YES					
Epirubicin Ebewe 50 mg/ 25 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	25 mL of infusion solution concentrate in a glass bottle (with rubber stopper), supplied in a box		YES		YES					
Epivir tablets 150 mg	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	60 tablets in a polyethylene bottle, supplied in a box		YES	YES						
Epoetin injection 2000 IU/mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One ampoule in a box	YES		YES						
Epoetin injection 4000 IU/mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One ampoule in a box	YES		YES						
Eprex 10 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 bottles with rubber stoppers containing 1.0 mL of solution for injection, in protective packaging, supplied in a box		YES	YES		YES	YES			
Eprex 10 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 syringes with a needle (disposable) with 1.0 mL of solution, in protective packaging, supplied in a box		YES	YES		YES	YES			
Eprex 2 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 syringes with a needle (disposable) with 0.5 mL of solution, in protective packaging, supplied in a box		YES	YES		YES	YES			
Eprex 20 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	Pre-filled disposable syringe containing 0.5 mL of solution for injection in a protective container, supplied in a box		YES	YES		YES	YES			
Eprex 3 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 syringes with a needle (disposable) with 0.3 mL of solution, in protective packaging, supplied in a box		YES	YES		YES	YES			
Eprex 4 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 syringes with a needle (disposable) with 0.4 mL of solution, in protective packaging, supplied in a box		YES	YES		YES	YES			
Eprex 40 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	Vial containing 1 mL of solution for injection, with rubber stopper, in a protective container, supplied in a box		YES	YES		YES	YES			
Eprex 40 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	Pre-filled disposable syringe containing 1.0 mL of solution for injection in a protective container, supplied in a box		YES	YES		YES	YES			
Equoral 100 mg	soft capsules	IVAX-Pharmaceuticals s.r.o., Ostravská 29, Opava - Komarov, Czech Republic	50 (5x10) capsules in an Al/Al blister, supplied in a carton box		YES		YES					
Equoral 25 mg	soft capsules	IVAX-Pharmaceuticals s.r.o., Ostravská 29, Opava - Komarov, Czech Republic	50 (5x10) capsules in an Al/Al blister, supplied in a carton box		YES		YES					
Equoral 50 mg	soft capsules	IVAX-Pharmaceuticals s.r.o., Ostravská 29, Opava - Komarov, Czech Republic	50 (5x10) capsules in an Al/Al blister, supplied in a carton box		YES		YES					
Equoral solution	oral solution	IVAX-Pharmaceuticals s.r.o., Ostravská 29, Opava - Komarov, Czech Republic	50 mL of solution in an amber glass bottle in a protective container, 1 plastic syringe of 4 mL, 1 plastic pipe for extraction of bottle content in a protective plastic container and 1 plastic temper-evident screw cap, supplied in a carton box		YES		YES					

ERAZON capsules 10 mg	capsules, hard	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	20 (2x10) capsules in a blister (PVC - Al), supplied in a box	YES			YES					
ERAZON capsules 20 mg	capsules, hard	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	20 (2x10) capsules in a blister (PVC - Al), supplied in a box	YES			YES					
ERAZON suppositories	suppositories	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	10 (2x5) suppositories in a strip, supplied in a box	YES			YES					
Erbitux 2 mg/mL solution for infusion	solution for infusion	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	50 mL of solution in a glass bottle, supplied in a box		YES	YES		YES				
Ergometrin Lek 0.2 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 film coated tablets in an amber glass bottle, supplied in a box		YES		YES					
Ergometrin Lek 0.2 mg/mL solution for injection	solution for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 ampoules with 1 mL of solution, supplied in a carton box		YES		YES					
Eritromicin 250 mg capsules	capsules	Belupo, liječkovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	16 (1x16) capsules in a blister, supplied in a box	YES			YES					
Esberitox N tablets	tablets	Schaper & Brümmer GmbH & Co. KG, Salzgitter, Germany	50 (5x10) tablets in a blister (PVC/PVDC/Al), supplied in a box		YES					YES	YES	
Esmeron	solution for injection (for intravenous use)	N.V. Organon, Oss, The Netherlands	10 mL of solution for injection in a glass bottle with rubber stopper, 10 glass bottles in a box		YES	YES						
Esmeron	solution for injection (for intravenous use)	N.V. Organon, Oss, the Netherlands; ORGANON S.A., Usine Saint Charles, France	5 mL of solution for injection in a glass bottle with a rubber stopper, 12 glass bottles in a box		YES	YES						
Espumisan	capsules, soft	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	25 (1x25) capsules in a PVC/Al blister, supplied in a box		YES		YES			YES		
Estracomb TTS	transdermal patch	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	4 transdermal patches Estraderm TTS 50 and 4 transdermal patches Estragest TTS 250/50 (individually packed in a protective Surlyn/Al bag), supplied in a box		YES	YES						
Estracyt	capsules	Pliva Croatia Ltd., Zagreb, Republic of Croatia in cooperation with Pharmacia & Upjohn S.p.A., Milano, Italy	40 capsules in an amber glass bottle, supplied in a box	YES			YES					
Estraderm TTS 100	transdermal patch	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	6 (3x2) transdermal patches (individually packed in a protective Surlyn/Al bag), supplied in a box		YES	YES						
Estraderm TTS 25	patch	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	6 (3x2) transdermal patches (individually packed in a protective Surlyn/Al bag), supplied in a box		YES	YES						
Estraderm TTS 50	transdermal patch	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	6 (3x2) transdermal patches (individually packed in a protective Surlyn/Al bag), supplied in a box		YES	YES						
Estrofem 1 mg	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 tablets in a plastic calendar pack (dispenser with marked days of the week), supplied in a box		YES	YES			YES			

Estrofem 2 mg	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark	28 tablets in a plastic calendar dial pack (dispenser with marked days of the week), supplied in a box		YES	YES			YES		
Etambutol 400 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 tablets in an amber glass bottle, supplied in a box	YES			YES				
Etambutol Alkaloid	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	100 tablets in an amber glass bottle, supplied in a box		YES		YES				
ETOPOSIDE EBEWE 100 mg/5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution concentrate in an amber glass bottle (with a rubber stopper), supplied in a carton box		YES		YES				
ETOPOSIDE EBEWE 1000 mg/50 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	50 mL of solution concentrate in an amber glass bottle (with a rubber stopper), supplied in a carton box		YES		YES				
ETOPOSIDE EBEWE 200 mg/10 mL	solution concentrate for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	10 mL of concentrate in an amber glass bottle (with rubber stopper), supplied in a carton box		YES		YES				
ETOPOSIDE EBEWE 50 mg/2.5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	2.5 mL of solution concentrate in an amber glass bottle (with rubber stopper), supplied in a carton box		YES		YES				
EURAX emulsion	emulsion for application on skin	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	50 mL of emulsion in an amber glass bottle with a plastic measuring insert and a plastic stopper, supplied in a box		YES		YES			YES	
EURAX cream	cream	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	20 grams of cream in an aluminum tube with plastic cap, supplied in a box		YES		YES			YES	
Ethyrox 100 tablets	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	100 (4X25) tablets in a blister, supplied in a box		YES	YES					
Ethyrox 150 tablets	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	100 (4X25) tablets in a blister, supplied in a box		YES	YES					
Ethyrox 25 tablets	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	100 (4X25) tablets in a blister, supplied in a box		YES	YES					
Ethyrox 50 tablets	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	100 (4X25) tablets in a blister, supplied in a box		YES	YES					
Evista 60 mg film coated tablets	film coated tablets	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain	28 (2x14) film coated tablets in a blister (PVC/PE/Aclar//AI), supplied in a box		YES	YES			YES		
Evra transdermal patch	transdermal patch	Janssen Pharmaceutica NV, Turnhoutseweg 30, Beerse, Belgium	9 patches individually packaged in protective sachets (paper/LDPE/AI-foil/LDPE), wrapped à 3 in a transparent plastic bag, supplied in a box		YES	YES					
Evra transdermal patch	transdermal patch	Janssen Pharmaceutica NV, Turnhoutseweg 30, Beerse, Belgium	3 patches individually packaged in protective bags (paper/LDPE/AI-foil/LDPE) inserted in a common transparent plastic bag, supplied in a box		YES	YES					
Exforge 5 mg/160 mg film coated tablets	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (2x14) tablets in a blister (PVC/PVDC//AI), supplied in a box		YES	YES		YES	YES		
Exforge 5 mg/80 mg film coated tablets	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (2x14) tablets in a blister (PVC/PVDC//AI), supplied in a box		YES	YES		YES	YES		

EXJADE 125 mg tablets for oral suspension	tablets for oral suspension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES			
EXJADE 250 mg tablets for oral suspension	tablets for oral suspension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES			
EXJADE 500 mg tablets for oral suspension	tablets for oral suspension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES			
Extraneal	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	4 plastic (PVC) Viaflex bags with 2500 mL of solution, a supply/drain pipe (PVC), a connector with a protective cap, an attachment for drug administration, and a collective plastic Viaflex bag (individual packaging in a protective plastic bag), supplied in a box		YES		YES		YES			
Extraneal	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5 plastic (PVC) Viaflex bags with 2000 mL of solution, a supply/drain pipe (PVC), a connector with a safety cap, a dispensing unit and a collective plastic Viaflex bag (individual packaging in a protective plastic bag), supplied in a box		YES		YES		YES			
Extraneal	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5 plastic (PVC) Viaflex bags with 2000 mL of solution, with a connector with a safety cap and a dispensing unit (individual packaging in a protective plastic bag), supplied in a box		YES		YES		YES			
Ezetrol 10 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in an Aclar/PVC/Al blister, supplied in a box		YES	YES			YES			
Fabrazyme 35 mg	powder for concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial containing powder for concentrate, supplied in a box		YES	YES			YES			YES
Fabrazyme 5 mg	powder for concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial containing powder for concentrate, supplied in a box		YES	YES			YES			YES
Faktu suppositories	suppositories	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	10 (2x5) suppositories in a PVC/PE strip, supplied in a box		YES		YES					
Faktu ointment	ointment	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	20 grams of ointment in an aluminum tube and an applicator for rectal use, supplied in a box		YES		YES					
Famosan 20 mg	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	20 (1x20) tablets in a blister, supplied in a box		YES		YES					
Famosan 40 mg	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (1x10) tablets in a blister, supplied in a box		YES		YES					
Farmorubicin PFS 10 mg injection (2 mg/mL)	solution for intravenous and intravesical use	Pfizer Italia s.r.l., Viale Pasteur 10, Nerviano Plant, Milano, Italy	Box with a bottle with 5 mL of solution		YES		YES					
Farmorubicin PFS 50 mg injection (2 mg/mL)	solution for intravenous and intravesical use	Pfizer Italia s.r.l., Viale Pasteur 10, Nerviano Plant, Milano, Italy	Box with a bottle with 25 mL of solution		YES		YES					

Faslodex 250 mg/5 mL solution for injection	solution for injection (in a pre-filled syringe)	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	One glass syringe with 5 mL of solution, with child resistant closure, in a plastic container, supplied in a box		YES	YES		YES	YES			
Fastum Gel	gel	A. Menarini Manufacturing Logistic and Services S.r.l., Firenca, Italy	20 grams of gel in an aluminum tube with plastic cap, supplied in a box		YES		YES			YES		
Favora Eusin drops	drops, solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Amber glass bottle (10 mL) with a plastic screw cap and a dropper, supplied in a box	YES						YES	YES	
Favora Fitolax powder	powder	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	200 grams of powder in a PP vessel with PE cap and measuring spoon, supplied in a box	YES						YES	YES	
Favora Orasept lozenges	lozenges	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) lozenges in a blister, supplied in a box	YES						YES	YES	
Favora Urosal capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (2x25) capsules in a blister, supplied in a box	YES						YES	YES	
Feiba TIM 4 immuno 1000 FJ	lyophilisate for preparation of intravenous solutions	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with a bottle with lyophilisate, bottle with 20 mL of water for injection and dissolution and injection kit		YES							YES
Feiba TIM 4 immuno 500 FJ	lyophilisate for preparation of intravenous solutions	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with a bottle with lyophilisate, bottle with 20 mL of water for injection and dissolution and injection kit		YES							YES
Femara 2.5 mg film-tablets	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	30 (3x10) tablets in a PVC/PE/PVDC/Al blister, supplied in a box		YES	YES				YES		
Femoston 1/10	film coated tablets	Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA Olst, the Netherlands	28 (1x28) tablets (14 white and 14 grey) in a blister, supplied in a box		YES	YES						
Femoston 2/10	film coated tablets	Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA Olst, the Netherlands	28 (1x28) tablets (14 pink and 14 yellow) in a blister, supplied in a box		YES	YES						
Femoston Conti 1/5	film coated tablets	Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA Olst, the Netherlands	28 (1x28) tablets in a blister, supplied in a box		YES	YES						
Fenistil 0.1% oral drops	oral drops (solution)	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	20 mL of solution in an amber glass bottle with a polyethylene dropper and a polypropylene cap, supplied in a box		YES	YES						
Fenistil gel	gel	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	Al tube with 30 g of gel with a polyethylene cap, supplied in a box		YES	YES						
Fentanyl M Lek 100 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES					
Fentanyl M Lek 25 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES					
Fentanyl M Lek 50 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES					
Fentanyl R Lek 100 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES					
Fentanyl R Lek 25 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES					

Fentanyl R Lek 50 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES					
FENTANYL injection	solution for intravenous injection	Janssen Pharmaceutica NV, Turnhoutseweg 30, Beerse, Belgium	50 ampoules with 10 mL of solution for injection, supplied in a box		YES	YES						
FENTANYL injection	solution for intravenous injection	Janssen Pharmaceutica NV, Turnhoutseweg 30, Beerse, Belgium	50 ampoules with 2 mL of solution for injection, supplied in a box		YES	YES						
Ferrum Lek 100 mg chewing tablets	chewing tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3x10) chewable tablets in a strip, supplied in a box		YES		YES					
Ferrum Lek 50 mg/5 mL syrup	syrup	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	100 mL of syrup in an amber glass bottle and a measuring spoon, supplied in a box		YES		YES					
FERVEX	granules for oral solution	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrénées, Le Passage, France	8 bags each with 13.100 g of granules, supplied in a box		YES		YES		YES			
FERVEX sugar-free	granules for oral solution	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrénées, Le Passage, France	8 bags each with 4.950 g of granules, supplied in a box		YES		YES		YES			
FERVEX for children	granules for oral solution	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrénées, Le Passage, France	8 bags each with 3.0 g of granules, supplied in a box		YES		YES		YES			
Fevarin	film coated tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands Solvay Pharmaceuticals S.A.S., Châtillon sur Chalaronne, France	15 (1x15) film coated tablets in PVC/PVDC/Al blister, supplied in a box		YES	YES						
FINCAR 5 mg	film coated tablets	Cipla Ltd, Bangalore, India	28 (2x14) tablets in a blister (PVC/PVDC/Al), supplied in a box		YES		YES					
Flixonase nasal spray	water suspension	Glaxo Wellcome S.A., Aranda de Duero, Burgos, Spain	120 doses of suspension in a glass bottle with plastic dispenser, supplied in a box		YES	YES						
Flixotide 100 Diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Vel. Britanija; Glaxo Wellcome Production, Evreux, France	60 doses of powder in an aluminium blister, in a plastic housing, supplied in a box		YES	YES						
Flixotide 125 Inhaler	inhalation aerosol	GlaxoSmithKline Pharmaceuticals SA, poznan, Poland; Glaxo Wellcome Production, Evreux, France	Aluminium container with a plastic mouthpiece containing 60 doses		YES	YES						
Flixotide 250 Diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Vel. Britanija; Glaxo Wellcome Production, Evreux, France	60 doses of powder in an aluminium blister, in a plastic housing, supplied in a box		YES	YES						
Flixotide 250 Inhaler	inhalation aerosol	GlaxoSmithKline Pharmaceuticals SA, Poznan, Poland; Glaxo Wellcome Production, Evreux, France	Aluminium container with a plastic mouthpiece containing 60 doses		YES	YES						

Flixotide 50 Inhaler	inhalation aerosol	GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Poland	120 doses (not less than 10.0 g of suspension) in an aluminum container with metering valve in a plastic nebulizer, supplied in a box		YES	YES						
Flixotide 500 Diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Vel. Britanija; Glaxo Wellcome Production, Evreux, France	60 doses of powder in an aluminium blister, in a plastic housing, supplied in a box		YES	YES						
Flonidan 10 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 (1x10 ) tablets in a blister, suplied in a box		YES	YES						
Flonidan 5mg/5mL suspension	oral suspension	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	120 mL of solution in an amber glass bottle and plastic spoon, supplied in a box		YES	YES						
Flosteron suspension for injections	suspension for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 ampoules each with 1 mL of suspension, supplied in a box		YES	YES						
Fluacet gel	gel	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 g of gel in an aluminium tube, supplied in a box	YES		YES						
Fluad MF59C,1 adjuvanted vaccine against influenza in ready-to-use syringe, inactivated (surface antigens)	suspension for injection in pre-filled syringe	Novartis Vaccines & Diagnostics S.r.l., Siena, Italy and Imunološki zavod d.d., Zagreb, Republic of Croatia	Pre-filled syringe with a needle containing 0.5 mL of suspension, supplied in a box	YES								YES
Fluarix vaccine against influenza, inactivated, fragmented (without preservative)	suspension for injections	Sächsisches Serumwerk Dresden NL der SmithKline Beecham Pharma GmbH & Co. KG, Germany	Box with 1 glass syringe with a needle containing 1 dose of vaccine of 0.5 mL	YES								YES
Flucinom tablets 250 mg	tablets	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	100 (10x10) tablets in an orange (PVC/AI) blister, supplied in a box	YES	YES							
Fluconax 100 mg capsules	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	7 (1x7) capsules in (PVC/PVDC/AI) blister, supplied in a box	YES		YES						
Fluconax 150 mg capsules	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	One capsule in a PVC/PVDC/AI blister, supplied in a box	YES		YES						
Fluconax 200 mg capsules	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	7 (1x7) capsules in (PVC/PVDC/AI) blister, supplied in a box	YES		YES						
Fluconax 2mg/1mL solution for intravenous infusion	solution for intravenous infusion	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	100 mL of solution in a glass bottle for infusion and a plastic bottle holder, supplied in a box	YES		YES						
Fluconax 50 mg capsules	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	7 (1x7) capsules in (PVC/PVDC/AI) blister, supplied in a box	YES		YES						
Fludara	powder for solution for injection or infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	5 glass bottles with powder, supplied in a box	YES	YES							
Fludara oral 10 mg film coated tablets	film coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	20 (4x5) tablets in a blister (PA/AI/PP/AI) in a 150 mL plastic (HDPE) bottle with a plastic child resistant closure	YES	YES							YES
Fluimukan 100 mg granules for oral solution	granules for oral solution	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 bags each containing 5 g of granules, supplied in a box	YES		YES						YES
Fluimukan 200 mg granules for oral solution	granules for oral solution	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 bags with à 5 grams of granules, supplied in a box	YES		YES						YES

FLUIMUN, vaccine against influenza (surface antigen, inactivated)	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass vial containing 0.5 mL of suspension for injection, plastic syringe, needle for drawing suspension from the bottle (21Gx1", inch) and one needle for drug administration (23Gx1 inch or 25Gx1 inch or 25Gx5/8 inch), supplied in a box	YES									YES
FLUONATRIL 0.25 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	400 tablets in a plastic (PP) bottle with a stopper, supplied in a box	YES			YES						
FLUONATRIL 1 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	250 tablets in a plastic (PP) bottle with a cap, supplied in a box	YES			YES						
Fluorouracil Pliva injection 250 mg/5 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials each containing 5 mL of solution, supplied in a box	YES			YES						
Fluorouracil Pliva injection 500 mg/10 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One glass vial with 10 mL of solution, supplied in a box	YES			YES						
Fluval capsules 20 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 (2x7) capsules in a blister (PVC/PVDC//Al), supplied in a box		YES		YES						
Fluzepam capsules 15 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) capsules in a blister, supplied in a box		YES		YES						
Fluzepam capsules 30 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) capsules in a blister, supplied in a box		YES		YES						
Folacin	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 tablets in a PE vial, supplied in a carton box	YES			YES						
Forane	inhalation liquid	Abbott Laboratories Ltd, Queenborough, Great Britain	Box with 100 mL of liquid in an amber glass bottle		YES	YES							
Forteo 20 micrograms/80 microliters, solution for injection in a pre-filled pen-injector	solution for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	Pen-injector containing 3 mL of solution (750 µg teriparatide) in a glass cartridge		YES	YES							
Fortral solution for injection 30 mg/1 mL	solution for injection	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Sanofi, France	10 ampoules each containing 1 mL of solution, supplied in a box		YES		YES						
Fortral tablets 50 mg	tablets	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Sanofi, France	100 tablets in an amber glass bottle, supplied in a box		YES		YES						
Fortrans powder for oral solution	powder for oral solution	Beaufor Ipsen Industrie, Dreux, France	4 bags (LDPE/Al/paper) each with 73.69 g of powder for oral solution, supplied in a box		YES		YES						
Fortzaar	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	31 (2x14) film coated tablets in a blister, supplied in a carton box		YES	YES							
Fosamax T	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Box with 4 tablets (blister, 1 x 4 tbl.)		YES	YES				YES			
Fosavance tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	4 (1x4) tablets in a blister (Al/Al) in a carton casing (with a leaflet), supplied in a box		YES	YES				YES			

Fraxiparine 2850 IU AXa/0.3 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 0.3 mL of solution		YES	YES						
Fraxiparine 3800 IU AXa/0.4 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 0.4 mL of solution		YES	YES						
Fraxiparine 5700 IU AXa/0.6 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 0.6 mL of solution		YES	YES						
Fraxiparine 7600 IU AXa/0.8 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 0.8 mL of solution		YES	YES						
Fraxiparine 9500 IU AXa/1 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 1 mL of solution		YES	YES						
Fromilid 250 tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 tablets (2x7) in A/PVC/PVDC blister, supplied in a box		YES	YES						
Fromilid 500 tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 tablets (2x7) in A/PVC/PVDC blister, supplied in a box		YES	YES						
Fromilid 125 mg/5 mL granules for oral suspension	granules for oral suspension	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	25 grams of granules for the preparation of 60 mL of oral suspension in a glass bottle and a 5 mL plastic syringe for oral dose delivery, supplied in a box		YES	YES						
Fromilid uno prolonged-release tablets 500 mg	prolonged-release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 (2x7) tablets in a PVC/PVDC//AI blister, supplied in a box		YES	YES						
Fromilid uno 500 mg tablets with prolonged release	prolonged release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 (1x5) tablets in a PVC/PVDC//AI blister, supplied in a box		YES	YES						
FSME Immun inject, inactivated vaccine against viral tick-borne meningoencephalitis	intramuscular suspension	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with 1 pre-filled syringe with 1 dose of vaccine (0.5 mL susp), with a needle		YES							YES
FSME-IMMUN 0.25 mL Junior	suspension for injection	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Pre-filled syringe with needle containing one 0.25 mL of vaccine dose, supplied in a box		YES							YES
Funzol capsules 100 mg	capsules	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	7 (1x7) capsules in (PVC/PVDC/AI) blister, supplied in a box		YES	YES						
Funzol capsules 150 mg	capsules	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	One (1x1) capsule in a PVC/PVDC/AI blister supplied in a box		YES	YES						
Funzol capsules 50 mg	capsules	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	7 (1x7) capsules in (PVC/PVDC/AI) blister, supplied in a box		YES	YES						
Fursemid 20 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 ampoules each with 2 mL of solution in a plastic holder, supplied in a box	YES		YES						
Fursemid 40 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	12 (1x12) tablets in a blister, supplied in a box	YES		YES						
Fursemid 40 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a blister, supplied in a box	YES		YES						

Fursemid forte 500 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (2x10) tablets in PVC/AI blister, supplied in a box	YES		YES						
Gabalept capsules 100 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) capsules in a blister, supplied in a box	YES		YES						
Gabalept capsules 300 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 (5x10) capsules in a blister, supplied in a box	YES		YES						
Gabalept capsules 400 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 (5x10) capsules in a blister, supplied in a box	YES		YES						
Gadovist 1.0 mmol/mL injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	7.5 mL of solution in a glass syringe, 5 syringes individually packed in a blister, supplied in a box		YES	YES			YES			
Gadovist 1.0 mmol/mL solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	15 mL of solution in a glass bottle, 10 bottles in a box		YES	YES			YES			
Gammagard S/D 10 g	lyophilisate and solvent for preparation of solution for intravenous infusion	Baxter S.A, Hyland Immuno, Lessines, Belgium	Bottle with lyophilisate, bottle with 192 mL of diluent, sterile set for lyophilisate dissolution, and sterile application kit used with a filter, supplied in a box		YES							YES
Gammagard S/D 2.5 g	lyophilisate and diluent for preparation of solution for intravenous infusion	Baxter S.A, Hyland Immuno, Lessines, Belgium	Bottle with lyophilisate, bottle with 50 mL of diluent, sterile kit for lyophilisate reconstitution, and one sterile kit for use with filter, supplied in a box		YES							YES
Gammagard S/D 5 g	lyophilisate and diluent for preparation of solution for intravenous infusion	Baxter S.A, Hyland Immuno, Lessines, Belgium	Bottle with lyophilisate, bottle with 96 mL of diluent, sterile kit for lyophilisate reconstitution, and sterile kit for use with filter, supplied in a box		YES							YES
GANFORT eye drops	eye drops, solution	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	3 mL of solution in a 5 mL plastic (LDPE) bottle with dropper attachment and plastic (HDPE) temper-proof closure, 1 bottle in a box		YES	YES			YES			
Garasone eye/nasal drops	eye/nasal drops	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	5 mL of solution in a plastic (10 mL) bottle with a dropper		YES	YES						
GARDASIL, suspension for injections in a pre-filled syringe, vaccine against human papillomavirus [type 6, 11, 16, 18] (recombinant, absorbed)	suspension for injections in a pre-filled syringe	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Pre-filled glass syringe (glass type I) with 0.5 mL of suspension for injection, a needle with protective mechanism, and two needles, supplied in a box		YES	YES		YES	YES			YES
GARDASIL, suspension for injection, human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, absorbed)	suspension for injection	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Tyle 1 glass ampoule containing 0.5 mL of suspension, supplied in a box		YES	YES		YES	YES			YES
Gastal tablets peppermint	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	24 (4x6) tablets in a blister, supplied in a box	YES		YES			YES			
Gastal tablets spearmint	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	24 (4x6) tablets in a blister, supplied in a box	YES		YES			YES			
Gastal tablets, sour cherry	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	24 (4x6) tablets in a blister, supplied in a box	YES		YES			YES			
Gastrografin solution	solution	Berlimed S.A., Madrid, Spain	100 mL of solution in an amber glass bottle with plastic cap, supplied in a box		YES	YES						

Gemzar 1 g powder for solution for infusion	powder for solution for infusion	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	One glasss vial with lyophilisate, supplied in a box		YES	YES						
Gemzar 200 mg powder for solution for infusion	powder for solution for infusion	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	One glasss vial with lyophilisate, supplied in a box		YES	YES						
Genotropin 5.3 mg	powder and diluent for solution for subcutaneous injection	Pfizer Health AB, Stockholm, Sweden	5 two-part glass cartridges with lyophilisate (front part (I) and solvent (rear part (II)) in a plastic container, supplied in a box		YES	YES						
Gentamicin 120 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin 20 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin 40 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin 80 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin injection 120 mg	solution for injection	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	50 amber glass ampoules each with 2 mL of solution, supplied in a box		YES	YES						
Gentamicin injection 120 mg/2 mL	solution for injection	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	10 ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin injection 40 mg	solution for injection	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	50 amber glass ampoules each with 2 mL of solution, supplied in a box		YES	YES						
Gentamicin injection 40 mg/2 mL	solution for injection	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	10 ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin injection 80 mg	solution for injection	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	50 amber glass ampoules each with 2 mL of solution, supplied in a box		YES	YES						
Gentamicin injection 80 mg/2 mL	solution for injection	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	10 ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin Jadran 120	solution for injection	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 amber glass ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin Jadran 40	solution for injection	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 amber glass ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Gentamicin Jadran 80	solution for injection	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 amber glass ampoules each containing 2 mL of solution, supplied in a box	YES		YES						
Geokorton ointment 20 g	ointment	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Aluminium tube with 20 g of ointment, supplied in a box	YES		YES						

Geomycin	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	16 (2x8) capsules in a PVC/Al blister, supplied in a box	YES			YES					
Geonistin	vaginal tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 (2x3) tablets in a blister (PVC/Al), supplied in a box	YES			YES					
Ginkgo film-tablets	film coated tablets	Belupo, liječkovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES					YES	YES		
Glibenclamid Genericon 3.5 mg tablets	tablets	Genericon Pharma Ges.m.b.H, Lannach, Austria	30 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES					
Glibenclamid Genericon 3.5 mg tablets	tablets	Genericon Pharma Ges.m.b.H, Lannach, Austria	120 (12x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES					
Glivec 100 mg film coated tablets	film coated tablets	Novartis Pharma GmbH, Nurnberg, Germany	60 (6x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES			
Glivec 100 mg capsules	hard capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	120 (10x12) capsules in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES			
Glivec 100 mg capsules	capsules	Novartis Pharma A.G., Basel, Switzerland	120 (10x12) capsules in a blister, supplied in a box		YES	YES		YES	YES			
Glivec 400 mg film coated tablets	film coated tablets	Novartis Pharma GmbH, Nurnberg, Germany	30 (3x10) tablets in a PVC/PE/PVDC/Al blister, supplied in a box		YES	YES		YES	YES			
Glivec 50 mg capsules	capsules	Novartis Pharma A.G., Basel, Switzerland	30 (3x10) capsules in a blister, supplied in a box		YES	YES		YES	YES			
Glivec 50 mg capsules	hard capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	30 (3x10) capsules in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES			
GlucaGen HypoKit	powder and diluent for solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with lyophilisate and one glass syringe with needle (1 mL of diluent), in a plastic container		YES	YES						
Glucobay 100 mg tablets	tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 tablets (2x15) in a blister (polypropylene/Al), supplied in a box		YES	YES						
Glucobay 50 mg tablets	tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	32 (2x15) capsules in a PVC/Al blister, supplied in a box		YES	YES						
Glucomerck 1000 mg film coated tablets	film coated tablets	Merck SANTE s.a.s., Centre de Production de Semoy, 2 Rue du Pressior Vert - 45400 Semoy, France; Merck KGaA, Frankfurt Strasse 250, 64293 Darmstadt, Germany	60 (4x15) film coated tablets in a transparent blister (PVC/Al), supplied in a box		YES	YES						
Glucomerck 500 mg film coated tablets	film coated tablets	Merck SANTE s.a.s., Centre de Production de Semoy, 2 Rue du Pressior Vert - 45400 Semoy, France; Merck KGaA, Frankfurt Strasse 250, 64293 Darmstadt, Germany	100 (5x20) film coated tablets in transparent blister (PVC/Al), supplied in a box		YES	YES						
Glucomerck 850 mg film coated tablets	film coated tablets	Merck SANTE s.a.s., Centre de Production de Semoy, 2 Rue du Pressior Vert - 45400 Semoy, France; Merck KGaA, Frankfurt Strasse 250, 64293 Darmstadt,	30 (2x15) film coated tablets in a transparent PVC/Al blister, supplied in a box		YES	YES						

		Germany									
Glucophage 1000 mg film coated tablets	film coated tablets	Merck SANTE s.a.s./Centre de Production de Semoy, France Merck KGaA, Germany	30 (3x10) film coated tablets in a transparent blister (PVC/A1), supplied in a box		YES	YES		YES	YES		
Glucophage 500 mg film coated tablets	film coated tablets	Merck SANTE s.a.s./Centre de Production de Semoy, France Merck KGaA, Germany	50 (5x10) film coated tablets in a transparent blister (PVC/A1), supplied in a box		YES	YES		YES	YES		
Glucophage 850 mg tablets	film coated tablets	Merck Sante s.a.s., Lyon CEDEX 08, France	30 (2x15) tablets in a blister, supplied in a box		YES	YES		YES	YES		
Glucovance 500 mg/ 2.5 mg tablets	film coated tablets	Merck SANTE s.a.s., 2 Rue du Pressoir Vert - 45400 Semoy, France	30 (2x15) tablets in a blister (PVC/A1), supplied in a box		YES	YES					
Glucovance 500 mg/ 5 mg tablets	film coated tablets	Merck SANTE s.a.s., 2 Rue du Pressoir Vert - 45400 Semoy, France	30 (2x15) tablets in a PVC/A1 blister, supplied in a box		YES	YES					
Gluformin 850 mg tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	35 (3x10) tablets in a PVC/PVdC/AI blister, supplied in a box	YES			YES				
Gluformin tablets1g	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (2x15) tablets in a PVC/AI blister, supplied in a box	YES			YES				
Glukosalina I solution, 100mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of solution in an infusion bottle with rubber stopper protected by AI cap and plastic lid, 10 bottles with holders in a carton box	YES			YES				
Glukosalina I solution for intravenous infusion, 250mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	250-mL of solution in an infusion bottle with rubber stopper and protective AI cap with plastic lid (10 bottles with holders, supplied in a carton box)	YES			YES				
Glukosalina I solution for intravenous infusion, 500mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of solution in an infusion bottle with a rubber stopper and an aluminium cap with a plastic lid (10 bottles with holders, supplied in a carton box)	YES			YES				
Glukosalina III solution for intravenous infusion	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of solution in an infusion bottle with a rubber stopper and an aluminium cap with a plastic lid (10 bottles with holders, supplied in a carton box)	YES			YES				
Glucose 10% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES		YES				
Glucose 10% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	1000 mL of infusion solution in a plastic bottle (10 bottles in a box)		YES		YES				
Glucose 10% solution for intravenous infusion, 100 mL	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of solution in a glass bottle	YES			YES				
Glucose 10% solution for intravenous infusion, 250 mL	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	250-mL of solution in a glass bottle	YES			YES				
Glucose 10% solution for intravenous infusion, 500 mL	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of solution in a glass bottle	YES			YES				

Glucose 10% Pliva solution for infusion	solution for intravenous infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	12 PVC bags with 500 mL of solution, supplied in a box	YES		YES						
Glucose 10% Pliva solution for infusion 250 mL	solution for intravenous infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	250-mL of solution in a glass infusion bottle with rubber stopper and combi-cap (10 bottles with polyethylene holder supplied in a box)	YES		YES						
Glucose 10% Pliva solution for infusion 500mL	solution for intravenous infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials with 500 mL of solution, supplied in a box	YES		YES						
Glucose 5 %, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	30 plastic Viaflo bags with 250 mL of solution for infusion in a protective bag, supplied in a box		YES	YES						
Glucose 5 % Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	10 plastic Viaflo bags with sa 1000 mL of infusion solution, in a protective bag, supplied in a box		YES	YES						
Glukose 5 %, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	50 plastic Viaflo bags with 50 mL of solution for infusion in a protective bag, supplied in a box		YES	YES						
Glucose 5 %, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	50 plastic bags Viaflo with 100 mL of solution for infusion, in a protective bag, supplied in a box		YES	YES						
Glucose 5 % Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	20 plastic Viaflo bags with 500 mL of infusion solution, in a protective bag, supplied in a box		YES	YES						
Glucose 5%	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of solution in a glass bottle	YES		YES						
Glucose 5%	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of solution in a glass bottle	YES		YES						
Glucose 5%	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	250-mL of solution in a glass bottle	YES		YES						
Glucose 5% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	1000 mL of infusion solution in a plastic bottle (10 bottles in a box)		YES	YES						
Glucose 5% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	250-mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES	YES						
Glucose 5% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES	YES						
Glucose 5% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	100 mL of infusion solution in a plastic bottle (20 bottles in a box)		YES	YES						
Glucose 5% Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution in a PVC bag, with a draining attachment (closed with combiflack stopper) and an application attachment, 12 bags in a box	YES		YES						

Glucose 5% Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution in a glass infusion bottle with a rubber stopper and a protective cap, 10 bottles in a box	YES			YES					
Glurenorm 30 mg tablets	tablets	Boehringer Ingelheim Ellas A.E., Atena, Greece	60 (6x10) tablets in a white blister (PVC/PVDC//Al), supplied in a box	YES	YES							
GONAL-f 1050 IU/1.75 mL	powder and diluent (in a syringe) for solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and syringe with 2 mL of diluent, supplied in a box	YES	YES			YES				
GONAL-f 300 IU/0.5 mL	solution for injection in pen syringe	Industria Farmaceutica Serono S.p.A., Bari, Italy	Pen-syringe with 0.5 mL of solution (in a 3-mL glass cartridge) and 5 needles in a plastic container, supplied in a box	YES	YES			YES				
GONAL-f 450 IU/0.75 mL	powder and diluent (in a syringe) for solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and syringe with 1 mL of diluent, supplied in a box	YES	YES			YES				
GONAL-f 450 IU/0.75 mL	solution for injection in pen syringe	Industria Farmaceutica Serono S.p.A., Bari, Italy	Pen-syringe with 0.75 mL of solution (in a 3-mL glass cartridge) and 7 needles in a plastic container, supplied in a box	YES	YES			YES				
GONAL-f 75 IU	powder and diluent (in a syringe) for solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and syringe with 1 mL of diluent in a plastic container, supplied in a box	YES	YES			YES				
GONAL-f 900 IU/1.5 mL	solution for injection in pen syringe	Industria Farmaceutica Serono S.p.A., Bari, Italy	Pen syringe with 1.5 mL of solution (in a 3-mL glass cartridge) and 14 needles in a plastic container, supplied in a box	YES	YES			YES				
Gopten 0.5 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) capsules in a blister, supplied in a box	YES	YES							
Gopten 2 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) capsules in a blister, supplied in a box	YES	YES							
Gopten 4 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) capsules in a blister, supplied in a box	YES	YES							
Grippostad C	capsules	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	20 (2x10) capsules in a blister (PVC/PVDC-Al), supplied in a box	YES		YES				YES		
Grippostad Good Night syrup	syrup	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	90 mL of syrup in a glass bottle with a plastic temper-evident stopper (white PP/PE), supplied in a box	YES		YES				YES		
Grippostad hot drink	effervescent powder	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	10 bags (Al/paper/PE) each containing 5.0 g of powder, supplied in a box	YES		YES				YES		
Haemate P 500	powder and diluent for solution for injection/infusion	ZLB Behring GmbH, Emil-von-Behring Str. 76, Marburg, Germany	Glass vial with powder, glass vial with 10 mL of Water for Injection, transfer kit, and disposable filter, supplied in a box	YES								YES
Haldol depo solution for injection 50 mg/1 mL	oily solution for intramuscular injection	Krka d.d., Novo mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	5 brown ampoules (in a blister) each with 1 mL of solution, supplied in a box	YES		YES						
Haldol 10 mg/1 mL oral drops	oral drops	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 mL of solution in an amber glass bottle, supplied in a box	YES		YES						

Haldol oral drops 2 mg/1 mL	oral drops	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	10 mL of solution in an amber glass bottle, supplied in a box		YES	YES						
Haldol solution for injection 5 mg/1 mL	solution for injection for intramuscular and intravenous use	Krka d.d., Novo mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	10 (2x5) ampoules each containing 1 mL solution in a blister, supplied in a box		YES	YES						
Haldol 10 mg tablets	tablets	Krka d.d., Novo mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 tablets in an amber glass bottle, supplied in a box		YES	YES						
Haldol tablets 2 mg	tablets	Krka d.d., Novo Mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	25 tablets in an amber glass bottle, supplied in a carton box		YES	YES						
Halea 100 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) tablets in a blister, supplied in a box	YES		YES						
Halea 50 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) tablets in a blister, supplied in a box	YES		YES						
Heferol	capsules	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 capsules in a bottle, supplied in a box		YES	YES						
Helicobacter test INFAI for infrared spectroscopy	oral powder	INFAI Institut für Biomedizinische Analytik & NMR Imaging GmbH, Bochum, Germany	75 mg of 13 C-urea in a polystyrene container with a closed polyethylene "snap" stopper; equipment for sampling and transfer of samples of expired air (4 glass "vacutainer" test tubes or plastic "vacutette" of 10 mL and 1 flexible straw), inserted in a box		YES	YES		YES				
Helicobacter test INFAI for infrared spectroscopy	powder for preparation of oral solution	INFAI Institut für Biomedizinische Analytik & NMR Imaging GmbH, Bochum, Germany	50 polystyrene jars with polyethylene snap cap containing 75 mg 13C-urea powder for oral solution, with a kit for sampling and transporting of breath samples, 50x2 bags with plastic attachments, and 50x1 bendable plastic straws, supplied in a box		YES	YES		YES				
Helicobacter test INFAI for mass spectrometry	powder for oral solution	INFAI Institut für Biomedizinische Analytik & NMR Imaging GmbH, Bochum, Germany	75 mg of 13 C-urea in a polystyrene container with a closed polyethylene "snap" stopper; equipment for sampling and transfer of samples of expired air (4 glass "vacutainer" test tubes or plastic "vacutette" of 10 mL and 1 flexible straw), inserted in a box		YES	YES		YES				
Hemofil M 250 IU human coagulation factor VIII, monoclonally purified	lyophilisate and solvent for preparation of intravenous solution (injection/infusion)	Baxter S.A., Hyland Immuno, Lessines, Belgium	Glass bottle with lyophilisate and a glass bottle with 10 m of solvent, sterile double dissolution needle, sterile filter needle, sterile mini infusion kit, sterile disposable syringe of 10 mL, supplied in a box		YES							YES
Hemofil M 500 IU human coagulation factor VIII, monoclonally purified	lyophilisate and solvent for preparation of intravenous solution (injection/infusion)	Baxter S.A., Hyland Immuno, Lessines, Belgium	Glass bottle with lyophilisate and a glass bottle with 10 m of solvent, sterile double dissolution needle, sterile filter needle, sterile mini infusion kit, sterile disposable syringe of 10 mL, supplied in a box		YES							YES
Hemofil M 500 IU human coagulation factor VIII, monoclonally purified	lyophilisate and solvent for preparation of intravenous solution (injection/infusion)	Baxter S.A., Hyland Immuno, Lessines, Belgium	Glass bottle with lyophilisate and a glass bottle with 10 m of solvent, sterile double dissolution needle, sterile filter needle, sterile mini infusion kit, sterile disposable syringe of 10 mL,		YES							YES

			supplied in a box								
Hepan gel	gel	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 50 g of gel in an Al tube	YES		YES		YES			
Hepan cream	cream	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 50 g of cream in an Al tube	YES		YES		YES			
HEPARIN injection	solution for injection (for s.c. and i.v. use)	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 mL of solution in a glass bottle (with a rubber stopper and an Al cap), 10 bottles in a box	YES		YES					
Heptanon injection	solution for intramuscular and subcutaneous injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 ampoules with 1 mL of solution, supplied in a box	YES		YES					
Heptanon drops	oral drops, solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 mL of solution in an amber glass bottle with plastic dropper attachment, supplied in a box	YES		YES					
Heptanon solution	oral solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of solution in a 125-mL brown plastic bottle with aluminum cap, supplied in a box	YES		YES					
Heptanon tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES		YES					
HERCEPTIN 150 mg powder for concentrate for solution for infusion	powder for concentrate for solution for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass vial with powder, supplied in a box		YES	YES		YES	YES		
Hermes Cevitt lemon	effervescent powder	Hermes Arzneimittel GmbH, München, Germany	20 effervescent tablets in a polypropylene tube		YES	YES			YES		
Hermes Cevitt naranca	effervescent powder	Hermes Arzneimittel GmbH, München, Germany	20 effervescent tablets in a polypropylene tube		YES	YES			YES		
Herplex 400 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	35 (7x5) tablets in a PVC/Al blister, supplied in a box	YES		YES					
Herplex 400 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	35 (7x5) tablets in a PVC/Al blister, supplied in a box	YES		YES					
Herplex cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	2 grams of cream in a tube, supplied in a box	YES		YES			YES		
Hiberix vaccine against Haemophilus influenzae type B, glycoconjugated	lyophilisate	GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, Rixensart, Belgium	Box with one bottle with 1 dose of lyophilised vaccine and 1 syringe with solvent and 2 needles		YES					YES	
Hiramicin	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 (1x5) capsules in a blister, supplied in a box	YES		YES					
Holyplant Purgal tablets	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES					YES	YES	
Holyplant Sena tea	herbal tea	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	50 g of tea in a polypropylene transparent bag, supplied in a box	YES					YES	YES	
Holyplant Septogal oriblettes	oriblettes	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 (3x10) oriblettes in a PVC/Al blister, supplied in a box	YES		YES			YES		

Humaject M3 (30/70) 100 IU/mL (3.0 mL)	suspension for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 disposable injectors with glass cartridges each with 3 mL of solution, supplied in a box		YES	YES							
Humaject N 100 IU/mL (3.0 mL)	suspension for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 disposable injectors with glass cartridges each with 3 mL of solution, supplied in a box		YES	YES							
Humaject R 100 IU/mL (3.0 mL)	suspension for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 disposable injectors with glass cartridges each with 3 mL of solution, supplied in a box		YES	YES							
Humalog 100 IU/mL cartridge (3.0 mL)	solution for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 cartridges with 3 mL of solution in a blister, supplied in a box		YES	YES							
Humalog Mix25 100 IU/mL (suspension in cartridge 3.0 mL)	suspension for injection	Lilly France S.A.S., Fegersheim, France i Lilly S.A., Alcobendas-Madrid, Spain	5 glass cartridges with 3.0 mL of suspension to be administered with a pen injector, in protective packaging, supplied in a box		YES	YES							
Humalog Mix25 Pen 100 IU/mL	suspension for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge with 3.0 mL of suspension, supplied in a box		YES	YES							
Humalog Mix50 100 IU/mL (suspension in cartridge 3.0 mL)	suspension for injection	Lilly France S.A.S., Fegersheim, France i Lilly S.A., Alcobendas-Madrid, Spain	5 glass cartridges with 3.0 mL of suspension to be administered with a pen injector, in protective packaging, supplied in a box		YES	YES							
Humalog Mix50 Pen 100 IU/mL	suspension for injections	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge each with 3.0 mL of suspension, supplied in a box		YES	YES							
Humalog Pen 100 IU/mL (3 mL)	solution for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge with 3 mL of solution, supplied in a carton box		YES	YES							
Human albumin 20% immuno 50 mL	solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with 1 bottle containing 50 mL of solution		YES								YES
HUMAN ALBUMIN 20% OCTAPHARMA 100 mL	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria and Octapharma SA, Lingolsheim, France	One glass vial with 100 mL of solution for infusion, supplied in a box		YES								YES
Human Albumin 20% Octapharma 100 mL	intravenous solution	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	Paper box with 1 glass bottle with human albumin solution à 100 mL		YES								YES
HUMAN ALBUMIN 20% OCTAPHARMA 50 mL	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria and Octapharma SA, Lingolsheim, France	One glass vial containing 50 mL of solution for infusion, supplied in a box		YES								YES
Human Albumin 20% Octapharma 50 mL	intravenous solution	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	Paper box with 1 glass bottle with human albumin solution à 50 mL		YES								YES
Human albumin 5% immuno 250 mL	solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with 1 bottle containing 250 mL of solution		YES								YES
Human Albumin 5% Octapharma 100 mL	intravenous solution	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	Paper box with 1 glass bottle with human albumin solution à 100 mL		YES								YES
HUMAN ALBUMIN 5% OCTAPHARMA 100 mL	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	One glass vial with 100 mL of solution for infusion, supplied in a box		YES								YES
Human Albumin 5% Octapharma 250 mL	intravenous solution	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	Paper box with 1 glass bottle with human albumin solution à 250 mL		YES								YES

HUMAN ALBUMIN 5% OCTAPHARMA 250 mL	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	One glass vial with 250 mL of solution for infusion, supplied in a box		YES								YES
Humatrop 12 mg	lyophilisate for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	One cartridge with lyophilisate, a syringe with 3.15 mL of diluent and a diluent feed line, supplied in a box		YES	YES							
Humatrop 6 mg	lyophilisate and diluent for solution for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	One cartridge with lyophilisate, a syringe with diluent, and a needle with protective plastic cap, supplied in a box		YES	YES							
Humira solution for injection	solution for injection	Abbott Biotechnology Deutschland GmbH, Max-Planck-Ring 2, Wiesbaden, Germany	Pre-filled glass syringe containing 0.8 mL of solution and one alcohol drenched cotton wool roll in a blister		YES	YES							
Humulin M3 (30/70) 100 IU/mL (3.0 mL cartridge)	suspension for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 (1x5) cartridges with 3 mL of suspension per blister, supplied in a box		YES	YES							
Humulin M3 Pen 100 IU/mL	suspension for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge each with 3 mL of suspension, supplied in a carton box		YES	YES						YES	
Humulin N 100 IU/mL (3.0 mL cartridge)	suspension for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 (1x5) cartridges with 3 mL of suspension per blister, supplied in a box		YES	YES							
Humulin N Pen 100 IU/mL	solution for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge each with 3 mL of suspension, supplied in a carton box		YES	YES						YES	
Humulin R 100 IU/mL (cartridge 3.0 mL)	solution for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 (1x5) cartridges with 3 mL of solution per blister, supplied in a box		YES	YES							
HUSTAGIL	oral solution	Dentinox Gesellschaft für pharmazeutische Präparate Lenk & Schuppan, Berlin, Germany	150 mL of solution in an amber glass bottle with Alu cap, supplied in a box		YES							YES	YES
Hycamtin	lyophilisate for preparation of infusion	SmithKline Beecham Pharmaceuticals, West Sussex, Great Britain i GlaxoSmithKline Manufacturing S.p.A., Parma, Italy	5 glass bottles of 5 mL with lyophilisate, supplied in a box		YES	YES							
Hydrocyclin	ointment	Galenika a.d., Beograd - Zemun, Srbija	5 g of ointment in an aluminium tube, supplied in a box		YES	YES							
Hyperici Aktiv granules	granules	Cedevita d.o.o., Zagreb, Republic of Croatia	15 bags (paper/Al/PE) containing 5 g, supplied in a box	YES								YES	YES
HYPNOMIDATE	solution for injection	Janssen Pharmaceutica NV, Turnhoutseweg 30, Beerse, Belgium	5 ampoules with 10 mL of solution, supplied in a box		YES	YES							
Hyzaar	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	32 (2x14) film coated tablets in a blister, supplied in a carton box		YES	YES							
Ibuprofen 100 mg/5 mL oral suspension	oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of suspension in an amber glass bottle, supplied in a box	YES			YES						
Ibuprofen 400 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES						
Ibuprofen 600 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	31 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES						

Ibuprofen 800 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets in a white polyethylene (PE) bottle, with a PE screw cap, supplied in a box	YES			YES					
Ibuprofen gel	gel	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	50 g of gel in an aluminium tube with a plastic stopper, supplied in a box		YES		YES		YES			
Ibuprofen 200 mg coated tablets	coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box	YES			YES					
Ibuprofen 400 mg coated tablets	coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box	YES			YES					
Ibuprofen retard 800 mg tablets	prolonged release tablets	Farmal d.d., Ludbreg, Republic of Croatia, in cooperation with Valpharma Int. s.a., San Marino	Box with 30 tablets (blister, 3x10 tbl.)	YES			YES					
Imacort cream	cream	Spirig Pharma AG, Egerkingen, Switzerland	20 grams of cream in an aluminum tube, supplied in a box		YES		YES					
Imazol cream-paste	paste	Spirig Pharma AG, Egerkingen, Switzerland	30 g of paste in an aluminium tube		YES		YES					
Imazol Plus	cream	Spirig Pharma AG, Egerkingen, Switzerland	30 g of cream in an aluminium tube, supplied in a box		YES		YES					
Imigran nasal spray of 20 mg	nasal spray	GlaxoSmithKline S.p.A., Parma, Italy	Two plastic measuring devices (for nasal spray) in a blister, supplied in a box		YES	YES						
Imigran tablets 50 mg	film coated tablets	Glaxo Wellcome Operations, Greenford, Middlesex, Great Britain i GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Poland	2 tablets in aluminum blister (Al/Al), supplied in a carton box		YES	YES						
Immucyst, BCG Immunotherapeutic agent	lyophilisate and diluent for intravesical instillation	Sanofi Pasteur Limited, Toronto, Ontario, Canada	One glass vial with BCG 81g (lyophilisate) and one glass bottle with 3 mL of diluent, supplied in a box		YES					YES		
Immunate 1000 IU	lyophilisate and diluent for preparation of solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Bottle with lyophilisate, bottle with 5 mL of diluent, and set for dissolution and injection of medicinal product, supplied in a box		YES						YES	
Immunate 250 IU	lyophilisate and diluent for preparation of solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Bottle with lyophilisate, bottle with 5 mL of diluent, and set for dissolution and injection of medicinal product, supplied in a box		YES						YES	
Immunate 500 IU	lyophilisate and diluent for preparation of solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Bottle with lyophilisate, bottle with 5 mL of diluent, and set for dissolution and injection of medicinal product, supplied in a box		YES						YES	
Immunine 1200 IU	lyophilisate and solvent for preparation of solution for i.v. injection/infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Lyophilisate in a glass bottle, 10 mL of solvent in a glass bottle and dissolution and injection kit, supplied in a box		YES						YES	
Immunine 200 IU	lyophilisate and solvent for preparation of solution for i.v. injection/infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Lyophilisate in a glass bottle, 5 mL of solvent in a glass bottle and dissolution and injection kit, supplied in a box		YES						YES	

Immunine 600 IU	lyophilisate and solvent for preparation of solution for i.v. injection/infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Lyophilisate in a glass bottle, 5 mL of solvent in a glass bottle and dissolution and injection kit, supplied in a box		YES									YES
IMOVAx POLIO inactivated poliomyelitis vaccine	suspension for intramuscular or subcutaneous injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	0.5-mL of suspension in a glass syring, supplied in a box		YES									YES
Human rabies immunoglobulin	solution for intramuscular use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Bottle with 5 mL of preparation (not less than 500 IU), supplied in a box	YES										YES
Human rabies immunoglobulin	solution for intramuscular use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Bottle with 2 mL of preparation (not less than 200 IU), supplied in a box	YES										YES
Human hepatitis B immunoglobulin, 250 IU	solution for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	One glass vial with 250 IU of immunoglobulin, supplied in a carton box	YES										YES
Human hepatitis B immunoglobulin, 500 IU	solution for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	One glass vial with 500 IU of immunoglobulin, supplied in a carton box	YES										YES
Human tetanus immunoglobulin	solution for intramuscular use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box containing 1 ampoule of preparation - 250 IU/ampoule	YES										YES
Human immunoglobulin for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 50 mL of solution and an infusion kit, supplied in a box	YES										YES
Human immunoglobulin for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 100 mL of solution and an infusion kit, supplied in a box	YES										YES
Human immunoglobulin for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 10 mL of solution with a needle and a filter, supplied in a box	YES										YES
Imuran tablets	film coated tablets	Heumann PCS GmbH, Feucht, Germany	100 (4 x 25) tablets in PVC/AI blister, supplied in a box		YES	YES								
Indamid SR tablets	prolonged-release tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a white PVC/AI blister, supplied in a box	YES			YES							
INDAP	capsules	Pro. Med.CS Praha a.s., Prag, Czech Republic	30 (3x10) capsules in a blister (PVC/AI), supplied in a box		YES		YES							
Indap	capsules	Pro. Med.CS Praha a.s., Prag, Czech Republic	30 (3x10) capsules in a blister, supplied in a box		YES		YES							
Indapamid SR Pliva tablets	prolonged-release tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a white PVC/AI blister, supplied in a box	YES			YES							
Indometacin 100 mg suppositories	suppositories	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) suppositories in a strip, supplied in a box	YES			YES							
Indometacin 25 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a blister, supplied in a box	YES			YES							
Indometacin 75 mg retard capsules	prolonged-release capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/AI blister, supplied in a box	YES			YES							

Inegy 10 mg/10 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister (Al/Al), supplied in a box		YES	YES			YES		
Inegy 10 mg/20 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister (PVC/Aclar/Al), supplied in a box		YES	YES			YES		
Inegy 10 mg/40 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (4x7) tablets in a blister (PVC/Aclar/Al), supplied in a box		YES	YES			YES		
Inegy 10 mg/80 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (4x7) tablets in a blister (PVC/Aclar/Al), supplied in a box		YES	YES			YES		
Infanrix, diphtheria, tetanus and pertussis (acellular) vaccine, absorbed	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with one glass syringe containing 1 dose of vaccine (0.5 mL), needle and needle protection		YES					YES	
Infanrix Hexa	lyophilisate and suspension for parenteral use	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	One glass syringe with 0.5 mL of liquid vaccine component (DTP-HBV-IPV), one glass bottle with Hib lyophilisate and two needles with protective caps, supplied in a box		YES					YES	
INFANRIX-IPV+Hib, Combined Diphtheria, Tetanus, acellular Pertussis,inactivated Polio and Haemophilus influenzae type B conjugate Vaccine	powder and suspension for preparation of suspension for injection	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with 1 glass syringe containing 0.5 mL of suspension (component Infanrix IPV), 1 glass bottle with powder (component Hib) and 2 needles with protection		YES					YES	
Influvac (inactivated influenza vaccine, surface antigen)	suspension for injection	Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA Olst, the Netherlands	Box with 1 pre-filled syringe (glass, type I) with 1 dose of vaccine (0.5 mL of suspension)		YES					YES	
Infusol (solution for infusion)	solution for intravenous infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials with 500 mL of solution, supplied in a box	YES		YES					
Inspra 25 mg tablets	film coated tablets	Pharmacia Limited, Whalton Road, Morpeth, Northumberland NE613YA, Great Britain	30 (3x10) film coated tablets in a nontransparent PVC/Al blister, supplied in a carton box		YES	YES		YES	YES		
Inspra 50 mg tablets	film coated tablets	Pharmacia Limited, Whalton Road, Morpeth, Northumberland NE613YA, Great Britain	30 (3x10) film coated tablets in a nontransparent PVC/Al blister, supplied in a carton box		YES	YES		YES	YES		
Instillagel 11 mL	gel	Almed GmbH, Motzener Str. 41, Berlin, Germany	10 syringes each containing 11 mL of gel in a blister, supplied in a box		YES		YES				
Instillagel 6 mL	gel	Almed GmbH, Motzener Str. 41, Berlin, Germany	10 syringes each containing 6 mL of gel in a blister, supplied in a box		YES		YES				
Insulatard HM 100	solution for injection (for s.c. use)	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark	10 mL of suspension in a glass bottle, supplied in a box		YES	YES					
Insulatard Penfill	suspension for subcutaneous injection	Novo Nordisk A/S, Novo Allé, Bagsværd, Denmark Novo Nordisk Production SAS, 45, Avenue d'Orléans, Chartres, France	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box		YES	YES					
Integrilin solution for infusion 0.75 mg/mL	solution for infusion	Schering-Plough Labo N.V., Heist-op-den-Berg, Belgium and Glaxo Operations UK Ltd., Great Britain	One glass vial with 10 mL of solution, supplied in a box		YES	YES		YES	YES		
Integrilin solution for injection 2 mg/mL	solution for injection	Schering-Plough Labo N.V., Heist-op-den-Berg, Belgium and Glaxo Operations UK Ltd., Great Britain	One glass vial with 10 mL of solution, supplied in a box		YES	YES		YES	YES		

Intralipid 10%	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria and Fresenius Kabi AB, Uppsala, Sweden	Glass infusion bottle containing 500 mL of emulsion, 10 bottles in a carton box		YES		YES					
Intralipid 10%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 500 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES					
Intralipid 10%	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria and Fresenius Kabi AB, Uppsala, Sweden	Glass infusion bottle containing 100 mL of emulsion, 10 bottles in a carton box		YES		YES					
Intralipid 10%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 100 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES					
Intralipid 20%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 100 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES					
Intralipid 20%	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria and Fresenius Kabi AB, Uppsala, Sweden	Glass infusion bottle containing 500 mL of emulsion, 10 bottles in a carton box		YES		YES					
Intralipid 20%	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria and Fresenius Kabi AB, Uppsala, Sweden	Glass infusion bottle containing 100 mL of emulsion, 10 bottles in a carton box		YES		YES					
Intralipid 20%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 500 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES					
Intron A 18 million IU solution for injection, multi-dose syringe	solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	One multi-dose syringe with a cartridge containing 1.2 mL of solution otopine, 12 needles and 12 cotton wool rolls, supplied in a box		YES	YES		YES				
Intron A 30 million IU solution for injection, multi-dose syringe	solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	One multi-dose syringe with a cartridge containing 1.2 mL of solution otopine, 12 needles and 12 cotton wool rolls, supplied in a box		YES	YES		YES				
Intron A solution for injection 18 mil.IU, multidozni injektor	solution for subcutaneous administration	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Box with 1 pen injection device with a glass cartridge containing 1.2 mL of solution, 6 Novofine needles and 6 gauze pads		YES	YES		YES				
Intron A solution for injection 30 mil.IU, multidozni injektor	solution for subcutaneous administration	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Box with 1 pen injection device with a glass cartridge containing 1.2 mL of solution, 6 Novofine needles and 6 gauze pads		YES	YES		YES				
Invanz 1 g powder for concentrate for infusion solution	powder for concentrate for infusion solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	20-mL glass bottle with powder supplied in a box		YES	YES		YES				

lopamiro 300 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	30 mL of solution in a glass bottle, supplied in a box		YES	YES						
lopamiro 300 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	100 mL of solution in a glass bottle, supplied in a box		YES	YES						
lopamiro 300 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	50 mL of solution in a glass bottle, supplied in a box		YES	YES						
lopamiro 370 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	100 mL of solution in a glass bottle, supplied in a box		YES	YES						
lopamiro 370 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	30 mL of solution in a glass bottle, supplied in a box		YES	YES						
lopamiro 370 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	50 mL of solution in a glass bottle, supplied in a box		YES	YES						
lopamiro 370 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	200 mL of solution in a glass bottle, supplied in a box		YES	YES						
IRUMED 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (2x30) tablets in a blister (PVC/PVDC-Al foil), supplied in a box	YES			YES					
Irumed 2.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-Al foil), supplied in a box	YES			YES					
Irumed 20 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-Al foil), supplied in a box	YES			YES					
Irumed 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-Al foil), supplied in a box	YES			YES					
Iruzid 10/12.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a transparent blister (PVC/PVDC-Al foil), supplied in a box	YES			YES					
Iruzid 20/12.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	31 (1x30) tablets in a transparent blister (PVC/PVDC-Al foil), supplied in a box	YES			YES					
Iruzid 20/25 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	32 (1x30) tablets in a transparent blister (PVC/PVDC-Al foil), supplied in a box	YES			YES					
ISMN Genericon 20 mg tablets	tablets	Genericon Pharma Ges.m.b.H, Lannach, Austria	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES					
ISMN Genericon 40 mg tablets	tablets	Genericon Pharma Ges.m.b.H, Lannach, Austria	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES					
ISMN Jadran 20	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	60 (6x10) tablets in a blister, supplied in a box	YES			YES					
ISMN Jadran 40	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	60 (6x10) tablets in a blister, supplied in a box	YES			YES					
Isoptin 120 tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in PVC/Al blister, supplied in a box	YES			YES					

Isoptin 40 tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film coated tablets in a PVC/Al blister, supplied in a box	YES		YES					
Isoptin 80 tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 (5x10) film coated tablets in a blister (PVC/Al), supplied in a box	YES		YES					
Isoptin injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	2 mL of solution in a glass ampoule, 50 (5x10) ampoules in a plastic holder, supplied in a box	YES		YES					
ISOPTIN RR tablets	prolonged-release tablets	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Abbott GmbH and Co. KG, Ludwigshafen, Germany	20 (2x10) prolonged-release tablets in PVC/PVDC//Al blister, supplied in a box	YES		YES					
ISOPTO TEARS eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	15 mL of solution in a plastic bottle with dropper attachment, supplied in a box		YES	YES		YES			
ITRAC 3 capsules	capsules, hard	Belupo, lijekovi i kozmetika, d.d., Koprivnica, Republic of Croatia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	4 capsules in a blister (PVC/PE/PVDC/Al), supplied in a box	YES		YES					
Izosorbide MN retard 40 mg tablets	prolonged release tablets (film coated)	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	Box with 50 tablets (blister, 5x10 tablets)	YES		YES					
Izosorbide MN retard 60 mg tablets	prolonged release tablets (film coated)	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	Box with 50 tablets (blister, 5x10 tablets)	YES		YES					
Isotonic solution of sodium chloride 0.9% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES	YES					
Sodium chloride isotonic solution 0.9% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	1000 mL of infusion solution in a plastic bottle (10 bottles in a box)		YES	YES					
Sodium chloride isotonic solution 0.9% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	250-mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES	YES					
Sodium chloride isotonic solution 0.9% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	100 mL of infusion solution in a plastic bottle (20 bottles in a box)		YES	YES					
Jeanine film tablets	film coated tablets	Jenapharm GmbH & Co KG, Jena, Germany	3x21 tablets in a blister, supplied in a box		YES	YES					
Jeanine film tablets	film coated tablets	Jenapharm GmbH & Co KG, Jena, Germany	1x21 tablets in a blister, supplied in a box		YES	YES					
Jumex 5 mg	tablets	CHINOIN Pharmaceutical and Chemical Works Co. Ltd., Budimpešta, Madarska i CHINOIN Pharmaceutical and Chemical Works Co. Ltd., Veresegyház, Madarska	50 (5x10) tablets in an Al/OPA/PVC/Al blister, supplied in a box		YES	YES					
Kabiven	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 1540 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES	YES			YES		
Kabiven	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 1026 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES	YES			YES		

Kabiven	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 2053 mL of blend (in three separate compartments) in a plastic protective casing, 2 bags in a box		YES		YES		YES		
Kabiven	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 2566 mL of blend (in three separate compartments) in a plastic protective casing, 2 bags in a box		YES		YES		YES		
Kabiven Peripheral	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 1440 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES		YES		YES		
Kabiven Peripheral	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 1920 mL of blend (in three separate compartments) in a plastic protective casing, 2 bags in a box		YES		YES		YES		
Calzium folinate Pliva injection 200 mg/20 mL	solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	20-mL bottle containing solution, with bromobutyl stopper and aluminum cap, supplied in a box		YES		YES				
Calcium folinate Pliva injection 500 mg/50 mL	solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	50-mL bottle with solution, closed bromobutyl stopper and aluminum cap, supplied in a box		YES		YES				
Calcium Folinate Pliva injection 100 mg/10 mL	solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	10-mL bottle containing solution, with bromobutyl stopper and aluminum cap, supplied in a box		YES		YES				
Calcium carbonate Krka 1 g tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	50 tablets in a bottle, supplied in a box		YES		YES				
KALETRA 133.3 mg/33.3 mg soft capsules	capsules, soft	Abbott Laboratories Ltd., Kent, Great Britain, Abbott S.p.A., Campoverde di Aprilia, Italy	2 plastic (HDPE) bottles each containing 90 capsules, supplied in a box		YES	YES		YES	YES		
KALETRA 200 mg/50 mg film-tablets	film coated tablets	Abbott Laboratories Ltd., Kent, Great Britain, Abbott GmbH&Co. KG, Ludwigshafen, Germany	120 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES		YES	YES		
Kaletra 80 mg + 20 mg/mL oral solution	oral solution	Abbott Laboratories Ltd., Kent, Great Britain, Abbott S.p.A., Campoverde di Aprilia, Italy	5 plastic (PET) brown bottles for multiple use with 60 mL of solution, supplied in a box		YES	YES		YES	YES		
Kaletra capsules	capsules	Abbott Laboratories Ltd, Queenborough, Great Britain	Box with 2 plastic bottles each containing 90 capsules		YES	YES		YES	YES		
Kaletra oral solution	oral solution	Abbott Laboratories Ltd, Queenborough, Great Britain	Box with 5 plastic bottles each with 60 mL of solution and 5 filling syringes of 5 mL		YES	YES		YES	YES		
POTASSIUM CHLORIDE JADRAN 500 mg tablets for oral solution	tablets for oral solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets for oral solution in a blister (PVC/AI), supplied in a box	YES			YES				
Kalinor effervescent tablets	effervescent tablets	Nordmark Arzneimittel GmbH & Co. KG, Pinnaallee 4, Uetersen, Germany	Plastic tube with 15 effervescent tablets, supplied in a box		YES		YES				
KAMIREN tablets 1 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	21 (2x10 tablets in PVC/PVDC/AI blister, supplied in a box		YES		YES				
KAMIREN tablets 2 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	22 (2x10 tablets in PVC/PVDC/AI blister, supplied in a box		YES		YES				
KAMIREN tablets 4 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	23 (2x10 tablets in PVC/PVDC/AI blister, supplied in a box		YES		YES				

Kamiren XL	modified release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 (6x10) tablets in an OPA/AI/PVC//AI blister, supplied in a box		YES	YES						
Kamiren XL	modified release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in a OPA/AI/PVC//AI blister, supplied in a box		YES	YES						
Katena 100 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (2x10) capsules in a blister, supplied in a box	YES		YES						
Katena 300 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (5x10) capsules in a blister, supplied in a box	YES		YES						
Katena 400 mg tablets	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (5x10) capsules in a blister, supplied in a box	YES		YES						
Kenalog 40 mg/1 mL suspension for injection	suspension for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 ampoules (each with 1 mL of suspension) in a blister, supplied in a box		YES	YES						
Keppra 100 mg/mL oral solution	oral solution	NextPharma SAS, Limay, France	300 mL of solution in an amber glass bottle with a plastic temper-evident stopper, supplied in a box		YES	YES		YES	YES			
Keppra 1000 mg film coated tablets	film coated tablets	UCB S.A., Braine l'Alleud, Belgium	60 (6x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES		YES	YES			
Keppra 250 mg film coated tablets	film coated tablets	UCB S.A., Braine l'Alleud, Belgium	60 (6x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES		YES	YES			
Keppra 500 mg film coated tablets	film coated tablets	UCB S.A., Braine l'Alleud, Belgium	60 (6x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES		YES	YES			
KERASAL ointment	ointment	Spirig Pharma AG, Egerkingen, Switzerland	50 g of ointment in an aluminium tube with a plastic stopper, supplied in a box		YES	YES			YES			
Ketek 400 mg	film coated tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	10 (1x10) tablets in a blister, supplied in a box		YES	YES						
Ketocef injection 1.5 g	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES		YES						
Ketocef injection 250 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES		YES						
Ketocef injection 750 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES		YES						
KetoGel 2.5% gel	gel	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 g of gel in an aluminium tube, supplied in a box		YES	YES			YES			
Ketonal 100 mg suppositories	suppositories	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	12 suppositories in a strip (AI/PE), supplied in a box		YES	YES						
Ketonal 100 mg/2 mL injection	solution for injection	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	2 mL of solution for injection in a glass ampoule, 10 ampoules in a box		YES	YES						
Ketonal 150 mg prolonged-release tablets	prolonged-release tablets	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 prolonged-release tablets in an amber glass bottle with plastic cap, supplied in a box		YES	YES						

Ketonal 5% cream	cream	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 g of cream in an aluminium tube, supplied in a box		YES		YES		YES		
Ketonal 50 mg capsules	capsules, hard	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	25 capsules in an amber glass bottle with plastic cap, supplied in a box		YES		YES				
Ketonal DUO 150 mg capsules	modified release capsules, hard	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) capsules in a blister (PVC/TE/PVDC//PVC/AI), supplied in a box		YES		YES				
Ketonal forte 100 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 film coated tablets in an amber glass bottle with plastic cap, supplied in a box		YES		YES				
KLAVAX BID 1000 mg tablets	film coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Bilim Pharmaceuticals Inc., Turkey	14 tablets in a A/AI blister, supplied in a box	YES			YES				
KLAVAX BID syrup 400/57 mg	powder for preparation of oral suspension	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Bilim Pharmaceuticals Inc., Turkey	Glass bottle of 100 mL with a polyethylene cap, supplied in a box	YES			YES				
Klavocin bid syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for preparation of 70 mL of suspension (by the addition of 59 mL of water) in an amber glass bottle with a plastic stopper (high density polyethylene) and a 5 mL measuring syringe (polystyrene/polyethylene low density), supplied in a box	YES			YES				
Klavocin bid syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for preparation of 140 mL of suspension (by the addition of 118 mL of water) in an amber glass bottle with a plastic stopper (high density polyethylene) and a 5 mL measuring syringe (polystyrene), supplied in a box	YES			YES				
Klavocin bid syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for preparation of 35 mL of suspension (by the addition of 29.5 mL of water) in an amber glass bottle with a plastic stopper (high density polyethylene) and a 5 mL measuring syringe (polystyrene/polyethylene low density), supplied in a box	YES			YES				
Klavocin bid tablets 1 g	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (2x5) film coated tablets in a Al/Al blister, supplied in a box	YES			YES				
Klavocin 1.2 g injection	powder for injection solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 bottles (glass of hydrolytic group I) with a rubber stopper and a protective flip-off Al cap, supplied in a box	YES			YES				
Klavocin injection 600 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 bottles (glass of hydrolytic group I) with a rubber stopper and a protective flip-off Al cap, supplied in a box	YES			YES				
Klimicin 150 mg capsules	capsules	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	16 capsules in an amber glass bottle, supplied in a box		YES		YES				
Klimicin 300 mg capsules	capsules	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	16 capsules in an amber glass bottle, supplied in a box		YES		YES				
Klimicin 300 mg/2 mL injection	solution for intramuscular and intravenous injection	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	10 glass ampoules each containing 2 mL of solution, supplied in a box		YES		YES				

Klimicin 600 mg/4 mL injection	solution for intramuscular and intravenous injection	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	10 glass bottles with à 4 mL of solution, supplied in a box		YES	YES						
Klimicin T 1% gel	gel	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 g of gel in a tube, supplied in a box		YES	YES						
Klimicin T 1% dermal solution	dermal solution	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 mL of solution in a plastic bottle, supplied in a box		YES	YES						
Klimicin V 2% vaginal cream	vaginal cream	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	40 g of cream in a tube with 7 plastic applicators, supplied in a box		YES	YES						
Kliogest	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 film-coated tablets in a plastic container (dispenser with marked days of the week), supplied in a box		YES	YES						
Klomifen 50 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Klosterfrau Sedinal sugar-coated tablets	sugar-coated tablets	M.C.M. Klosterfrau Vertriebs GmbH, Germany	60 (2x30) sugar coated tablets in a blister, supplied in a box		YES					YES	YES	
Knavon 100 mg suppositories	suppositories	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	12 (2x6) suppositories in a strip, supplied in a box	YES		YES						
Knavon 100 mg/2 mg injection	intramuscular injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 glass ampoules with à 2 mL of solution in a plastic container, supplied in a box	YES		YES						
Knavon 50 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	25 (1x25) capsules in a blister, supplied in a box	YES		YES						
Knavon forte 100 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in an amber glass bottle with AI cap, supplied in a carton box	YES		YES						
Knavon retard 150 mg tablets	prolonged-release tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in an amber glass bottle, supplied in a carton box	YES		YES						
Kofan tablets	tablets	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	20 (2x10) tablets in PVC/AI blister, supplied in a box		YES	YES				YES		
Kogenate Bayer 1000 IU powder and diluent for injection solution	powder and diluent for solution for injection	Bayer Biologicals S.r.l., Torri-Sovicille, Italy	Vial with Bio-set device containing powder, pre-filled syringe with diluent, separate plunger, venipuncture set, two disposable sterile cotton pads drenched in a Acohol, two dry cotton pads and two plasters, supplied in a box		YES	YES		YES	YES			YES
Kogenate Bayer 250 IU powder and diluent for injection solution	powder and diluent for solution for injection	Bayer Biologicals S.r.l., Torri-Sovicille, Italy	Vial with Bio-set device containing powder, pre-filled syringe with diluent, separate plunger, venipuncture set, two disposable sterile cotton pads drenched in a Acohol, two dry cotton pads and two plasters, supplied in a box		YES	YES		YES	YES			YES
Kogenate Bayer 500 IU powder and diluent for injection solution	powder and diluent for solution for injection	Bayer Biologicals S.r.l., Torri-Sovicille, Italy	Vial with Bio-set device containing powder, pre-filled syringe with diluent, separate plunger, venipuncture set, two disposable sterile cotton pads drenched in a Acohol, two dry cotton pads and two plasters, supplied in a box		YES	YES		YES	YES			YES

Kompensan	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES		YES		
Konakion MM injection 10mg/1mL	solution for intravenous injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules (amber glass) with 1 mL of solution, supplied in a box		YES	YES					
Konakion MM 2 mg/0.2 mL, paediatric	solution for peroral, intramuscular and intravenous injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules (amber glass) with 0.2 mL of solution and 5 plastic measuring devices, supplied in a box		YES	YES					
Kreon 10 000	capsules filled with gastric-resistant granules	Solvay Pharmaceuticals GmbH, Hannover, Germany	20 tablets in a plastic bottle		YES		YES				
Kreon 10 000	capsules filled with gastric-resistant granules	Solvay Pharmaceuticals GmbH, Hannover, Germany	100 capsules in a plastic bottle		YES		YES				
Kreon 25 000	capsules filled with gastric-resistant granules	Solvay Pharmaceuticals GmbH, Hannover, Germany	100 capsules in a plastic bottle		YES		YES				
KREON 40 000	hard capsules with gastric-resistant granules	Solvay Pharmaceuticals GmbH, Neustadt, Germany	50 capsules in a plastic (HDPE) container, supplied in a box		YES	YES					
Kromoglicin STADA eye drops	eye drops, solution	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	10 mL of solution in a polyethylene bottle with dropper attachment and cap, supplied in a box		YES		YES		YES		
Kromoglicin STADA nasal spray	nasal spray, solution	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	15 mL of solution in a polyethylene bottle with nebulizer, supplied in a box		YES		YES		YES		
Kuterid 0.05 % cream	cream	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 grams of cream in an aluminum tube, supplied in a box		YES		YES				
Kuterid 0.05% ointment	ointment	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 grams of ointment in an aluminum tube, supplied in a box		YES		YES				
Kybernin P 500	powder for solution for injection or infusion	CSL Behring GmbH, Marburg, Germany	One glass vial with powder, one glass vial with 10 mL of diluent and one transfer spike, supplied in a box		YES						YES
Kytril 1mg/1 mL concentrate for solution for infusion	concentrate for infusion solution (for intravenous use)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules with 1 mL of solution, supplied in a box		YES	YES					
Kytril 3 mg/3 mL concentrate for solution for infusion	concentrate for solution for intravenous infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules with 3 mL of solution, supplied in a box		YES	YES					
Kytril film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 tablets in a PVC/Al blister, supplied in a box		YES	YES					
Laaven HD tablets	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	60 (6x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES		YES					
Laaven HD tablets	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	33 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES		YES					
Laaven HL 20 tablets	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	34 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES		YES					

Laaven HL tablets	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	30 (3x10) in a blister (PVC/PVDC/AI), supplied in a box	YES		YES						
Laaven tablets 10 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	31 (3x10) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Laaven tablets 10 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	90 (9x10) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Laaven tablets 2.5 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	90 (9x10) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Laaven tablets 20 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	32 (3x10) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Laaven tablets 5 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	33 (3x10) tablets in a PVC/AI blister, supplied in a box	YES		YES						
LACIDIPIN PLIVA tablets 4 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) film coated tablets in a blister (PA/AI/PVC//PE/AI), supplied in a box	YES		YES						
Lacipil tablets 4 mg	film coated tablets	Glaxo Wellcome S.A., Burgos, Aranda de Duero, Spain and GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	28 (4x7) tablets in a blister, supplied in a box		YES	YES						
Lacipil tablets 6 mg	film coated tablets	Glaxo Wellcome S.A., Aranda de Duero, Burgos, Spain	28 (4x7) tablets in a blister (OPA/AI/PVC//AI), supplied in a box		YES	YES						
Lakea 50 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a OPA/AI/PVC//AI blister, supplied in a box		YES	YES						
Lamal 100 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	33 (2x15) capsules in a PVC/AI blister, supplied in a box		YES	YES						
Lamal 200 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	34 (2x15) capsules in a PVC/AI blister, supplied in a box		YES	YES						
Lamal 25 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 (3x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Lamal 50 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 (3x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Lameptil 100 mg dispersible tablets	dispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3x10) dispersible tablets in a blister (PVC/PE/PVDC//AI), supplied in a box		YES	YES		YES				
Lameptil 200 mg dispersible tablets	dispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	31 (3x10) dispersible tablets in a blister (PVC/PE/PVDC//AI), supplied in a box		YES	YES		YES		YES		
Lameptil 25 mg dispersible tablets	dispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	32 (3x10) dispersible tablets in a blister (PVC/PE/PVDC//AI), supplied in a box		YES	YES		YES		YES		
Lameptil 50 mg dispersible tablets	dispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	33 (3x10) dispersible tablets in a blister (PVC/PE/PVDC//AI), supplied in a box		YES	YES		YES		YES		

Lamictal 100 mg tablets	tablets	Glaxo Wellcome Operations, Greenford, Great Britain	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Lamictal 25 mg tablets	tablets	Glaxo Wellcome Operations, Greenford, Great Britain	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Lamictal 50 mg tablets	tablets	Glaxo Wellcome Operations, Greenford, Great Britain	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Lamictal 5 mg chewing tablets / tablets for oral suspension 5 mg	chewing tablets/ tablets for oral suspension	Glaxo Operations UK Limited, Ware, Hertfordshire, Great Britain (Glaxo Wellcome Operations, Greenford, Great Britain), GlaxoSmithKline Pharmaceuticals, Poznan, Poland	30 (3x10) tablets in a blister (PVC/PVDC//Al), inserted in a carton box		YES	YES						
LAMISIL 1 % aerosol for external use	aerosol for external use, solution	Novartis Pharma S.A.S., Huningue Cedex, France	30 mL of solution in a plastic bottle with a spray attachment, supplied in a box		YES	YES						
LAMISIL 1% cream	cream	Novartis Pharma Produktions GmbH, Wehr, Germany and Novartis Consumer Health SA, Nyon, Switzerland	15 g of cream in an aluminum tube, supplied in a box		YES	YES						
Lamisil 250 mg tablets	tablets	Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, Great Britain	14 (1x14) tablets in a blister (PVC/Al), supplied in a box		YES	YES						
Lamisil DermGel 1% gel	gel	Novartis Pharma Produktions GmbH, Wehr, Germany and Novartis Consumer Health SA, Nyon, Switzerland	5 g of gel in an aluminium tube with a propylene stopper, supplied in a box		YES	YES						
Lamisil once 1% dermal solution	dermal solution	Novartis Consumer Health S.A., Route de l'Etraz, Nyon, Switzerland	4 g of solution in an aluminium (PE/Al/PE) tube with a plastic stopper, supplied in a protective plastic box		YES	YES			YES			
Lanicor tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	22 (2x10) tablets in a blister (PVC/Al), supplied in a box	YES			YES					
Lanitop injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 2-mL ampoules supplied in a box	YES			YES					
Lanitop tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 (5x10) tablets in a blister, supplied in a box	YES			YES					
Lantus 100 IU/mL ( 3-mL cartridge for OptiClik)	solution for subcutaneous injection	Sanofi - Aventis Deutschland GmbH, Frankfurt am Main, Germany	5 glass cartridges with 3 mL of solution (with an integrated plastic injector holder), supplied in a box		YES	YES			YES			
Lantus 100 IU/mL ( 3 mL glass cartridge)	solution for subcutaneous injection	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	Box with 5 glass cartridges each with 3 mL of solution (in a blister)		YES	YES						
Lantus 100 IU/mL OptiSet (injector with glass cartridge of 3 mL)	solution for injection in a cartridge	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	5 injectors with cartridges each with 3 mL of solution, supplied in a box		YES	YES						
Lanzul capsules 30 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 (2X7) capsules in a PVC/PE/PVDC – Al blister, supplied in a box		YES		YES					
LARONA 15 mg	gastric-resistant capsules, hard	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	28 capsules in a plastic (HDPE) bottle with PP closure (with desiccant), supplied in a box	YES			YES					

LARONA 30 mg	gastric-resistant capsules, hard	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	29 capsules in a plastic (HDPE) bottle with PP closure (with desiccant), supplied in a box	YES		YES						
Lazid tablets 80 mg	tablets	CP Pharmaceuticals Ltd, Wrexham, Great Britain	60 (3x20) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
LAZOL 15 mg capsules	gastric-resistant capsules, hard	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) capsules in a blister (OPA/AI/PVC//AI), supplied in a box	YES		YES						
LAZOL 30 mg capsules	gastric-resistant capsules, hard	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	14 (2x7) capsules in a blister (OPA/AI/PVC//AI), supplied in a box	YES		YES						
Legofer	oral solution	Alkaloid AD, Skopje, Bulevar A. Makedonski 12, FYROM in cooperation-under the licence (concession) Italfarmaco S.p.A., Milano, Italy	150 mL of solution in an amber glass bottle with plastic cap and measuring vessel, supplied in a box		YES	YES						
Lekadol 500 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	18 (3x6) tablets in a blister, supplied in a box		YES	YES			YES			
Lekadol direkt 500 mg tablets	orodispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	12 (2x6) dispersible tablets in PA/AI/PVC-AI blister, supplied in a box		YES	YES			YES			
Lekadol plus C granules	granules for preparation of suspension	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 bags each containing 5 g of granules, supplied in a box		YES	YES			YES			
Lekadol tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES	YES						
Lekoklar 250 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	14 (2x7) tablets in a A/PVC blister, supplied in a box		YES	YES						
Lekoklar 500 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	14 (2x7) tablets in a A/PVC blister, supplied in a box		YES	YES						
Lekoklar XL 500 mg film-coated tablets with modified release	modified-release film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	5 (1x5) tablets in an AI/AI blister, supplied in a box		YES	YES						
Lekotam 1.5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	45 (3x10) tablets in a PVC/AI blister, supplied in a box		YES	YES						
Lekotam 3 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	46 (3x10) tablets in a PVC/AI blister, supplied in a box		YES	YES						
Lekotam 6 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/AI blister, supplied in a box		YES	YES						
Lendacin 1g power for injection solution	powder for preparation of injection for i.v. and i.m. solution	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 glass bottles with powder, supplied in a box		YES	YES						
Lendacin 2 g powder for solution for infusion	powder for solution for infusion	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	5 glass bottles with powder for solution for infusion, supplied in a box		YES	YES						
Leponex 100 mg tablets	tablets	Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, Great Britain	50 (5x10) tablets in a blister, supplied in a box		YES	YES						

Leponex 25 mg tablets	tablets	Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, Great Britain	50 (5x10) tablets in a blister, supplied in a box		YES	YES						
Lercanil	film coated tablets	Berlin-Chemie AG (Menarini Group), Berlin, Germany; Recordati Industria Chimica e Farmaceutica S.p.A., Milano, Italy	7 (1x7) tablets in a blister (non-transparent PVC/AI), supplied in a box		YES	YES						
Lescol 40 mg capsules	capsules	Novartis Farmacéutica S.A., Ronda Santa María 158, Barcelona, Spain	28 (4x7) capsules in a blister, supplied in a box		YES	YES						
Lescol XL 80 mg prolonged-release tablets	prolonged-release tablets	Novartis Farmacéutica S.A., Ronda Santa María 158, Barcelona, Spain	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Letizen film coated tablets 10 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) film coated tablets in a (PVC/AI) blister, supplied in a box		YES		YES					
Letizen oral solution 1 mg/1 mL	oral solution	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	120 mL of solution in an amber glass bottle with plastic cap, supplied in a box		YES		YES					
Letizen S 10 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) film coated tablets in a (PVC/AI) blister, supplied in a box		YES		YES			YES		
Letrox 100	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	50 (2x25) tablets in a white non-transparent (PVDC/PVC//AI) blister, supplied in a box		YES		YES					
Letrox 150	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	50 (2x25) tablets in a white non-transparent (PVDC/PVC//AI) blister, supplied in a box		YES		YES					
Letrox 50	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	50 (2x25) tablets in a white non-transparent (PVDC/PVC//AI) blister, supplied in a box		YES		YES					
Levemir FlexPen	solution for injection in cartridge for subcutaneous use	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 pens with a FlexPen glass cartridge containing 3 mL of solution, supplied in a carton box		YES	YES			YES			
Levemir Penfill	solution for injection in cartridge for subcutaneous use	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 Penfill glass cartridges with 3 mL of solution, supplied in a carton box		YES	YES			YES			
Levitra 10 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	2 tablets in a PP/AI blister, supplied in a box		YES	YES						
Levitra 20 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	2 tablets in a PP/AI blister, supplied in a box		YES	YES						
Levitra 5 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	2 tablets in a PP/AI blister, supplied in a box		YES	YES						
Lexaurin tablets 1.5 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (2x15) tablets in a blister, supplied in a box		YES		YES					
Lexaurin tablets 3 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (2x15) tablets in a blister, supplied in a box		YES		YES					
Lexaurin tablets 6 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (2x15) tablets in a blister, supplied in a box		YES		YES					

Lexilium 1.5 mg tablets	tablets	Alkaloid AD, Skopje, FYROM in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Lexilium 3 mg tablets	tablets	Alkaloid AD, Skopje, FYROM in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Lexilium 6 mg tablets	tablets	Alkaloid AD, Skopje, FYROM in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Lidacef injection 1g	powder for preparation of solution for i.v. and i.m. injection	Pliva Krakow, Krakow, Poland	Glass bottle (10 mL) with powder, supplied in a box		YES	YES						
Lidacef injection 2 g	powder for preparation of solution for i.v. infusion	Pliva Krakow, Krakow, Poland	Glass bottle (20 mL) with powder, supplied in a box		YES	YES						
LINOLA FETT ÖLBAD	bath additive, solution	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	200 mL of solution, dropper, cap, and measuring 20 mL cup, supplied in a box		YES	YES			YES			
LINOLA UREA	cream	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	75 g of cream in an aluminium tube, supplied in a box		YES	YES			YES			
Linoladiol	vaginal cream	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	100 grams of cream in an aluminum tube and a plastic vaginal applicator in a protective bag, supplied in a box		YES	YES						
Linoladiol	vaginal cream	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	50 g of cream in an aluminium tube and a plastic vaginal applicator in a protective bag, supplied in a box		YES	YES						
Linola-fett	oily cream (water/oil emulsion)	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	Box with 75 g of cream in an Al tube		YES	YES			YES			
Lioresal 10 mg tablets	tablets	Novartis Farma S.p.A., Torre Annunziata (Napoli), Italy	50 (5x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Lioresal 25 mg tablets	tablets	Novartis Farmacéutica S.A., Ronda Santa María 158, Barcelona, Spain	50 (5x10) tablets in a blister (PVC/PE/PVDC/AI), supplied in a box		YES	YES						
Lipex 10 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	20 (2x10) tablets in a blister, supplied in a box		YES	YES						
Lipex 20 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	20 (2x10) tablets in a blister, supplied in a box		YES	YES						
Lipex 40 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Lipex 80 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 (2x14) film coated tablets in a blister, supplied in a box		YES	YES						
Lipidil 145 mg	film coated tablets	Laboratoires Fournier S.A., Fontaine Les Dijon, France	31 (3x10) film coated tablets in a blister (PVC/PE/PVDC/AI), supplied in a box		YES	YES		YES	YES			
Lipidil 160 mg	film coated tablets	Laboratoires Fournier S.A., Fontaine Les Dijon, France	32 (3x10) film coated tablets in a blister (PVC/PE/PVDC/AI), supplied in a box		YES	YES		YES	YES			
LIPIDIL 200 M	capsules, hard	Laboratories Fournier S.A., Fontaine Les Dijon, France	30 (3x10) capsules in a blister (PVC/AI), supplied in a box		YES	YES			YES			

Lipofundin MCT/LCT 10%	emulsion for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of emulsion for infusion in a glass bottle, 10 bottles per box		YES	YES						
Lipofundin MCT/LCT 10%	emulsion for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	100 mL of emulsion in a glass bottle, 10 bottles in a box		YES	YES						
Lipofundin MCT/LCT 20%	emulsion for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of emulsion for infusion in a glass bottle, 10 bottles per box		YES	YES						
Lipofundin MCT/LCT 20%	emulsion for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	100 mL of emulsion for infusion in a glass bottle, 10 bottles in a box		YES	YES						
LISINOLEX 10 mg	tablets	Galex d.d., Murska Sobota, Republic of Slovenia	36 (3x10) tablets in a PVC/PVdC/AI blister, supplied in a box		YES	YES						
LISINOLEX 20 mg	tablets	Galex d.d., Murska Sobota, Republic of Slovenia	37 (3x10) tablets in a PVC/PVdC/AI blister, supplied in a box		YES	YES						
LISINOLEX 5 mg	tablets	Galex d.d., Murska Sobota, Republic of Slovenia	38 (3x10) tablets in a PVC/PVdC/AI blister, supplied in a box		YES	YES						
Litak 2 mg/mL solution for injection	solution for injection	Lipomed AG, Arlesheim, Switzerland	Clear type I glass vial, containing 5 mL of solution, with a rubber bromobutyl stopper and protective aluminium ring, supplied in a box		YES	YES		YES	YES			
Litak 2 mg/mL solution for injection	solution for injection	Lipomed AG, Arlesheim, Switzerland	5 colourless glass bottles (glass type I) with a rubber bromobutyl stopper and a protective aluminium ring containing 5 mL of solution, supplied in a box		YES	YES		YES	YES			
Litalir capsules	capsules	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	100 capsules in a brown plastic bottle, supplied in a box		YES	YES						
LITIJ KARBONAT JADRAN 300 mg tablets	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	100 tablets in an amber glass bottle, supplied in a box	YES		YES						
Livial 2.5 mg tablets	tablets	N.V. Organon, Oss, the Netherlands; Organon Republic of Ireland Ltd., Co. Dublin, Republic of Ireland	28 tablets in a blister, supplied in a box		YES	YES						
Lizinopril 10 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 tablets in a blister, supplied in a box	YES		YES						
Lizinopril 20 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 tablets in a blister, supplied in a box	YES		YES						
Lizinopril 5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 tablets in a blister, supplied in a box	YES		YES						
LIZINOPRIL H 10 mg/12.5 mg tablets	tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Actavis hf, Hafnarfjordur, Iceland	30 (3x10) tablets, supplied in a box	YES		YES						
LIZINOPRIL H 20 mg/12.5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 (3x10) tablets, supplied in a box	YES		YES						
Lizinopril Lek 10 mg tablets	tablets	Salutas Pharma GmbH, Dieselstrasse 5, Gerlingen, Germany	30 (3x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES		YES				

Lizinopril Lek 2.5 mg tablets	tablets	Salutas Pharma GmbH, Dieselstrasse 5, Gerlingen, Germany	30 (3x10) tablets in a blister (PVC/AI), supplied in a box		YES		YES		YES		
Lizinopril Lek 20 mg tablets	tablets	Salutas Pharma GmbH, Dieselstrasse 5, Gerlingen, Germany	30 (3x10) tablets in a blister (PVC/AI), supplied in a box		YES		YES		YES		
Lizinopril Lek 5 mg tablets	tablets	Salutas Pharma GmbH, Dieselstrasse 5, Gerlingen, Germany	30 (3x10) tablets in a blister (PVC/AI), supplied in a box		YES		YES		YES		
Lodoz 10 mg/6.25 mg film coated tablets	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany; Merck SANTE s.a.s., 2, Rue du Pressoir Vert, Semoy, France	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Lodoz 2.5 mg/6.25 mg film coated tablets	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany; Merck SANTE s.a.s., 2, Rue du Pressoir Vert, Semoy, France	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Lodoz 5 mg/6.25 mg film coated tablets	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany; Merck SANTE s.a.s., 2, Rue du Pressoir Vert, Semoy, France	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Logest coated tablets	coated tablets	Schering S.A., Lys Lez Lannoy, France	Box with 21 coated tablets in a blister		YES	YES					
Lopin tablets 10 mg	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Lopin tablets 5 mg	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	31 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Lorista 50 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a PVC/PVDC/Alu blister, supplied in a box		YES		YES				
Lorista H	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) film coated tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES	YES	YES		
Lorsilan 1 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/AI), supplied in a carton box	YES			YES				
Lorsilan 2.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a blister (PVC/AI), supplied in a carton box	YES			YES				
Losartic Plus tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Losartic tablets 25 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Losartic tablets 50 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Loseprazol 20 mg	capsules	Pro. Med.CS Praha a.s., Prag, Czech Republic	14 (2x7) capsules in a OPA/AI/PVC//AI blister, supplied in a box		YES		YES				
Loseprazol 20 mg	capsules	Pro. Med.CS Praha a.s., Prag, Czech Republic	14 (2x7) capsules in a blister, supplied in a box		YES		YES				

Lotriderm cream	cream	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES						
Lubor 10 mg capsules	capsules	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a blister (PVC/AI), supplied in a box	YES			YES					
Lubor 20 mg suppositories	suppositories	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) suppositories in a AI/PE strip, supplied in a box	YES			YES					
Lubor 20 mg capsules	capsules	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a blister (PVC/AI), supplied in a box	YES			YES					
Luboreta cream	cream	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 g of cream in an aluminium tube with a polyethylene stopper, supplied in a box	YES			YES			YES		
Lucentis 10 mg/mL solution for injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	One glass bottle with 0.3 mL of solution, supplied in a box		YES	YES		YES	YES			
Lumidol 100 mg/2 mL injections	solution for injection ( i.v., i.m. and s.c.)	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 glass ampoules with 2 mL of solution, supplied in a box	YES			YES					
LUMIDOL 100 mg/mL oral drops	oral drops, solution	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 mL of solution in an amber glass bottle with fitted plastic dropper and plastic cap, supplied in a box	YES			YES					
LUMIDOL 50 mg capsules	capsules, hard	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 capsules in a 50 mL plastic brown bottle with temper-proof closure, supplied in a box	YES			YES					
Lumidol 50 mg/mL injection	solution for injection ( i.v., i.m. and s.c.)	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 glass ampoules with 1 mL of solution, supplied in a box	YES			YES					
Lumigan 0.3 mg/mL eyel drops	eye drops, solution	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	3 mL solution in a plastic bottle, supplied in a box		YES	YES		YES				
LUPOCET 250 mg suppositories	suppositories	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) suppositories in a AI/PE strip foil, supplied in a box	YES			YES			YES		
Lupocet 500 mg tablets	tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a box	YES			YES			YES		
Lupocet BABY 120 mg suppositories	suppositories	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) suppositories in a PE/AI strip, supplied in a box	YES			YES			YES		
Lupocet flu	effervescent tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 effervescent tablets in a plastic tube, supplied in a box	YES			YES			YES		
Lupocet JUNIOR syrup	syrup	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of syrup in an amber glass bottle, supplied in a box	YES			YES			YES		
Lupocet TEEN 300 mg capsules	capsules	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (2x10) capsules in a (PVC/AI) blister, supplied in a box	YES			YES			YES		
Luveris 75 IU	powder and diluent for preparation of solution for injection (for subcutaneous use)	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and vial with diluent, in a protective container, supplied in a box		YES	YES		YES				

Luxeta tablets 100 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 tablets in a blister, supplied in a box	YES		YES					
Luxeta tablets 50 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 tablets in a blister, supplied in a box	YES		YES					
Lyrica 100 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	84 (4x21) capsules in a blister (PVC/AI), supplied in a box		YES	YES		YES			
Lyrica 150 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/AI), supplied in a box		YES	YES		YES			
Lyrica 200 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	84 (4x21) capsules in a blister (PVC/AI), supplied in a box		YES	YES		YES			
Lyrica 25 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/AI), supplied in a box		YES	YES		YES			
Lyrica 300 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/AI), supplied in a box		YES	YES		YES			
Lyrica 50 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/AI), supplied in a box		YES	YES		YES			
Lyrica 75 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/AI), supplied in a box		YES	YES		YES			
LYSOBACT oriblets	tablets for oral cavity oral (oriblettes)	Bosnaliyek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	30 (3x10) tablets in a blister, supplied in a box		YES	YES		YES			
MabCampath 30 mg/mL concentrate for infusion solution	concentrate for infusion solution	Schering AG, Muellerstrasse 170-178, Berlin, Germany	3x1 glass bottles with 1 mL of concentrate for solution for infusion, supplied in a box		YES	YES		YES			
MabThera 100 mg solution concentrate for infusion	solution concentrate for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 mL of infusion solution concentrate in a glass bottle, 2 bottles in a box		YES	YES		YES	YES		
MabThera 500 mg concentrate of solution for infusion	concentrate of solution for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	50 mL of solution for infusion concentrate in a glass bottle, supplied in a box		YES	YES		YES	YES		
Macugen 0.3 mg	solution for injection	Pfizer Health AB, Stockholm, Sweden	One glass pre-filled syringe with needle, in a protective bag, supplied in a box		YES	YES		YES	YES		
Madopar 125 tablets	tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 tablets in an amber glass bottle (with desiccant), supplied in a box		YES	YES					
Madopar HBS 125 capsules	capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 capsules in an amber glass bottle (with a desiccant), supplied in a box		YES	YES					
Madopar LIQ 125 tablets for oral suspension	tablets for oral suspension	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 tablets in an amber glass bottle (with a dessicant), supplied in a box		YES	YES					
Magnevist solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	20 mL of solution in a glass bottle with rubber stopper, supplied in a box		YES	YES					
Magnevist solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 mL of solution in a glass bottle with rubber stopper, supplied in a box		YES	YES					

Makcin 500 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES			YES					
MANIT 10%	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution in a glass infusion bottle with a rubber stopper and a protective cap, 10 bottles in a box	YES			YES					
MANIT 20%	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	250-mL of solution in a glass bottle for infusion with rubber stopper and protective cap, 10 bottles in a box	YES			YES					
Marivarin 3 mg tablets	tablets	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Orion Corporation, Espoo, Finland	50 tablets in an amber glass bottle with an aluminium stopper		YES		YES					
Materna with selenium	film coated tablets	Wyeth Lederle S.p.A., Catania, Italy	30 tablets in a HDPE bottle, supplied in a box		YES		YES			YES		
MAXALT RPD 10 mg oral lyophilisates	oral lyophilisate	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Netherlands	2 (2x1) oral lyophilisate in a blister (PVC/PVDC//Al) and protective bag (paper/PE/Al), in a plastic box, supplied in a carton box		YES	YES			YES			
MAXALT RPD 5 mg oral lyophilisates	oral lyophilisate	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	2 (2x1) oral lyophilisate in a blister (PVC/PVDC//Al) and protective bag (paper/PE/Al), in a plastic box, supplied in a carton box		YES	YES			YES			
MAXFLU lemon flavour	effervescent tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 effervescent tablets with or without an Al foil, in a polypropylene tube with a cap (PE) with silicagel and tamper-proof ring, supplied in a box	YES			YES			YES		
Maxidex 1 mg/g eye ointment	eye ointment	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	3.5 g of ointment in an aluminum tube, supplied in a box		YES	YES						
Maxidex 1 mg/mL eye drops, suspension	eye drops, suspension	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of suspension in a polyethylene bottle with a dropper, supplied in a box		YES	YES						
Maxipime 1 g	powder for preparation of i.m. and i.v. injections	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Glass bottle with powder, supplied in a box	YES			YES					
Maxipime 2 g	powder for preparation of i.m. and i.v. injections	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Glass bottle with powder, supplied in a box	YES			YES					
Maxipime 500 mg	powder for preparation of i.m. and i.v. injections	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Glass bottle with powder, supplied in a box	YES			YES					
Maxitrol eye drops, suspension	eye drops, suspension	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	Polyethylene bottle with 5 mL of drops, supplied in a box		YES	YES						
Maxitrol eye ointment	eye ointment	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	3.5 g of ointment in an aluminum tube, supplied in a box		YES	YES						
Medazol 0.5 % solution for infusion	solution for infusion	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of solution in a glass bottle for infusion, supplied in a box	YES			YES					
Medazol 250 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in a plastic (polypropylene) bottles, supplied in a box	YES			YES					
Medazol 400 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES					

Medazol 500 mg vaginal tablets	vaginal tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) vaginal tablets in a PVC/AI blister, supplied in a box	YES			YES					
Medical gas, O2 medical	medical gas	Messer Croatia Plin d.o.o., Zaprešić, Industrijska 1, Republic of Croatia	Pressurized steel bottles (150 or 200 bar) with 2, 3, 5, 10, 20, 27, 30, 40 or 50 liters of gaseous medical oxygen	YES			YES					
MEDROL tablets 16 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	50 (5x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
MEDROL tablets 32 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	20 (2x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
MEDROL 4 mg tablets	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	30 tablets in an amber glass bottle with a plastic stopper, supplied in a box		YES	YES						
Megace tablets 160 mg	tablets	Haupt Pharma Regensburg GmbH, Regensburg, Germany for Bristol-Myers Squibb	100 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES						
Meglimid 1 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in transparent PVC//AI blister, supplied in a box		YES		YES	YES	YES			
Meglimid 2 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (3x10) tablets in transparent PVC//AI blister, supplied in a box		YES		YES	YES	YES			
Meglimid 3 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) tablets in transparent PVC//AI blister, supplied in a box		YES		YES	YES	YES			
MEGOSTAT oral suspension	oral suspension	Bristol-Myers Squibb, Epernon, France	240 mL suspension in a plastic (HDPE) bottle with child resistant closure, 20 mL plastic measuring glass, supplied in a box		YES	YES						
Mendilex	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	50 (5x10) tablets in a blister (PVC/AI), supplied in a box		YES		YES					
Menopur	lyophilisate and diluent for preparation of solution for injection	Ferring GmbH, Wittland 1, Kiel, Germany	10 bottles with lyophilisate and 10 ampoules with diluent, supplied in a carton box		YES	YES				YES		
Menopur	lyophilisate and diluent for preparation of solution for injection	Ferring GmbH, Wittland 1, Kiel, Germany	5 bottles with lyophilisate and 5 ampoules with solvent, supplied in a box		YES	YES				YES		
MERIEUX INACTIVATED RABIES VACCINE	lyophilisate for preparation of intramuscular injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with 1 bottle with 1 dose of lyophilised vaccine, 1 pre-filled syringe containing 1 mL of water for injection and a needle		YES						YES	
Meronem i.v. 1 g	powder for preparation of i.v. injection	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	10 bottles with powder, supplied in a box		YES	YES						
Meronem i.v. 500 mg	powder for preparation of i.v. injection	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	10 bottles with powder, supplied in a box		YES	YES						
METHOTREXATE PLIVA injection 1000	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 20 mL of solution for injection (with rubber stopper, aluminum cap and plastic cover), supplied in a box	YES			YES					
METHOTREXATE PLIVA injection 20	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 2 mL of solution for injection (with rubber stopper, aluminum cap and plastic cover), supplied in a box	YES			YES					

METHOTREXATE PLIVA injection 5	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 2 mL of solution for injection (with rubber stopper, aluminum cap and plastic cover), supplied in a box	YES			YES					
METHOTREXATE PLIVA injection 50	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 5 mL of solution for injection (with rubber stopper, aluminum cap and plastic cover), supplied in a box	YES			YES					
Metopran	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	40 (4x10) tablets in a blister (PVC/AI), supplied in a box	YES			YES					
Metronidazol Genericon 0.5 % solution for infusion	solution for infusion	Genericon Pharma Ges.m.b.H., Hafnerstrasse 211, Graz, Austria	10 (10x1) glass bottles with 100 mL of infusion solution, supplied in a box		YES		YES					
Mexitil 200 mg capsules	capsules	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer Strasse 65, Biberach an der Riss, Germany	50 (5x10) capsules in a blister, supplied in a box		YES	YES						
Miacalcic 100 IU injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 ampoules with 1 mL of solution, supplied in a box		YES	YES						
Miacalcic 200 IU aerosol	nasal spray, solution	Novartis Pharma S.A.S., Huningue Cedex, France	Solution in a glass bottle with spray (for nasal use), supplied in a box		YES	YES						
Micardis 40 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	28 (4x7) tablets in a blister (PA/AI/PVC/AI), supplied in a box		YES	YES		YES				
Micardis 80 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	28 (4x7) tablets in a blister (PA/AI/PVC/AI), supplied in a box		YES	YES		YES				
MicardisPlus 40/12.5 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	28 (4x7) tablets in a blister (PA/AI/PVC/AI), supplied in a box		YES	YES		YES				
MicardisPlus 80/12.5 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	28 (4x7) tablets in a blister (PA/AI/PVC/AI), supplied in a box		YES	YES		YES				
MIDAZOLAM TORREX 15 mg/3 mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 3 mL of solution, on a plastic tray, supplied in a box		YES		YES					
MIDAZOLAM TORREX 2 mg/2 mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 2 mL of solution, on a plastic tray, supplied in a box		YES		YES					
MIDAZOLAM TORREX 5 mg/5 mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 5 mL of solution, on a plastic tray, supplied in a box		YES		YES					
MIDAZOLAM TORREX 5 mg/mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 1 mL of solution, on a plastic tray, supplied in a box		YES		YES					
MIDAZOLAM TORREX 50 mg/10 mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 10 mL of solution, on a plastic tray, supplied in a box		YES		YES					

Minerva sugar-coated tablets	sugar-coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	63 (3x21) tablets in a PVC/AI blister, supplied in a box		YES	YES						
Minirin Melt 120 µg	oral lyophilisate	Ferring AB, Limhamn, Sweden	30 (3x10) oral lyophilisate in a blister (AI/AI), supplied in a box		YES	YES						
Minirin Melt 60 µg	oral lyophilisate	Ferring AB, Limhamn, Sweden	31 (3x10) oral lyophilisate in a blister (AI/AI), supplied in a box		YES	YES						
Minirin nasal spray	nasal spray (solution)	Ferring AB, Limhamn, Sweden; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	5 mL of solution (50 doses à 10 µg) in an amber glass bottle with a spray attachment and a plastic attachment for nasal use, supplied in a box		YES	YES						
Minirin 0.2 mg tablets	tablets	Ferring AB, Limhamn, Sweden; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	30 tablets in a plastic bottle, supplied in a box		YES	YES						
Mirapexin tablets 0.25 mg	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	30 (3x10) tablets in a PA/AI/PVC-AI blister, supplied in a box		YES	YES			YES			
Mirapexin tablets 1 mg	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	31 (3x10) tablets in a PA/AI/PVC-AI blister, supplied in a box		YES	YES			YES			
Mirena intrauterine system	intrauterine system (20 mcg/24 h release of active substance) with integrated applicator	Schering OY, Turku, Finland	Intrauterine system with integrated applicator in a blister (APET/Tyvek), supplied in a box		YES	YES						
Mirocef injection 1 g	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES			YES					
Mirocef injection 500 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES			YES					
Mirzaten 30 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 tablets (3x10) in a PVC//PVDC/AI blister, supplied in a box		YES		YES					
Mirzaten 45 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 tablets (3x10) in a PVC/PVDC/AI blister, supplied in a box		YES		YES					
Misar 0.25 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES			YES					
Misar 0.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES			YES					
Misar 1 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES			YES					
Misar SR 0.5 mg tablets	prolonged-release tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) tablets in a blister, supplied in a box	YES			YES					
Misar SR 1 mg tablets	prolonged-release tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) tablets in a blister, supplied in a box	YES			YES					
Mitoxantrone Pliva	concentrate of solution for infusion solutio	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Colourless glass bottle with 15 mL of concentrate of solution for infusion, closed with a rubber stopper and an aluminium cap with a plastic lid,	YES			YES					

			supplied in a box								
Mixtard 30 Penfill 3 mL	suspension for isubcutaneous injection	Novo Nordisk A/S, Novo Allé, Bagsværd, Denmark Novo Nordisk Production SAS, 45, Avenue d' Orleans, Chartres, France	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box	YES	YES						
Mixtard 40 Penfill 3 mL	suspension for isubcutaneous injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box	YES	YES						
Mixtard 50 Penfill 3 mL	suspension for isubcutaneous injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box	YES	YES						
Moditen depo injections 25 mg/1 mL	oily solution for intramuscular injection	Krka d.d., Novo mesto, R. Republic of Slovenia in cooperation with Bristol-Myers Squibb, New York, USA	5 amber glass ampoules each with 1 mL of solution, supplied in a carton box	YES	YES						
Moditen coated tablets 1 mg	coated tablets	KRKA d.d., Novo Mesto, Republic of Slovenia in cooperation with Bristol-Myers Squibb, NY, USA	25 tablets in an amber glass bottle, supplied in a box	YES	YES						
Moditen coated tablets 2.5 mg	coated tablets	KRKA d.d., Novo Mesto, Republic of Slovenia in cooperation with Bristol-Myers Squibb, NY, USA	100 tablets in an amber glass bottle, supplied in a carton box	YES	YES						
Moditen coated tablets 5 mg	coated tablets	KRKA d.d., Novo Mesto, Republic of Slovenia in cooperation with Bristol-Myers Squibb, NY, USA	100 tablets in an amber glass bottle, supplied in a carton box	YES	YES						
Moduretic tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	40 tablets in an amber glass bottle, supplied in a box	YES	YES						
Monopril 10 mg	tablets	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	28 (2x14) tablets in a blister (white PVC/PVDC//Al), supplied in a box	YES		YES					
Monopril 20 mg	tablets	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	28 (2x14) tablets in a blister (white PVC/PVDC//Al), supplied in a box	YES		YES					
Monopril plus 20/12.5	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	28 (2x14) tablets in a nontransparent PVC/PVDC/Alu blister, supplied in a box	YES		YES					
Monsalic ointment	ointment	Schering-Plough Farma, Lda, Casal do Colaride, Aguavla Cacem, Portugal	25 grams of ointment in a white enamel tube with white polypropylene screw cap, supplied in a carton box	YES	YES		YES	YES			
ALKALOID Morphine hydrochloride 20 mg/1 mL	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 amber glass ampoules each containing 1 mL of solution, supplied in a box	YES	YES						
ALKALOID Morphine hydrochloride 4 mg/1 mL	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 amber glass ampoules each containing 1 mL of solution, supplied in a box	YES	YES		YES				
Mostrafin tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister, supplied in a box	YES		YES					

Mostrafin tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES					
Movalis 15 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	20 (1x20) tablets in a PVC/PVDC/AI blister, supplied in a box	YES	YES							
Movalis 15 mg/1.5 mL injection	solution for injection	Boehringer Ingelheim Espana, S.A., Sant Cugat del Valles (Barcelona), Spain	5 ampoules with 1.5 mL of solution, supplied in a box	YES	YES							
Movalis 7.5 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	20 (1x20) tablets in a PVC/PVDC/AI blister, supplied in a box	YES	YES							
MST CONTINUS 10 mg	prolonged-release film coated tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Germany, Mundipharma Ges.m.b.H, Vienna, Austria	30 (3x10) tablets in a blister (PVdC/PVC/AI), supplied in a box	YES	YES							
MST Continus 10 mg	film coated tablets with prolonged-release	Bard Pharmaceuticals Limited, Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Njema&#269;ka, Mundipharma Ges.m.b.H, Be&#269;, Austria	60 (2x30) tablets in a blister (PVC/PVDC-AI), supplied in a box	YES	YES							
MST Continus 100 mg	film coated tablets with prolonged-release	Bard Pharmaceuticals Limited, Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Njema&#269;ka, Mundipharma Ges.m.b.H, Be&#269;, Austria	60 (2x30) tablets in a blister (PVC/PVDC-AI), supplied in a box	YES	YES							
MST CONTINUS 100 mg	prolonged-release film coated tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Germany, Mundipharma Ges.m.b.H, Vienna, Austria	30 (3x10) tablets in a blister (PVdC/PVC/AI), supplied in a box	YES	YES							
MST Continus 30 mg	film coated tablets with prolonged-release	Bard Pharmaceuticals Limited, Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Njema&#269;ka, Mundipharma Ges.m.b.H, Be&#269;, Austria	60 (2x30) tablets in a blister (PVC/PVDC-AI), supplied in a box	YES	YES							
MST CONTINUS 30 mg	prolonged-release film coated tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Germany, Mundipharma Ges.m.b.H, Vienna, Austria	30 (3x10) tablets in a blister (PVdC/PVC/AI), supplied in a box	YES	YES							
MST CONTINUS 60 mg	prolonged-release film coated tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Germany, Mundipharma Ges.m.b.H, Vienna, Austria	30 (3x10) tablets in a blister (PVdC/PVC/AI), supplied in a box	YES	YES							
MST Continus 60 mg	film coated tablets with prolonged-release	Bard Pharmaceuticals Limited, Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Njema&#269;ka, Mundipharma Ges.m.b.H, Be&#269;, Austria	60 (2x30) tablets in a blister (PVC/PVDC-AI), supplied in a box	YES	YES							
Mukolen coated tablets 50 mg	coated tablets	Krka tovarna zdravil, d.d., Novo mesto, Republic of Slovenia in cooperation with E Pharma, France	20 (2x10) coated tablets in PVC/AI blister, supplied in a box	YES		YES						
MULTIBIONTA FORTE N capsules	capsules, soft	Merck Selbstmedikation GmbH, Darmstadt, Germany	20 (2x10) capsules in PVC/PVDC/AI blister, supplied in a box		YES		YES		YES			

Myfortic 180 mg tablets	gastric-resistant tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	120 (12x10) tablets in a PA/AI/PVC- AI blister, supplied in a box		YES	YES			YES		
Myfortic 360 mg tablets	gastric-resistant tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	120 (12x10) tablets in a PA/AI/PVC- AI blister, supplied in a box		YES	YES			YES		
Myoflex	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/AI), supplied in a box	YES			YES				
Naclof	eye drops, solution	EXCELVISION, Annonay, France	5 mL of solution in a white plastic (LDPE) bottle with a dropper and a plastic (HDPE) stopper with a safety ring, supplied in a box		YES	YES					
NAGLAZYME 5 mL concentrate for solution for infusion	concentrate for solution for infusion	Cardinal Health, Northamptonshire, Great Britain; Cardinal Health, Westhoughton, Bolton, Great Britain	One glass vial with 5 mL of concentrate, supplied in a box		YES	YES		YES	YES		
Naklofen suppositories 50 mg	suppositories	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (2x5) suppositories in a AI/PE//PE/AL strip, supplied in a carton box		YES	YES					
Naklofen duo capsules 75 mg	hard capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) hard capsules in a blister (PVC/PE/PVDC/PE/PVC//AI), supplied in a box		YES	YES					
Naklofen gel	gel	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 g of gel in an aluminium tube, supplied in a carton box		YES	YES			YES		
Naklofen solution for injection 75 mg/3mL	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	3 mL solution for injection in a glass ampoule, 5 ampoules in a box		YES	YES					
Naklofen SR	prolonged-release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) prolonged-release tablets in PVC/AI blister, supplied in a box		YES	YES					
Naklofen gastric-resistant tablets 50 mg	gastric-resistant tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) gastric-resistant tablets in PVC/AI blister, supplied in a box		YES	YES					
Nakom 250 mg / 25 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	100 (10x10) tablets in PVC/AI blister, supplied in a box		YES	YES					
Nalgesin forte 550 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) film coated tablets in a PVC/AI blister, supplied in a box		YES	YES					
Nalgesin S 275 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) film coated tablets in a PVC/AI blister, supplied in a box		YES	YES					
Nanotiv 1000 IU	powder and diluent for solution for injection	Octapharma AB, Stockholm, Sweden	Box with powder and a box with a bottle containing 10 mL of water for injection, application kit, supplied in a box		YES					YES	
Nanotiv 500 IU	powder and diluent for solution for injection	Octapharma AB, Stockholm, Sweden	Box with powder and a box with a bottle containing 5 mL of water for injection, application kit, supplied in a box		YES					YES	
Nasivin 0.05% nasal spray	nasal spray, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in a white plastic bottle with a plastic attachment (with internal atomizing tube) and plastic cap, supplied in a box		YES	YES			YES		
Nasivin 0.05% nasal spray without preservative	nasal spray, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in a white plastic bottle with a 3K system and protective cap, supplied in a box		YES	YES			YES		

Nasivin D 0.05% nasal spray	nasal spray, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in an amber glass bottle with a plastic atomizer pump and protective cap, supplied in a box		YES	YES			YES		
Nasivin K 0.01% nasal drops	nasal drops, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	5 mL of solution in an amber glass bottle with a plastic stopper and a glass dropper with a rubber pump, supplied in a box		YES	YES			YES		
Nasivin K 0.025% nasal drops	nasal drops, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in an amber glass bottle with a yellow plastic cap and glass dropper with rubber bulb, supplied in a box		YES	YES			YES		
Nasivin K 0.05% nasal drops	nasal drops, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in an amber glass bottle with white plastic cap and glass dropper with rubber bulb, supplied in a box		YES	YES			YES		
Nasonex nasal spray	nasal spray, suspension	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	Plastic bottle with an attachment for nasal administration containing 120 doses, supplied in a box		YES	YES					
Natrii chloridi infundibile compositum Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution for infusion in a glass bottle with a rubber stopper and an aluminium cap with a plastic lid, 10 bottles in a box	YES		YES					
Natrii chloridi infundibile solution for intravenous infusion, 100 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL in a glass infusion bottle, (10 bottles with plastic holders in a box)	YES		YES					
Natrii chloridi infundibile solution for intravenous infusion, 1000 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	1000 mL in a glass infusion bottle (10 bottles with plastic holders in a box)	YES		YES					
Natrii chloridi infundibile solution for intravenous infusion, 250 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	250 mL in a glass infusion bottle, (10 bottles with plastic holders, supplied in a box)	YES		YES					
Natrii chloridi infundibile solution for intravenous infusion, 500 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL in a glass infusion bottle (10 bottles with plastic holders, supplied in a box)	YES		YES					
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 bags with 2000 mL of solution, supplied in a box	YES		YES					
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	12 bags with 1000 mL of solution, supplied in a box	YES		YES					
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	12 bags with 500 mL of solution, supplied in a box	YES		YES					
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials with 250 mL of solution, supplied in a box	YES		YES					
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials with 500 mL of solution, supplied in a box	YES		YES					
SODIUM HYDROGENCARBONATE 1-molar solution PLIVA	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 mL of infusion solution in a glass ampoule (clear glass, colourbreak), 10 ampoules in a box	YES		YES					
Sodium chloride 0.9% Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	10 plastic Viaflo bags with sa 1000 mL of infusion solution, in a protective bag, supplied in a box		YES	YES					

Sodium chloride 0.9%, Vialfo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	50 plastic Vialfo bags with 100 mL of solution for infusion in a protective bag, supplied in a box	YES	YES						
Sodium chloride 0.9% Vialfo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	20 plastic Vialfo bags with 500 mL of infusion solution, in a protective bag, supplied in a box	YES	YES						
Sodium chloride 0.9%, Vialfo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	30 plastic Vialfo bags with 250 mL of solution for infusion in a protective bag, supplied in a box	YES	YES						
Sodium chloride 0.9%, Vialfo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	50 plastic Vialfo bags with 50 mL of solution for infusion in a protective bag, supplied in a box	YES	YES						
Sodium chloride 10% electrolytes concentrate, 50 mL	concentrate for intravenous use after reconstitution	Hrvatski zavod za transfuzijsku medicinu, Pétrova 3, Zagreb, Republic of Croatia	50 mL in a glass injection bottle (40 bottles per bag)	YES		YES					
Natural Wealth Ginkgo Forte	film coated tablets	NBTY Inc., New York, USA	48 (2x24) film coated tablets in a blister (PVC/AI), supplied in a box	YES					YES	YES	
Natural Wealth Vitamin E-200 IU, capsules	capsules	NBTY Inc. New York, USA	100 capsules in a brown plastic bottle, supplied in a box	YES	YES						
Navoban injection 5 mg/5 mL	solution for injection and infusion, oral solution	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 mL of solution in a glass ampoule, 10 ampoules in a box	YES	YES						
Navoban capsules 5 mg	capsules, hard	Novartis Farmacéutica S.A., Ronda Santa María 158, Barcelona, Spain	5 (1x5) capsules in a blister (PVC/PVDC//AI), supplied in a box	YES	YES						
Nazol 0.05% nasal drops, solution	nasal drops, solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 mL of nasal drops in a clear plastic (PE) bottle with a dropper attachment, supplied in a box	YES		YES			YES		
Nazol 0.1% nasal drops, solution	nasal drops, solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 mL of nasal drops in a clear plastic (PE) bottle with a dropper attachment, supplied in a box	YES		YES			YES		
Nebido 1000 mg/4 mL solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	4 mL of solution in an amber glass ampoule, 1 ampoule in a box	YES	YES		YES		YES		
Nebilet	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	14 (2x7) tablets in a PVC/AI blister, supplied in a carton box	YES	YES		YES		YES		
Nebilet	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	14 (1x14) tablets in a PVC/AI blister, supplied in a carton box	YES	YES		YES		YES		
Neloren 300 mg/mL injection	solution for injection for intramuscular use and intravenus infusion	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 ampoules each containing 1 mL of solution, supplied in a box	YES	YES						
Neloren 600 mg/2 mL injection	solution for injection for intramuscular use and intravenus infusion	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 ampoules each containing 2 mL of solution, supplied in a box	YES	YES						
Neo-angin sugar-free lozenges	lozenges	DIVAPHARMA GmbH, Motzener Straße 41, Berlin, Germany	24 (2x12) lozenges in a PVC/PE/PVDC-AI blister, supplied in a box	YES	YES		YES		YES		

Neo-angin lozenges	lozenges	DIVAPHARMA GmbH, Motzener Straße 41, Berlin, Germany	24 (2x12) lozenges in a PVC/PVDC-AI blister, supplied in a box		YES		YES		YES		
Neodolpassé	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	Box with 10 glass bottles with 250 mL of solution		YES		YES				
Neofen 200 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (2x10) tablets in a blister (PVC/AI), supplied in a box	YES			YES		YES		
Neofen forte	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a carton box	YES			YES		YES		
NeoRecormon 10.000 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.6 mL of solution, in protective packaging, supplied in a carton box		YES	YES		YES			
NeoRecormon 1000 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES		YES			
NeoRecormon 2000 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES		YES			
NeoRecormon 30.000 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	One glass syringe (with needle) containing 0.6 mL of solution, in a protective container, supplied in a carton box		YES	YES		YES			
NeoRecormon 3000 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES		YES			
NeoRecormon 4000 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES		YES			
NeoRecormon 500 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES		YES			
NeoRecormon 6000 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES		YES			
NeoRecormon Multidose 100 000 IU powder and diluent for solution for injection	powder and diluent for solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	Vial with powder for solution for injection and ampoule with diluent, supplied in a box		YES	YES		YES			
NeoRecormon Multidose 50 000 IU powder and diluent for solution for injection	powder and diluent for solution for injection	Roche Diagnostics GmbH, Sandhoefer Strasse 116, D-68305 Mannheim, Germany	Vial with powder for solution for injection and ampoule with diluent, supplied in a carton box		YES	YES		YES			
Neostigmin injection	solution for injection (for i.m., i.v. and s.c.use)	Rotexmedica GmbH, Trittau, Germany	1-mL of solution in an amber glass ampoule, 10 ampoules in a box		YES		YES				
Neotigason capsules 10 mg	capsules, hard	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) capsules in a blister (PVC/PE/PVDC//AI), supplied in a box		YES	YES					
Neotigason capsules 25 mg	capsules, hard	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) capsules in a blister (PVC/PE/PVDC//AI), supplied in a box		YES	YES					

Nephrolect	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass infusion bottles with 250 mL (10x250mL) of solution, supplied in a carton box		YES		YES					
Nephrolect	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass infusion bottles with 500 mL (10x500mL) of solution, supplied in a carton box		YES		YES					
Netromycine injection 150 mg/1.5 mL	solution for injection for intramuscular and intravenous use	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	1.5-mL of solution in a glass vial, supplied in a box		YES	YES						
Neupogen 30	solution for injection (for s.c. and i.v. use)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe with needle containing 0.5 mL of solution, in a plastic container, supplied in a box		YES	YES						
Nexavar 200 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	112 (4x28) tablets in transparent (PP/AI) blister, supplied in a box		YES	YES		YES	YES			
Nexium 20 mg	gastric-resistant tablets	AstraZeneca AB, Södertälje, Sweden	14 (2x7) tablets in a A/AI blister, supplied in a box		YES	YES						
Nexium 40 mg	gastric-resistant tablets	AstraZeneca AB, Södertälje, Sweden	14 (2x7) tablets in a A/AI blister, supplied in a box		YES	YES						
Nexium i.v. 40 mg	powder for preparation of injection/infusion solution	AstraZeneca AB, Södertälje, Sweden	10 bottles, supplied in a box		YES	YES						
Niaspan 1000 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany, Merck Santé s.a.s., Sémoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-AI), supplied in a box		YES		YES					
Niaspan 1000 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany Merck SANTE s.a.s., Sémoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-AI), supplied in a box		YES		YES					
Niaspan 375 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany, Merck Santé s.a.s., Sémoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-AI), supplied in a box		YES		YES					
Niaspan 375 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany Merck SANTE s.a.s., Sémoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-AI), supplied in a box		YES		YES					
Niaspan 500 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany, Merck Santé s.a.s., Sémoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-AI), supplied in a box		YES		YES					
Niaspan 500 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany Merck SANTE s.a.s., Sémoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-AI), supplied in a box		YES		YES					
Niaspan 750 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany Merck SANTE s.a.s., Sémoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-AI), supplied in a box		YES		YES					
Niaspan 750 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany, Merck Santé s.a.s., Sémoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-AI), supplied in a box		YES		YES					
NIBEL 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 (1x14) tablets in a blister (PVC/PE/PVDC/AI), supplied in a box	YES			YES					
Nicorette Freshmint Gum 2 mg	chewing gum	Pfizer Health AB, Norrbroplatsen 2, Helsingborg, Sweden	15 (1x15) chewing gums in a blister (PVC/PVDC//AI), supplied in a box		YES		YES			YES		
Nicorette Freshmint Gum 4 mg	chewing gum	Pfizer Health AB, Norrbroplatsen 2, Helsingborg, Sweden	15 (1x15) chewing gums in a blister (PVC/PVDC//AI), supplied in a box		YES		YES			YES		

Nicorette patch 10 mg/16 h	transdermal patch	Pfizer Health AB, Norrbroplasten 2, Helsingborg, Sweden	7 (7x1) transdermal patches in a protective (PE/A1/Barex) bag, supplied in a box		YES		YES		YES		
Nicorette patch 15 mg/16 h	transdermal patch	Pfizer Health AB, Norrbroplasten 2, Helsingborg, Sweden	7 (7x1) transdermal patches in a protective (PE/A1/Barex) bag, supplied in a box		YES		YES		YES		
Nicorette patch 5 mg/16 h	transdermal patch	Pfizer Health AB, Norrbroplasten 2, Helsingborg, Sweden	7 (7x1) transdermal patches in a protective (PE/A1/Barex) bag, supplied in a box		YES		YES		YES		
Nifedipin retard 20 mg tablets	prolonged release tablets	Farmal d.d., Ludbreg, Republic of Croatia, in cooperation with Valpharma Int. s.a., San Marino	Box with 30 tablets (blister, 3x10 tbl.)	YES			YES				
Nimotop S film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	100 (10x10) film coated tablets in PP/AI blisters, supplied in a box		YES	YES					
Nimotop S solution for infusion	solution for infusion	Bayer HealthCare AG, 51368 Leverkusen, Germany	50 mL of solution for infusion in an amber glass bottle and a plastic (PE) infusion pipe, supplied in a box		YES	YES					
Ninur 50 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Box with 30 capsules (blister, 3x10 capsules)	YES			YES				
NINUR 50 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/AI blister, supplied in a box	YES			YES				
Niquitin CQ 14 mg	transdermal patch	Cardinal Health, Northamptonshire, Great Britain; Cardinal Health, Westhoughton, Bolton, Great Britain	7 (7x1) transdermal patches in a protective (PET/LDPE/AI/acrylonitrile) bag, supplied in a box		YES		YES		YES	YES	
Niquitin CQ 21 mg	transdermal patch	Cardinal Health, Northamptonshire, Great Britain; Cardinal Health, Westhoughton, Bolton, Great Britain	7 (7x1) transdermal patches in a protective (PET/LDPE/AI/acrylonitrile) bag, supplied in a box		YES		YES		YES	YES	
Niquitin CQ 7 mg	transdermal patch	Cardinal Health, Northamptonshire, Great Britain; Cardinal Health, Westhoughton, Bolton, Great Britain	7 (7x1) transdermal patches in a protective (PET/LDPE/AI/acrylonitrile) bag, supplied in a box		YES		YES		YES	YES	
Nistatin Pliva drops	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Amber glass bottle with a dropper containing powder, supplied in a box	YES			YES				
Nistatin Pliva ointment	ointment	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Aluminum tube containing 20 g of ointment, supplied in a box	YES			YES				
Nitrolingual aerosol	sublingual spray	G.Pohl- Boskamp GmbH&Co., Germany	12.2 mL of solution in a clear glass bottle (coated with red plastic layer on the outside) with metering pump and plastic spray activator with plastic protective cap, supplied in a box		YES		YES				
Nolicin film coated tablets 400 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Noliprel 2 mg/0.625 mg	tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	30 (1x30) tablets in a blister (PVC/AI) inserted into a protective bag (PE/AI/PE) with desiccant, supplied in a box		YES	YES					
Nolpaza 20 mg	gastric-resistant film-coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister (OPA/AI/PVC//AI), supplied in a box	YES			YES				

Nolpaza 40 mg	gastric-resistant film-coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister (OPA/AI/PVC//AI), supplied in a box	YES			YES					
Nolvadex tablets	film tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	30 (3x10) tablets in an aluminium blister, supplied in a box		YES	YES						
Norcuron 4 mg	powder for solution for i.v. Injection	N.V. Organon, Oss, the Netherlands; Organon S.A., Egragny Sur Epte, France	50 ampoules with powder and 50 ampoules with 1 mL of water for injection, supplied in a box		YES	YES						
Norditropin SimpleXx 10 mg/1.5 mL	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass cartridge with 1.5 mL of solution (with a rubber plunger and rubber stopper with aluminium ring and plastic closure) in a plastic container, supplied in a box		YES	YES		YES				
Norditropin SimpleXx 15 mg/ 1.5 mL	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass cartridge with 1.5 mL of solution (with a rubber plunger and rubber stopper with aluminium ring and plastic closure) in a plastic container, supplied in a box		YES	YES		YES				
Norditropin SimpleXx 5 mg/1.5 mL	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass cartridge with 1.5 mL of solution (with a rubber plunger and rubber stopper with aluminium ring and plastic closure) in a plastic container, supplied in a box		YES	YES		YES				
Normabel 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES					
Normabel 10 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 amber glass ampoules each containing 2 mL of solution, supplied in a box	YES			YES					
Normabel 2 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) film coated tablets in a PVC/AI blister, supplied in a box	YES			YES					
Normabel 5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	31 (1x30) film coated tablets in a PVC/AI blister, supplied in a box	YES			YES					
Norprolac tablets 150 µg	tablets	Ferring GmbH, Wittland 1, Kiel, Germany	30 (3x10) tablets in a blister (A1/A1), supplied in a box		YES	YES			YES			
Norprolac tablets 25 µg/ 50 µg	tablets	Ferring GmbH, Wittland 1, Kiel, Germany	3 tablets of 25 µg + 3 tablets of 50 µg in a blister(PVC/PVDC//AI), inserted a protective aluminium sachet, supplied in a box		YES	YES			YES			
Norprolac tablets 75 µg	tablets	Ferring GmbH, Wittland 1, Kiel, Germany	31 (3x10) tablets in a blister (A1/A1), supplied in a box		YES	YES			YES			
Novantrone 20 concentrate for preparation of infusion solution	concentrated solution for infusion	Wyeth Medica Republic of Ireland, Co. Kildare, Republic of Ireland and Wyeth Lederle S.p.A., Catania, Italy	Vial with 10 mL of concentrated solution and stopper with aluminium cap, supplied in a box		YES	YES						
Novocef tablets 125 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film tablets in a blister, supplied in a box	YES			YES					
Novocef tablets 250 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film tablets in a blister, supplied in a box	YES			YES					

Novocef tablets 500 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film tablets in a blister, supplied in a box	YES			YES					
Novofem	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 tablets (16 red and 12 white tablets) in a plastic, circular calendar pack, supplied in a box	YES	YES							
NovoMix 30 FlexPen	suspension for subcutaneous injection	Novo Nordisk A/S, Novo Allé, Bagsvaerd, Denmark Novo Nordisk Production SAS, 45, Avenue d'Orléans, Chartres, France	Box with 5 injection devices each with 3 mL of suspension in a glass cartridge	YES	YES		YES	YES				
NovoMix 30 Penfill	suspension for subcutaneous injection	Novo Nordisk A/S, Novo Allé, Bagsvaerd, Denmark Novo Nordisk Production SAS, 45, Avenue d'Orléans, Chartres, France	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box	YES	YES		YES	YES				
NovoMix 50 FlexPen	suspension for injections, cartridge in a pre-filled pen	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 pens (injectors) with a glass cartridge containing 3 mL of suspension, supplied in a box	YES	YES			YES				
NovoMix 50 Penfill	suspension for injection in a cartridge	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 glass cartridges each with 3 mL of suspension in protective packaging, supplied in a box	YES	YES			YES				
NovoMix 70 FlexPen	suspension for injection, cartridge in a pre-filled pen	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 pens (injectors) with a glass cartridge containing 3 mL of suspension, supplied in a box	YES	YES			YES				
NovoMix 70 Penfill	suspension for injection in a cartridge	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 glass cartridges each with 3 mL of suspension in protective packaging, supplied in a box	YES	YES			YES				
NovoNorm 0.5 mg	tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	30 (2x15) tablets in a blister, supplied in a box	YES	YES							
NovoNorm 1 mg	tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	30 (2x15) tablets in a blister, supplied in a box	YES	YES							
NovoNorm 2 mg	tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	30 (2x15) tablets in a blister, supplied in a box	YES	YES							
NovoRapid	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with 10 mL of solution, supplied in a box	YES	YES							
NovoRapid FlexPen	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 injectors, with 3 mL of solution per glass cartridge, supplied in a box	YES	YES							
NovoRapid Penfill	solution for injection	Novo Nordisk A/S, Bagsvaerd, Denmark i Novo Nordisk Productions SAS, Chartres, France	5 glass cartridges each with 3 mL of solution in protective packaging, supplied in a box	YES	YES		YES	YES				
NovoSeven 1.2 mg	powder and diluent for solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with powder and one glass vial with 2.2 mL of Water for Injection in a box, one sterile attachment for reconstitution vial, one disposable sterile syringe for reconstitution and administration of medicinal product, one sterile infusion set	YES	YES		YES	YES				

NovoSeven 2.4 mg	powder and diluent for solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with powder and one glass vial with 4.3 mL of Water for Injection in a box, one sterile attachment for reconstitution vial, one disposable sterile syringe for reconstitution and administration of medicinal product, one sterile infusion set	YES	YES	YES	YES					
NovoSeven 4.8 mg	powder and diluent for solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with powder and one glass vial with 8.5 mL of Water for Injection in a box, one sterile attachment for reconstitution vial, one disposable sterile syringe for reconstitution and administration of medicinal product, one sterile infusion set	YES	YES	YES	YES					
Novuroxim injection 1500 mg	powder for preparation of solution for i.v. injection	Pliva Krakow, Krakow, Poland	5 (20 mL) glass bottles with powder, supplied in a box	YES	YES							
Novuroxim injection 250 mg	powder for preparation of solution/suspension for i.m. and i.v. injection	Pliva Krakow, Krakow, Poland	5 (7.5 mL) glass bottles with powder, supplied in a box	YES	YES							
Novuroxim 750 mg injection	powder for preparation of solution/suspension for i.m. and i.v. injection	Pliva Krakow, Krakow, Poland	5 (10 mL) glass bottles with powder, supplied in a box	YES	YES							
Novuroxim tablets 125 mg	film tablets	Pliva Krakow, Krakow, Poland	10 (1x10) tablets in a blister, supplied in a box	YES	YES							
Novuroxim tablets 250 mg	film tablets	Pliva Krakow, Krakow, Poland	10 (1x10) tablets in a blister, supplied in a box	YES	YES							
Novuroxim tablets 500 mg	film tablets	Pliva Krakow, Krakow, Poland	10 (1x10) tablets in a blister, supplied in a box	YES	YES							
Nozid 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 tablets in an amber glass bottle, supplied in a box	YES		YES						
Nozinan 100 mg tablets	film coated tablets	Famar Lyon, 29 Avenue du General de Gaulle 69230 Saint Genis Laval, France	20 (2x10) tablets in a blister, supplied in a box	YES	YES							
Nozinan 100 mg tablets	film coated tablets	Famar Lyon, 29 Avenue du General de Gaulle 69230 Saint Genis Laval, France	20 (2x10) tablets in a blister (PVC/AI), supplied in a box	YES	YES							
Nozinan 25 mg tablets	film coated tablets	Famar Lyon, 29 Avenue du General de Gaulle 69230 Saint Genis Laval, France	20 (2x10) tablets in a blister, supplied in a box	YES	YES							
Nozinan 25 mg tablets	film coated tablets	Famar Lyon, 29 Avenue du General de Gaulle 69230 Saint Genis Laval, France	20 (2x10) tablets in a blister (PVC/AI), supplied in a box	YES	YES							

NUROFEN Cold and Flu film coated tablets	film coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) film coated tablets in PVC/PVdC/Al blister, supplied in a box		YES	YES			YES		
NUROFEN Cold and Flu film coated tablets	film coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) film coated tablets in PVC/PVdC/Al blister, supplied in a box		YES	YES			YES		
Nurofen Liquid capsules	capsules, soft	Reckitt Benckiser Healthcare International Ltd., Nottingham, Great Britain, in cooperation with Banner Pharmacaps Europe B.V., Tilburg, the Netherlands	10 (1x10) capsules in a PVC/PVdC/Al blister, supplied in a box		YES	YES			YES		
Nurofen Liquid capsules	capsules, soft	Reckitt Benckiser Healthcare International Ltd., Nottingham, Great Britain in cooperation with Banner Pharmacaps Europe B.V., Tilburg, the Netherlands	10 (1x10) capsules in a PVC/PVdC/Al blister, supplied in a box		YES	YES			YES		
NUROFEN coated tablets	coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) coated tablets in a PVC/PVdC/Al blister, supplied in a carton box		YES	YES			YES		
NUROFEN coated tablets	coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) coated tablets in a PVC/PVdC/Al blister, supplied in a plastic box		YES	YES			YES		
NUROFEN coated tablets	coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) coated tablets in a PVC/PVdC/Al blister, supplied in a plastic box		YES	YES			YES		
NUROFEN coated tablets	coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) coated tablets in a PVC/PVdC/Al blister, supplied in a carton box		YES	YES			YES		
NUROFEN oral suspension for children	oral suspension	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	101 mL of suspension in a brown plastic (PET) bottle with temper-proof closure with protective plastic ring, and 5-mL graduated plastic syringe, supplied in a box		YES	YES					
NUROFEN oral suspension for children	oral suspension	Boots Contract Manufacture Ltd., Nottingham, Great Britain or Hermal Kurt Herrmann GmbH&Co, Reinbeck, Germany	100 mL of suspension in a brown plastic (PET) bottle with temper-proof closure with protective plastic ring, and 5-mL graduated plastic syringe, supplied in a box		YES	YES					
Nutrineal PD4 with 1.1% amino acids	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	Plastic (PVC) Vialflex bag containing 2000 mL of solution for peritoneal dialysis, feeding tube (PVC), connector with protective cap, drain tube, drug administration attachment and a Vialex plastic collection bag (individual packages)		YES	YES					
NuvaRing	intravaginal ring	N.V. Organon, Oss, The Nederlands; Organon Republic of Ireland Ltd., Co. Dublin, Republic of Ireland	Intravaginal ring in protective Al sachet, supplied in a box		YES	YES			YES		
OCTAGAM 1 g	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria, Octapharma S.A.S., Lingolsheim, France and Octapharma AB, Stockholm, Sweden	One glass vial with 20 mL of solution for infusion, supplied in a box		YES						YES
OCTAGAM 10 g	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria, Octapharma S.A.S., Lingolsheim, France and Octapharma AB, Stockholm, Sweden	One glass vial with 200 mL of solution for infusion, supplied in a box		YES						YES

OCTAGAM 2.5 g	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria, Octapharma S.A.S., Lingolsheim, France and Octapharma AB, Stockholm, Sweden	One glass vial containing 50 mL of solution for infusion, supplied in a box	YES								YES
OCTAGAM 5 g	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria, Octapharma S.A.S., Lingolsheim, France and Octapharma AB, Stockholm, Sweden	One glass vial with 100 mL of solution for infusion, supplied in a box	YES								YES
Octaplas SD blood type 0	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	200 mL of solution in sterile PVC transfusion bags coated with polyamide/polyethylene film	YES								YES
Octaplas SD blood type A	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	200 mL of solution in sterile PVC transfusion bags coated with polyamide/polyethylene film	YES								YES
Octaplas SD blood type AB	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	200 mL of solution in sterile PVC transfusion bags coated with polyamide/polyethylene film	YES								YES
Octaplas SD blood type B	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	200 mL of solution in sterile PVC transfusion bags coated with polyamide/polyethylene film	YES								YES
Octenisept	solution	Schulke & Mayr GmbH, Norderstedt, Germany	50 mL of solution in a plastic bottle with a spray pump	YES	YES							YES
Oikamid	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 60 capsules in a blister (5x12)	YES		YES						
Oikamid injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 ampoules each containing 5 mL of solution, supplied in a box	YES		YES						
Oikamid injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 ampoules each containing 5 mL of solution, supplied in a box	YES		YES						
Oikamid capsules	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 60 capsules in a blister (5x12)	YES		YES						
Oksazepam 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3X10) tablets in a PVC/AI foil blister, supplied in a carton box	YES		YES						
Oksazepam 30 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Olanzapin CIPLA 10 mg	film coated tablets	Cipla Ltd., Kurkumbh Industrial Area, Maharashtra State, India	30 (3x10) film coated tablets in a blister (OPA/AI/PVC//AI), supplied in a box		YES	YES						
Olanzapin CIPLA 2.5 mg	film coated tablets	Cipla Ltd., Kurkumbh Industrial Area, Maharashtra State, India	31 (3x10) film coated tablets in a blister (OPA/AI/PVC//AI), supplied in a box		YES	YES						
Olanzapin CIPLA 5 mg	film coated tablets	Cipla Ltd., Kurkumbh Industrial Area, Maharashtra State, India	32 (3x10) film coated tablets in a blister (OPA/AI/PVC//AI), supplied in a box		YES	YES						
Olicard 40 mg retard	prolonged release capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (5x10) capsules in a blister (PVC/AI), supplied in a box	YES		YES						

Olicard 60 mg retard	prolonged release capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (5x10) capsules in a blister (PVC/Al), supplied in a box	YES		YES						
OliClinomel N4 - 550E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag for 2000 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES	YES						
OliClinomel N4 - 550E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag with 1000 mL of blend (in three separate compartments) in a plastic protective casing, 6 bags in a carton box		YES	YES						
OliClinomel N6 - 900 E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag for 2000 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES	YES						
OliClinomel N7 - 1000 E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag for 2000 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES	YES						
OliClinomel N7 - 1000 E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag with 1000 mL of blend (in three separate compartments) in a plastic protective casing, 6 bags in a carton box		YES	YES						
Olivin 10 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES					
Olivin 20 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES					
Olivin 5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES					
Olynth 0.05% nasal spray	nasal spray, solution	Pfizer PGM, Orleans Cedex, France	10 mL of solution in an amber glass bottle with a plastic atomizer extension and protective cap, supplied in a box		YES		YES			YES		
Olynth 0.1% nasal drops	nasal drops, solution	Pfizer PGM, Orleans Cedex, France	10 mL of solution in an amber glass bottle with dropper, supplied in a box		YES		YES			YES		
Olynth 0.1% nasal spray	nasal spray, solution	Pfizer PGM, Orleans Cedex, France	10 mL of solution in an amber glass bottle with a plastic atomizer extension and protective cap, supplied in a box		YES		YES			YES		
Olynth 0.5% nasal drops	nasal drops, solution	Pfizer PGM, Orleans Cedex, France	10 mL of solution in an amber glass bottle with dropper, supplied in a box		YES		YES			YES		
Olynth HA 0.05% nasal spray	nasal spray, solution	URSAPHARM Arzneimittel GmbH&Co., Saarbrücken, Germany	10 mL of solution in a white plastic bottle with a 3K system and protective cap, supplied in a box		YES		YES			YES		
Olynth HA 0.1% nasal spray	nasal spray, solution	URSAPHARM Arzneimittel GmbH&Co., Saarbrücken, Germany	10 mL of solution in a white plastic bottle with a 3K system and protective cap, supplied in a box		YES		YES			YES		
Omacor	capsules (soft, transparent, gelatinous)	Solvay Pharmaceuticals GmbH, Neustadt, Germany	28 capsules in a plastic bottle		YES	YES				YES		
Omegaven	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass bottles with 100 mL of emulsion (10x100 mL), supplied in a box		YES		YES					
Omegaven	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass bottles with 50 mL of emulsion (10x50 mL), supplied in a box		YES		YES					

Omezol capsules 20 mg	gastric-resistant capsules, hard	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	14 (2x7) capsules in a OPA/Al/PVC//Al blister, supplied in a box	YES		YES						
Omnic 0.4 mg	prolonged-release capsules	Astellas Pharma Europe B.V., Elisabethhof 19, Leiderdorp, the Netherlands	Box with 3x10 prolonged release capsules in an Al/polypropylene blister		YES	YES						
Omnipaque 240 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 10 mL of solution, supplied in a box		YES	YES						
Omnipaque 300 solution	solution for injection/infusion	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 100 mL of solution, supplied in a box		YES	YES						
Omnipaque 300 solution	solution for injection/infusion	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 50 mL of solution, supplied in a box		YES	YES						
Omnipaque 300 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 10 mL of solution, supplied in a box		YES	YES						
Omnipaque 350 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	6 bottles with 200 mL of solution, supplied in a box		YES	YES						
Omnipaque 350 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	25 bottles each with 20 mL of solution, supplied in a box		YES	YES						
Omnipaque 350 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 50 mL of solution, supplied in a box		YES	YES						
Omnipaque 350 solution	solution for injection/infusion	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 100 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	10 glass bottles with 20 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	10 glass bottles with 10 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection (pre-filled syringe)	solution for injection	GE Healthcare AS, Nydalen, Oslo, Norway	10 plastic syringes with 20 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection (pre-filled syringe)	solution for injection	GE Healthcare AS, Nydalen, Oslo, Norway	10 plastic syringes with 10 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection (pre-filled syringe)	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	10 plastic syringes with 5 mL of solution, supplied in a box		YES	YES						
Opatanol 1 mg/mL eye drops	eye drops	Alcon Couvreur N.V., Rijksweg 14, Puurs, Belgium; Alcon Cusi S.A., Camil Fabra 58, El Masnou, Barcelona, Spain	Plastic bottle (low density polyethylene) with a dropper and a stopper (polypropylene) containing 5 mL of solution, supplied in a box		YES	YES						
Operil 0.05% nasal drops	nasal drops	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of solution in a plastic bottle with a dropper, supplied in a box		YES	YES			YES			

Operil 0.05% nasal spray	nasal spray (solution)	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of solution in a plastic box with atomizer extension, supplied in a box		YES		YES		YES		
Operil P 0.025% nasal drops	nasal drops	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of solution in a plastic bottle with a dropper, supplied in a box		YES		YES		YES		
Operil P 0.025% nasal spray	nasal spray (solution)	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of solution in a plastic box with atomizer extension, supplied in a box		YES		YES		YES		
Optimon 10 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/AI), supplied in a box	YES			YES				
Optimon 20 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/AI), supplied in a box	YES			YES				
Optimon 5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/AI), supplied in a box	YES			YES				
Optimon Plus 10/12.5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/PVDC/AI), supplied in a box	YES			YES				
Optimon Plus 20/12.5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/PVDC/AI), supplied in a box	YES			YES				
Ornidol 100 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES			YES				
Ornidol 25 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets (3x10) in a PVC/AI blister, supplied in a box	YES			YES				
Ornidol 50 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets (3x10) in a PVC/AI blister, supplied in a box	YES			YES				
Oronazol cream	cream	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 g of cream in a tube, supplied in a box		YES		YES				
Oronazol shampoo	shampoo	Janssen Pharmaceutica NV, Turnhouteweg 30, Beerse, Belgium	100 mL of shampoo in a plastic bottle, supplied in a box		YES	YES			YES		
Oronazol tablets	tablets	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	20 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Ortalox 10 mg	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	14 capsules in a plastic bottle (HDPE), supplied in a box	YES			YES				
Ortalox 20 mg	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	14 capsules in a plastic bottle (HDPE), supplied in a box	YES			YES				
Ortanol 20 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	7 capsules in an amber glass bottle, supplied in a box		YES		YES				
Ortanol 40 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	7 (1x7) capsules in a blister, supplied in a box		YES		YES				

Ortonol S 10 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	7 (1x7) capsules in a blister, supplied in a box		YES		YES					
Ortonol S 10 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	28 (4x7) capsules in a blister, supplied in a box		YES		YES					
Osseor 2 g	granules for oral suspension	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	7 bags (paper/PE/Al/PE) with granules, supplied in a box		YES	YES			YES			
OVITRELLE 250 mg	powder and diluent for preparation of solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and vial with diluent with 1 mL of Water for Injection, supplied in a box		YES	YES			YES			
OVITRELLE 250 micrograms/0.5 mL	solution for injection in a syringe	Industria Farmaceutica Serono S.p.A., Bari, Italy	One glass syringe with needle in a plastic container, supplied in a box		YES	YES			YES			
Oxaliplatin Pliva 100 mg	powder for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for solution for infusion in a glass bottle (50 mL) with a rubber stopper, aluminium ring and plastic cap, supplied in a box	YES			YES					
Oxaliplatin Pliva 50 mg	powder for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for solution for infusion in a glass bottle (26 mL) with a rubber stopper, aluminium ring and plastic cap, supplied in a box	YES			YES					
Oxetin film coated tablets 20 mg	film coated tablets	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina in cooperation with JMP, Jordan	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES					
OxyContin 10 mg	prolonged-release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 tablets (3x10) in a PVC/Al blister, supplied in a box		YES	YES						
OxyContin 20 mg	prolonged-release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 tablets (3x10) in a PVC/Al blister, supplied in a box		YES	YES						
OxyContin 40 mg	prolonged-release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 tablets (3x10) in a PVC/Al blister, supplied in a box		YES	YES						
OxyContin 80 mg	prolonged-release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 tablets (3x10) in a PVC/Al blister, supplied in a box		YES	YES						
OxyContin tablets 10 mg	prolonged release tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain	56 (4x14) tablets in a PVC/Al blister, supplied in a box		YES	YES						
OxyContin tablets 20 mg	prolonged release tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain	56 (4x14) tablets in a PVC/Al blister, supplied in a box		YES	YES						
OxyContin tablets 40 mg	prolonged release tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain	56 (4x14) tablets in a PVC/Al blister, supplied in a box		YES	YES						
OxyContin tablets 80 mg	prolonged release tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain	56 (4x14) tablets in a PVC/Al blister, supplied in a box		YES	YES						
Paclitaxel Ebewe 150 mg/25 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	25 mL of solution in a glass bottle, supplied in a box		YES		YES					
Paclitaxel Ebewe 30 mg/5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution in a glass bottle, supplied in a box		YES		YES					

Paclitaxel Pliva 100 mg/16.7 mL	concentrate for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One glass vial in a box	YES		YES					
Paclitaxel Pliva 30 mg/5 mL	concentrate for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One glass vial in a box	YES		YES					
PACLITAXEL PLIVA 300 mg/50 mL	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 mL of solution concentrate in a glass bottle (multi dose vial) with a rubber stopper, an aluminium cap and a protective lid, supplied in a box	YES		YES					
Paclitaxin 6 mg/mL	concentrate of solution for infusion	Pharmachemie B.V., Haarlem, the Netherlands	16.7 mL of concentrate for infusion solution in a clear glass bottle with teflon-coated rubber (bromobutyl) stopper and aluminium ring with plastic (PP) lid, supplied in a box		YES	YES	YES	YES			
Paclitaxin 6 mg/mL	concentrate of solution for infusion	Pharmachemie B.V., Haarlem, the Netherlands	5 mL of solution for infusion concentrate in a colourless glass bottle with a rubber (bromobutyl) stopper coated with Teflon and an Al ring with a plastic (PP) lid, supplied in a box		YES	YES	YES	YES			
Paclitaxin 6 mg/mL	concentrate of solution for infusion	Pharmachemie B.V., Haarlem, the Netherlands	25 mL of concentrate for infusion solution in a clear glass bottle with rubber (bromobutyl) stopper coated with teflon and Al ring with plastic (PP) lid, supplied in a box		YES	YES	YES	YES			
Paclitaxin 6 mg/mL	concentrate of solution for infusion	Pharmachemie B.V., Haarlem, the Netherlands	50 mL of solution for infusion concentrate in a colourless glass bottle with a rubber (bromobutyl) stopper coated with Teflon and an aluminium ring with a plastic (PP) lid, supplied in a box		YES	YES	YES	YES			
Palladone SR capsules 16 mg	prolonged-release capsules	Mundipharma Ges.m.b.H., Vienna, Austria	56 (4x14) capsules in a blister (PVDC/PVC//Al), supplied in a box		YES	YES					
Palladone SR capsules 4 mg	prolonged-release capsules	Mundipharma Ges.m.b.H., Vienna, Austria	56 (4x14) capsules in a blister (PVDC/PVC//Al), supplied in a box		YES	YES					
Palladone SR capsules 8 mg	prolonged-release capsules	Mundipharma Ges.m.b.H., Vienna, Austria	56 (4x14) capsules in a blister (PVDC/PVC//Al), supplied in a box		YES	YES					
Pamitor 15 mg/mL concentrate for infusion solution	concentrate for infusion solution	Torrex-Pharma GmbH, Vienna, Austria	One clear glass ampoule containing 4 mL of solution, supplied in a box		YES	YES					
Pamitor 15 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Torrex-Pharma GmbH, Vienna, Austria	Polyethylene ampoule containing 2 mL of solution, supplied in a box		YES	YES					
Pamitor 15 mg/mL concentrate for infusion solution	concentrate for infusion solution	Torrex-Pharma GmbH, Vienna, Austria	A clear glass ampoule containing 6 mL of solution, supplied in a box		YES	YES					
Pamitor 15 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Torrex-Pharma GmbH, Vienna, Austria	Polyethylene ampoule containing 4 mL of solution, supplied in a box		YES	YES					
Pamitor15 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Torrex-Pharma GmbH, Vienna, Austria	Polyethylene ampoule containing 6 mL of solution, supplied in a box		YES	YES					
Pamitor15 mg/mL concentrate for infusion solution	concentrate for infusion solution	Torrex-Pharma GmbH, Vienna, Austria	One clear glass ampoule containing 2 mL of solution, supplied in a box		YES	YES					

Panadol	film coated tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 (1x12) tablets in a PVC/AI blister, supplied in a box		YES	YES			YES		
Panadol Baby	oral suspension	Glaxo Wellcome Production, Avenue du General de Gaulle, Herouville Saint Clair, France	300 mL of suspension in an amber glass bottle with a plastic temper-evident stopper and a plastic measuring device (0.5 mL to 8 mL), supplied in a box		YES	YES			YES		
Panadol Baby	oral suspension	Glaxo Wellcome Production, Avenue du General de Gaulle, Herouville Saint Clair, France	100 mL of suspension in an amber glass bottle with plastic temper-proof closure and plastic dispenser (0.5 mL to 8 mL), supplied in a box		YES	YES			YES		
Panadol Extra	film coated tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 (1x12) tablets in a PVC/AI blister, supplied in a carton box		YES	YES			YES		
Panadol Rapid	film coated tablets	GlaxoSmith Kline Dungarvan Limited, Republic of Ireland	10 (1x10) tablets in a PVC/AI blister, supplied in a box		YES	YES			YES		
Panaze 10000 capsules	capsules (with gastric-resistant microfilm tablets)	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 capsules in an amber glass bottle, supplied in a box		YES	YES					
Pancuronium injection BP 4 mg	solution for intravenous injection	Rotexmedica GmbH, Trittau, Germany	2 mL of solution in a glass ampoule, 10 ampoules in a box		YES	YES					
Pankreoflat	coated tablets	Solvay Pharmaceuticals GmbH, Hannover, Germany	50 (2x25) tablets in a blister, supplied in a box		YES	YES			YES		
Pantexol cream	cream	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of cream in an aluminium tube with plastic cap, supplied in a box	YES		YES			YES		
Pantexol ointment	ointment	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of ointment in an aluminium tube with plastic cap, supplied in a box	YES		YES			YES		
Paracetamol JADRAN syrup 150 mL	syrup	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	150 mL of syrup in an amber glass bottle and a plastic measuring glass, supplied in a box	YES		YES			YES		
Paraplatin 150 mg/15 mL concentrate for solution for infusion	concentrate of solution for infusion	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	15 mL of concentrate for infusion solution in a glass bottle, supplied in a box		YES	YES					
Paraplatin 50 mg/5 mL concentrate for solution for infusion	concentrate of solution for infusion	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	5 mL of solution for infusion concentrate in a glass bottle, supplied in a box		YES	YES					
Partobulin SDF 1250 IU	solution for injection	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with one pre-filled syringe and a needle with one dose of 250 ug (1250 IU) of preparation		YES						YES
Patentex Oval N	pessary	Merz Pharma GmbH & Co KGaA, Frankfurt am Main, Germany	6 (1x6) pessaries in a PVC/PVDC/PE strip, supplied in a box		YES	YES			YES		
Pavulon 4 mg=2 mL	solution for injection	N.V. Organon, Oss, the Netherlands; Organon S.A., Eragny Sur Epte, France	50 ampoules with 2 mL of solution, supplied in a box		YES	YES					
PEDIACEL vaccine against diphtheria, tetanus, pertussis (acellular, five component), poliomyelitis (inactivated) and Haemophilus influenzae type B (conjugated), absorbed	suspension for injection	Sanofi Pasteur Limited, Toronto, Canada	0.5-mL of suspension in a glass bottle (glass type I, Ph.Eur), with a bromobutyl stopper that does not contain latex, supplied in a box		YES					YES	

PEGASYS 135 micrograms of solution for injection in pre-filled syringe	solution for injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	Box with 1 syringe containing 0.5 mL of solution and a needle		YES	YES		YES	YES			
PEGASYS 180 micrograms of solution for injection in pre-filled syringe	solution for injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	Box with 1 syringe containing 0.5 mL of solution and a needle		YES	YES		YES	YES			
Pegltron 100 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES			
Pegltron 100 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES			
Pegltron 120 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES			
Pegltron 120 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES			
Pegltron 150 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES			
Pegltron 150 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES			
Pegltron 50 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES			
Pegltron 50 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES			
Pegltron 80 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES			
Pegltron 80 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES			

Penbritin injection 1 g	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 colourless glass bottles with powder, supplied in a box	YES			YES					
Penbritin injection 500 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 colourless glass bottles with powder, supplied in a box	YES			YES					
Pentamon	film coated tablets with prolonged-release	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/AI) blister, supplied in a box	YES			YES					
Pentasa 1 g suppositories	suppositories	Ferring A/S, Vanlose, Denmark	28 (4x7) suppositories in an aluminium blister, supplied in a box		YES	YES						
Pentasa 1 g suspension for rectal administration	suspension for rectal administration	Ferring-Lečiva a.s., Jesenice u Prahy, Czech Republic	7 individually packed containers (in bags) with 100 mL of suspension and an application attachment, in a protective bag and 7 plastic hygiene bags, supplied in a box		YES	YES						
Pentasa 500 mg tablets	prolonged release tablets	Ferring A/S, Vanlose, Denmark; Ferring Intercontinental Center SA, St-Prix, Switzerland	100 (10x10) tablets in aluminum blisters, supplied in a box		YES	YES						
PENTAXIM, diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated), and Haemophilus influenzae type B conjugated vaccine	powder and suspension for suspension for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with a glass bottle with powder and a glass syringe with 0.5 mL of suspension with a needle and a needle protection		YES							YES
PENTILIN solution for injection 100 mg/5 mL	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 mL of solution for injection in a glass ampoule, 5 ampoules in a box		YES	YES						
PENTILIN tablets 400 mg	prolonged-release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) prolonged-release tablets in PVC/AI blister, supplied in a box		YES	YES						
Peptoran 75 tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film coated tablets in a OPA/AI/PVC//AI blister, supplied in a box	YES			YES			YES		
Perfalgan 10 mg/mL	solution for infusion	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	One glass vial with 100 mL of solution for infusion, 12 vials in a transparent protective container (polyethylene with thermo film)		YES		YES	YES	YES			
Perfalgan 10 mg/mL	solution for infusion	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	One glass vial with 50 mL of solution for infusion, 12 vials in a transparent protective container (polyethylene with thermo film)		YES		YES	YES	YES			
Persantin 75 mg coated tablets	coated tablets	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	50 coated tablets in a white plastic container (PP) with a white stopper (PE), supplied in a box		YES	YES						
Persen sugar-coated tablets	sugar-coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	Box with 40 sugar coated tablets (blister, 4x10 sugar coated tablets)		YES					YES	YES	
Persen forte capsules	capsules, hard	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	20 (2x10) capsules in a (PVC/PCTFE//AI) blister, supplied in a box		YES					YES	YES	
Persen forte capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	Box with 20 capsules (blister, 2x10 capsules)		YES					YES	YES	
Persen tablets	coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	40 (4x10) coated tablets in a blister (PVC/TE/PVDC//AI), supplied in a box		YES					YES	YES	

Phenobarbiton sodium injection	powder (lyophilisate) and diluent for preparation of injections	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 ampoules with powder and 5 ampoules each with 2 mL of solvent (water for injection), supplied in a box	YES			YES					
PHENOBARBITON PLIVA 100 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in an orange blister (PVC/AI), supplied in a box	YES			YES					
PHENOBARBITON PLIVA15 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in an orange blister (PVC/AI), supplied in a box	YES			YES					
PHOLCODIN 10 mg capsules	capsules	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	20 capsules in an amber glass bottle, supplied in a box		YES		YES					
PHOLCODIN 15 mg/15 mL oral solution	oral solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	150 mL of solution in an amber glass bottle with plastic closure and 15-mL plastic dispenser, supplied in a box		YES		YES					
PHOLCODIN 4 mg/5 mL oral solution for children	oral solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	60 mL of solution in an amber glass bottle with a plastic stopper and a plastic measuring unit of 2.5 mL, supplied in a box		YES		YES					
Physiotens 0.2	film coated tablets	Solvay Pharmaceuticals S.A.S., Châtillon sur Chalaronne, France	28 (1x28) film coated tablets in a PVC/PVDC/AI blister, supplied in a box		YES	YES						
Physiotens 0.4	film coated tablets	Solvay Pharmaceuticals S.A.S., Châtillon sur Chalaronne, France	28 (1x28) film coated tablets in a PVC/PVDC/AI blister, supplied in a box		YES	YES						
Pigrel	film coated tablets	Jadran -Galenski laboratorij d.d., Rijeka in cooperation with Krka Farma d.o.o., Zagreb	28 (4x7) tablets in a blister, supplied in a box	YES			YES					
Pilfud 2% lotion	lotion	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	60 mL of lotion in an amber glass bottle, supplied in a box		YES		YES			YES		
Pilfud 5% lotion	skin spray, solution	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	60 mL of solution in a plastic bag with a spray pump and a temper-evident stopper, supplied in a box		YES		YES			YES		
Piramil 1.25 mg tablets	tablets	LEK S.A., Stryków, Poland; LEK S.A., Warszawa, Poland	28 (7x4) tablets in a strip, supplied in a box		YES		YES					
Piramil 10 mg tablets	tablets	LEK S.A., Stryków, Poland; LEK S.A., Warszawa, Poland	28 (7x4) tablets in a blister, supplied in a box		YES		YES					
Piramil 2.5 mg tablets	tablets	LEK S.A., Stryków, Poland; LEK S.A., Warszawa, Poland	28 (7x4) tablets in a blister, supplied in a box		YES		YES					
Piramil 5 mg tablets	tablets	LEK S.A., Stryków, Poland; LEK S.A., Warszawa, Poland	28 (7x4) tablets in a blister, supplied in a box		YES		YES					
"Planinski čaj" - herbal laxative tea	herbal laxative tea	Trešnjevka laboratorij d.o.o., Jukićeva 32, Zagreb, Republic of Croatia	75 g of tea in a plastic (PP) bag, supplied in a box	YES						YES	YES	
Platinex 10 mg/20 mL concentrate for infusion solution	concentrate for infusion solution	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	20 mL of infusion solution concentrate in an amber glass bottle, supplied in a box		YES	YES						
Platinex 50 mg/100 mL concentrate for infusion solution	concentrate for infusion solution	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	100 mL of concentrate for infusion solution in an amber glass bottle, supplied in a box		YES	YES						

Plavix	film coated tablets	Sanofi Winthrop Industrie, Ambares et Lagrave, Carbon Blanc Cedex, France	28 (2x14) film coated tablets in a blister (Al/Al), supplied in a box		YES	YES		YES			
PLICET EFFECT tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film coated tablets in an orange PVC/PVDC//Al blister, supplied in a box	YES			YES		YES		
Plicet syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of syrup in an amber glass bottle and a 5-mL spoon, supplied in a box	YES			YES		YES		
Plicet tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in PVC/Al blister, supplied in a box	YES			YES		YES		
Plicet tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES		YES		
Plimycol cream	cream	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 grams of cream in an aluminium tube, supplied in a box	YES			YES				
PLIVADON	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in an orange blister (PVC/PVDC//Al), supplied in a box	YES			YES		YES		
PLIVIT B1 injection 100 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	1-mL of solution for injection in a glass ampoule, 50 ampoules in a box	YES			YES				
PLIVIT B1 injection 250 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	2 mL of solution for injection in a glass ampoule, 50 ampoules in a box	YES			YES				
PLIVIT B1 tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES			YES		YES		
PLIVIT B6 injection 250 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 mL of solution for injection in an amber glass ampoule, 50 ampoules in a box	YES			YES				
PLIVIT B6 injection 50 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	2 mL of solution for injection in an amber glass ampoule, 50 ampoules in a box	YES			YES				
PLIVIT B6 tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES			YES		YES		
PLIVIT C 1000 mg sugar-free effervescent tablets, lemon flavoured	effervescent tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 effervescent tablets in a polypropylene tube (cap with silicagel and tamper-proof ring), supplied in a box	YES			YES		YES		
PLIVIT C 1000 mg sugar-free effervescent tablets, lemon flavoured	effervescent tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 effervescent tablets in a polypropylene tube (cap with silicagel and tamper-proof ring), supplied in a box	YES			YES		YES		
PLIVIT C tablets 50 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES		YES		
PLIVIT C tablets 500 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES			YES		YES		
PLIVIT C 500 mg prolonged-release tablets	film coated prolonged-release tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) prolonged-release film coated tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES		YES		

Plivit D3	oral drops, solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 mL of solution in an amber glass bottle with plastic dropper attachment, supplied in a box	YES			YES					
Plymicol vaginal tablets	vaginal tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	3 vaginal tablets in a blister, supplied in a box	YES			YES					
PNEUMO 23 Pneumococcal polysaccharide vaccine	solution for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with 1 glass syringe containing 0.5 mL of vaccine and a needle with protection		YES						YES	
Poliosabin (Oral) trivalent live, attenuated vaccine against poliomyelitis, Sabin strain, stabilized in MgCl <sub>2</sub>	oral suspension	GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, Rixensart, Belgium	Box with 25 plastic tubes with one vaccine dose		YES						YES	
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	One 1.5 mL of suspension in a glass vial, 3 glass syringes and 4 needles for injection, supplied in a box	YES							YES	
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	3 red glass syringes each containing 0.5 mL of suspension and 4 needles for injection, supplied in a box	YES							YES	
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	3 glass syringes each containing 0.5 mL of suspension and 4 needles for injection, supplied in a box	YES							YES	
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	3 glass bottles each containing 1 mL of suspension, 5 syringes and 6 needles for injection, supplied in a box	YES							YES	
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	One 1.5 mL of suspension in a glass vial, 3 glass syringes and 4 needles for injection, supplied in a box	YES							YES	
Pollinex grass and rye, extract of grass and rye for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	4 glass syringes each containing 0.5 mL of suspension and 4 needles for injection, supplied in a box	YES							YES	
Pollinex grass and rye, extract of grass and rye for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	4 glass bottles each containing 1 mL of suspension, 5 syringes and 6 needles for injection, supplied in a box	YES							YES	
Pollinex grass and rye, extract of grass and rye for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	5 glass syringes each containing 0.5 mL of suspension and 4 needles for injection, supplied in a box	YES							YES	
Portal 20 mg capsules	capsules	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	28 (4x7) capsules in a blister, supplied in a box		YES	YES						
Portal 20 mg capsules	capsules	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	14 (2x7) capsules in a blister, supplied in a box		YES	YES						
Portalak syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 bags (PET/Al/PE) with à 15 mL of syrup, supplied in a box	YES			YES			YES		
Portalak syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 (PET/Al/PE) bags each with 15 mL of syrup, supplied in a box	YES			YES			YES		
Portalak syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	250-mL of syrup in a plastic bottle with screw cap, supplied in a box	YES			YES			YES		

Prazine sugar-coated tablets 100 mg	sugar-coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 sugar coated tablets (5x10) in a blister, supplied in a box	YES		YES						
Prazine sugar-coated tablets 25 mg	sugar-coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 sugar coated tablets (5x10) in a blister, supplied in a box	YES		YES						
Prazine injection 100 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 ampoules with 2 mL of solution	YES		YES						
Prazine injection 50 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 ampoules with 1 mL of solution	YES		YES						
Productal	film coated tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	60 (2x30) tablets in a PVX/AI blister, supplied in a box		YES	YES						
PRENESSA tablets 4 mg	tablets	Krka d.d., Novo mesto, Republic of Slovenia; KRKA Polska Sp.z.o.o., Warszawa, Poland	30 (3x10) tablets in PVC/PE/PVDC//AI blister, supplied in a box		YES	YES	YES	YES	YES			
Prevenar S. Pneumoniae saccharide conjugated vaccine, absorbed	suspension for injection	John Wyeth & Brother Ltd., Hants, Great Britain	One glass vial with 0.5 mL of vaccine suspension, one syringe and two needles, supplied in a box		YES							YES
Prevenar, saccharide, conjugated and absorbed vaccine against S. pneumoniae	suspension for injection	John Wyeth & Brother Ltd., Hants, Great Britain	10 syringes with 0.5 mL of vaccine suspension, supplied in a box		YES							YES
Prevenar S. Pneumoniae saccharide conjugated vaccine, absorbed	suspension for injections	John Wyeth & Brother Ltd., Hants, Great Britain	One syringe with 0.5 mL of vaccine suspension, supplied in a box		YES							YES
Prevenar S. Pneumoniae saccharide conjugated vaccine, absorbed	suspension for injections	John Wyeth & Brother Ltd., Hants, Great Britain	One syringe with 0.5 mL of vaccine suspension, with separate needle, supplied in a box		YES							YES
Prevenar S. Pneumoniae saccharide conjugated vaccine, absorbed	suspension for injection	John Wyeth & Brother Ltd., Hants, Great Britain	One glass vial with 0.5 mL of vaccine suspension, supplied in a box		YES							YES
Prexanil 4 mg	tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	30 (1x30) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
PREXANIL 8 mg tablets	tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	30 (1x30) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Prexanil Combi	tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	30 (1x30) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Primolut-Nor tablets	tablets	Schering GmbH und Co. Produktions KG, Doeberinerstrasse 20, Weimar, Germany	20 tablets in an amber glass bottle, supplied in a carton box		YES	YES						
Primus tea	tea	Fitofarmacija d.o.o., Zagreb, Republic of Croatia	14 bags each containing 5 g of tea, supplied in a box	YES						YES	YES	
Prinivil 10 mg tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES						

Prinivil 20 mg tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Prinivil 5 mg tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Prinzide 20/12.5 mg tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a PVC/AI blister, supplied in a box		YES	YES						
PRIORIX, combined, live lyophilized vaccine against morbilli, parotitis and rubella	powder and diluent for solution for injection	GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, Rixensart, Belgium	Vial containing single dose of lyophilised vaccine (powder), syringe with pre-filled 0.5 mL of diluent, Water for injection, and two needles with protective caps, supplied in a box		YES	YES		YES	YES		YES	
PRITOR 40 mg tablets	tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (4x7) tablets in a blister (PA/AI/PVC//AI), supplied in a box		YES	YES		YES	YES			
PRITOR 80 mg tablets	tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (4x7) tablets in a blister (PA/AI/PVC//AI), supplied in a box		YES	YES		YES	YES			
PriorPlus 40/12.5 mg tablets	tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (4x7) tablets in a blister (OPA/AI/PVC/AI blister), supplied in a box		YES	YES			YES			
PriorPlus 80/12.5 mg tablets	tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (4x7) tablets in a blister (OPA/AI/PVC/AI blister), supplied in a box		YES	YES			YES			
Procoralan 5 mg film coated tablets	film coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France; Servier (Republic of Ireland) Industries Ltd., Gorey Road, Arklow, Co. Wicklow, Republic of Ireland; Przedsiębiorstwo Farmaceutyczne Anpharm S.A., Ul. Annopol 603-236, Warszawa, Poland	29 (2x14) film coated tablets in a PVC/AI blister, supplied in a carton box		YES	YES		YES	YES			
Procoralan 7.5 mg film coated tablets	film coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France; Servier (Republic of Ireland) Industries Ltd., Gorey Road, Arklow, Co. Wicklow, Republic of Ireland; Przedsiębiorstwo Farmaceutyczne Anpharm S.A., Ul. Annopol 603-236, Warszawa, Poland	30 (2x14) film coated tablets in a PVC/AI blister, supplied in a carton box		YES	YES		YES	YES			
Proctosan	ointment	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	20 grams of ointment in an aluminum tube with a plastic cap, supplied in a box		YES	YES			YES			
Proctosan forte	suppositories	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	10 (2x5) suppositories in a strip (PVC/LDPE foil), supplied in a box		YES	YES			YES			
Proculin	eye drops, solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 mL of solution in an amber glass bottle and plastic sterile dropper attachment in a protective plastic bag, supplied in a box		YES	YES						
Pro-famosal 20 mg	coated tablets	Pro. Med.CS Praha a.s., Prag, Czech Republic	Box with 20 tablets (blister)		YES	YES						

Pro-famosal 20 mg	coated tablets	Pro. Med.CS Praha a.s., Prag, Czech Republic	Box with 20 tablets (blister)		YES	YES					
Pro-famosal 40 mg	coated tablets	Pro. Med.CS Praha a.s., Prag, Czech Republic	Box with 10 tablets (blister)		YES	YES					
Pro-famosalL 40 mg	coated tablets	Pro. Med.CS Praha a.s., Prag, Czech Republic	Box with 10 tablets (blister)		YES	YES					
Prograf capsules 0.5 mg	capsules, hard	Astellas Republic of Ireland Co. Ltd., Killorglin, Republic of Ireland	30 (3x10) capsules in a blister (PVC/PVDC//Al), in protective aluminum envelope with desiccant, supplied in a box		YES	YES		YES			
Prograf capsules 1 mg	capsules	Astellas Republic of Ireland Co. Ltd., Killorglin, Republic of Ireland	60 (6x10) capsules in a blister, in protective aluminium foil, supplied in a box		YES	YES		YES			
Prograf capsules 5 mg	capsules	Astellas Republic of Ireland Co. Ltd., Killorglin, Republic of Ireland	30 (3x10) capsules in a blister, in protective aluminium envelope, supplied in a box		YES	YES		YES			
Prolax suppositories for children	suppositories	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 (2x5) suppositories in a Al/PE strip, supplied in a box	YES		YES		YES			
Prolax suppositories for children	suppositories	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 (2x5) suppositories in a Al/PE strip, supplied in a box	YES		YES		YES			
Propafenon Alkaloid 150 mg film coated tablets	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	50 tablets in an amber glass bottle with an aluminium stopper, supplied in a box		YES	YES					
Propafenon Alkaloid 35 mg/10 mL solution for injection	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (2x5) ampoules each containing 10 mL of solution, supplied in a box		YES	YES					
Propafenon Genericon 150 mg film coated tablets	film coated tablets	Genericon Pharma Ges.m.b.H., Hafnerstrasse 211, Graz, Austria	50 (5x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Propafenon Genericon 300 mg film coated tablets	film coated tablets	Genericon Pharma Ges.m.b.H., Hafnerstrasse 211, Graz, Austria	50 (5x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Propecia 1 mg	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Propiltiouracil Alkaloid 50 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	20 tablets in an amber glass bottle, supplied in a carton box		YES	YES					
Propranolol Lek 40 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 tablets in a glass bottle, supplied in a box		YES	YES					
Proscar 5 mg	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Prospan acute effervescent tablets	effervescent tablets	Engelhard Arzneimittel GmbH & Co.KG, Niederdorfelden, Germany	10 effervescent tablets in a plastic tube (desiccant in polyethylene cap), supplied in a box		YES				YES	YES	
Prospan Liquid	oral solution	Engelhard Arzneimittel GmbH & Co.KG, Niederdorfelden, Germany	30 bags each with 5 mL of solution, supplied in a box		YES				YES	YES	

Prospan oral solution	oral solution	Engelhard Arzneimittel GmbH & Co.KG, Niederdorfelden, Germany	100 mL of solution in an amber glass bottle with plastic extension/attachment, screw cap and 10 mL measuring glass, supplied in a box		YES					YES	YES		
Prospera 1 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/PE/PVDC/AI blister, supplied in a box	YES		YES							
Prospera 2 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/PE/PVDC/AI blister, supplied in a box	YES		YES							
Prospera 3 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/PE/PVDC/AI blister, supplied in a box	YES		YES							
Prospera 4 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/PE/PVDC/AI blister, supplied in a box	YES		YES							
Protecta 10 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (1x28) tablets in a transparent blister (PVC/PE/PVDC//AI), supplied in a box	YES		YES							
Protecta 20 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (2x14) tablets in a transparent blister (PVC/PE/PVDC//AI), supplied in a box	YES		YES							
Protecta 40 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	29 (2x14) tablets in a transparent blister (PVC/PE/PVDC//AI), supplied in a box	YES		YES							
PROVERA tablets 10 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	30 (3x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES							
PROVERA tablets 5 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	24 tablets in an amber glass bottle with plastic cap, supplied in a box		YES	YES							
Prozac 20 mg capsules	capsules	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	14 (1x14) capsules in a blister (PVC/AI), supplied in a box		YES	YES							
Prozac dispersible tablets 20 mg	freely dispersible tablets	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain	14 (1x14) tablets in a blister (PVC/PE/Aclar//AI), supplied in a box		YES	YES							
Prozac Liquid 20 mg/5 mL oral solution	oral solution	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain; Patheon France, 40, boulevard de Champaret, Bourgoin-Jallieu, France	70 mL of oral solution in an amber glass bottle and a plastic measuring cup (with a 5 mL graduate line), supplied in a box		YES	YES							
Psorimed	dermal solution	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	100 grams of solution in a plastic (HDPE) bottle with applicator-shaped PP cap, supplied in a box		YES	YES							
Pulmozyme	solution for inhalation	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	2.5 mL of solution in a plastic (polyethylene) ampoule, 6 ampoules in a protective foil, supplied in a box		YES	YES							
Purisan granules	granules	Cedevita d.o.o., Zagreb, Republic of Croatia	14 bags in a box	YES						YES	YES		
PYRAZINAMID Krka tablets 500 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 tablets in an amber glass bottle with aluminum cap, supplied in a box		YES	YES							
Ramipril 10 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a AI/OPA/PVC/AI blister, supplied in a box	YES		YES							

Ramipril 2.5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES		YES						
Ramipril 5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES		YES						
Ramipril H 2.5mg/12.5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES		YES						
Ramipril H 5 mg/25 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES		YES						
RAMIPRIL PLIVA 10 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA/PVC/Al), supplied in a box	YES		YES						
RAMIPRIL PLIVA 2.5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA/PVC/Al), supplied in a box	YES		YES						
RAMIPRIL PLIVA 5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA/PVC/Al), supplied in a box	YES		YES						
RAMIPRIL PLUS PLIVA 2.5/12.5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA/PVC/Al), supplied in a box	YES		YES						
RAMIPRIL PLUS PLIVA 5/25 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA/PVC/Al), supplied in a box	YES		YES						
Ranisan 150 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	20 (2x10) tablets in a blister, supplied in a box		YES	YES						
Ranisan 150 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	60 (6x10) tablets in a blister (Al/Al), supplied in a box		YES	YES						
Ranisan 150 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	20 (2x10) tablets in a blister (Al/Al), supplied in a box		YES	YES						
Ranisan 150 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	30 (3x10) tablets in a blister (Al/Al), supplied in a box		YES	YES						
Ranisan 75 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	10 (1x10) tablets in a blister, supplied in a box		YES	YES			YES			
Ranisan 75 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	10 (1x10) tablets in a Al/Al blister, supplied in a box		YES	YES			YES			
Ranital injection 50 mg/2 mL	solution for injection	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	5 ampoules each with 2 mL of water for injection in a blister, supplied in a box	YES		YES						
Ranital tablets 150 mg	film coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	20 (2x10 tablets in Al/Al blister, supplied in a box	YES		YES						
Ranital tablets 300 mg	film coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a Al/Al blister, supplied in a box	YES		YES						

Ranitidin Europharma injection 50 mg/2 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 ampoules each with 2 mL of solution, supplied in a box	YES			YES					
Ranitidin Europharma tablets 150 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES					
Ranitidin Europharma tablets 300 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in a blister, supplied in a box	YES			YES					
Ranix 150	film tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES					
Ranix 300	film tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 (1x10) tablets in a blister, supplied in a box	YES			YES					
Ranix injection	solution for intramuscular and intravenous injection	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	5 amber glass ampoules with 2 mL of solution, supplied in a box	YES			YES					
Rapamune 1 mg coated tablets	coated tablets	Wyeth Pharmaceuticals, New Lane, Havant, Hampshire P09 2NG, Great Britain	30 (3x10) tablets in a PVC/PE/Aclar/Al blister, supplied in a box		YES	YES			YES			
Rapilysin 10 U powder and diluent for injection solution	powder and diluent for solution for injection	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim, Germany	2 glass bottles with 10 units of powder, 2 pre-filled syringes with 10 mL of diluent, 2 reconstitution kits and 2 injection needles		YES	YES		YES	YES			
Raptiva 100 mg/mL	powder and diluent for solution for injection	Laboratories Serono S.A., Aubonne, Switzerland   Industria Farmaceutica Serono S.p.A., Rome, Italy	One glass vial with powder, a syringe with 1.3 mL of diluent, a reconstitution needle and an injection needle, supplied in a box		YES	YES			YES			
RAWEL SR	prolonged-release film-coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES	YES		YES		
RAWEL SR	film coated tablets with prolonged-release	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 (6x10) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES	YES		YES		
REBETOL 200 mg hard capsules	hard capsules	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	84 (7x12) capsules in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES			
REBETOL 40 mg/mL oral solution	oral solution	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	100 mL of oral solution in an amber glass bottle with temper-proof plastic closure, 1 glass bottle in a box		YES	YES		YES	YES			
Rebif 22 micrograms -solution for injection	solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy   Laboratories Serono S.A., Aubonne, Switzerland	Pre-filled 1-mL glass syringe with fixed stainless steel needle containing a single 0.5 mL dose of solution for injection, supplied in a box		YES	YES						
Rebif 44 micrograms -solution for injection	solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy; Laboratories Serono S.A., Aubonne, Switzerland	Pre-filled 1-mL glass syringe with fixed stainless steel needle containing a single 0.5 mL dose of solution for injection, supplied in a box		YES	YES						
Recombinate 1000 IU	lyophilisate and solvent for preparation of intravenous solution (injections/infusion)	Baxter S.A, Hyland Immuno, Lessines, Belgium	30 mL bottle with lyophilized drug, bottle with 10 mL of solvent (water for injection), sterile double needle for dissolution, sterile filter needle, sterile mini infusion kit, disposable sterile syringe, supplied in a box		YES							YES
Recombinate 250 IU	lyophilisate and solvent for intravenous solution (injections/infusion)	Baxter S.A, Hyland Immuno, Lessines, Belgium	30 mL bottle with lyophilized drug, bottle with 10 mL of solvent (water for injection), sterile double needle for dissolution, sterile filter needle, sterile mini infusion kit, disposable sterile		YES							YES

			syringe, supplied in a box									
Recombinate 500 IU	lyophilisate and solvent for preparation of i.v. solution (injections/infusion)	Baxter S.A, Hyland Immuno, Lessines, Belgium	30 mL bottle with lyophilized drug, bottle with 10 mL of solvent (water for injection), sterile double needle for dissolution, sterile filter needle, sterile mini infusion kit, disposable sterile syringe, supplied in a box	YES								YES
Rectodelt 100 mg suppositories	suppositories	Trommsdorff GmbH & Co.KG Arzneimittel, Alsdorf, Germany	4 suppositories in a white non-transparent strip (PVC/PE), supplied in a box	YES	YES							
Reductil 10 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) capsules in a blister, supplied in a box	YES	YES							
Reductil 15 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) capsules in a blister, supplied in a box	YES	YES							
Reglan injection	solution for intramuscular injection and intravenous infusion	Alkaloid AD, Skopje, FYROM in cooperation with Sanofi-Synthelabo, France	30 ampoules (6 x 5 on a plastic pad) with 2 mL of solution, supplied in a box	YES		YES						
REGLAN solution	oral solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	120 mL of solution in an amber glass bottle with dispenser, supplied in a box	YES		YES						
Reglan tablets	tablets	Alkaloid AD, Skopje, FYROM in cooperation with Sanofi-Synthelabo, France	40 tablets in an amber glass bottle, supplied in a box	YES		YES						
Relenza	inhalation powder, dosed	GlaxoWellcome Production, Evreux, France and GlaxoSmithKline Australia Pty Ltd., Australia	5 rotadisk blisters (PVC/AI) each with 4 doses of powder, in a plastic box with 1 diskhaler (applicator), supplied in a box	YES	YES				YES			
Remicade powder for concentrate of infusion solution	powder for preparation of concentrate for infusion solution	Centocor B.V., Einsteinweg 101, 2333 CB Leiden, the Netherlands	One glass vial with powder supplied in a box	YES	YES							
Renagel 800 mg film coated tablets	film coated tablets	Genzyme Limited Great Britain; Genzyme Republic of Ireland Limited, Republic of Ireland	180 tablets in a plastic bottle	YES	YES		YES	YES				
Rennie	chewing tablets	Bayer Sante Familiale, 33 rue de L'industrie, 74240 Gaillard, France	24 (4x6) tablets in a blister, supplied in a box	YES		YES			YES			
Replagal 1 mg/1 mL concentrate for infusion solution	concentrate for infusion solution	TKT Europe AB, Danderyd, Sweden	5-mL glass bottle with 3.5-mL of concentrate supplied in a box	YES	YES		YES	YES				YES
Replagal 1 mg/1 mL concentrate for solution for infusion	concentrate for infusion solution	TKT Europe AB, Danderyd, Sweden	3-mL glass bottle with 1-mL of concentrate supplied in a box	YES	YES		YES	YES				YES
Requip 0.25 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	210 tablets in a PVC/PVDC blister, supplied in a box	YES	YES							
Requip 1 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	21 tablets in a PVC/PVDC blister, supplied in a box	YES	YES							
Requip 2 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	21 tablets in a PVC/PVDC blister, supplied in a box	YES	YES							
Requip 5 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	21 tablets in a PVC/PVDC blister, supplied in a box	YES	YES							

Retafer 100 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 tablets in an amber glass bottle with an aluminium stopper, supplied in a box		YES	YES							
Revatio 20 mg tablets	film coated tablets	Pfizer PGM, Poce sur Cisse, France	90 (6x15) tablets in a blister (PVC/AI), supplied in a box		YES	YES		YES	YES				
Revia	film coated tablets	Bristol-Myers Squibb, Epernon, France	28 (4x7) tablets in a white nontransparent PVC/PE/Aclar/AI blister, supplied in a box		YES	YES							
Rhesogamma P	solution for intramuscular injection	Aventis Boehringer GmbH, Emil-von-Behring Strasse 76, Marburg, Germany	Box with 1 ampoule with 1.5 mL of solution (not less than 300 µg = 1500 IU)		YES								YES
Rhesonativ 1250 IU	lyophilisate and diluent for preparation of solution for i.m. injection	Octapharma AB, Stockholm, Sweden	Lyophilisate in a glass bottle (8 mL) and 2 mL of solvent (water for injection) in an ampoule, supplied in a box		YES								YES
RHINOSTOP syrup	syrup	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	100 mL of syrup in an amber glass bottle with plastic cap and a 5-mL plastic measuring spoon, supplied in a box		YES	YES		YES					
RHINOSTOP tablets	tablets	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	10 (1x10) tablets in a Al/PVC blister, supplied in a box		YES	YES				YES			
Ringer's solution for intravenous infusion, 500 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petra 3, Zagreb, Republic of Croatia	500 mL in a glass infusion bottle with a chlorobutyl stopper protected with an aluminium cap with a plastic lid (10 bottles with plastic holders, supplied in a box)	YES			YES						
Ringer's solution	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	10 polyethylene bottles with 1000 mL of solution, supplied in a box		YES	YES							
Ringer's solution	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	10 polyethylene bottles with 500 mL of solution, supplied in a box		YES	YES							
Ringer's solution Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain	10 plastic Viaflo bags with 1000 mL of infusion solution, in a protective bag, supplied in a box		YES	YES							
Ringer's solution Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain	20 plastic Viaflo bags with 500 mL of infusion solution, in a protective bag, supplied in a box		YES	YES							
Rinolan syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of syrup in a 125 mL amber glass bottle with aluminum cap and a 5-mL plastic (polyethylene) spoon, supplied in a box	YES			YES						
Rinolan tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a box	YES			YES						
Rispolept 1 mg/mL solution for oral use	oral solution	Janssen Pharmaceutica NV, Turnhoutseweg 30, Beerse, Belgium	100 mL of oral solution in an amber glass bottle with temper-proof plastic closure and pipette, supplied in a box		YES	YES							
Rispolept Consta 25 mg	prolonged-release suspension for i.m. injections	Cilag AG, Schaffhausen, Switzerland for Janssen Pharmaceutica N.V., Beerse, Belgium	65.6 mg of powder (microspheres) in a glass bottle, 2 mL of solvent in a syringe, 2 needles for preparation of suspension and 1 needle for i.v. administration, in a plastic container, supplied in a box		YES	YES							
Rispolept Consta 37.5 mg	prolonged-release suspension for i.m. injections	Cilag AG, Schaffhausen, Switzerland for Janssen Pharmaceutica N.V., Beerse, Belgium	98.4 mg of powder (microspheres) in a glass bottle, 2 mL of solvent in a syringe, 2 needles for preparation of suspension and a needle for i.v.		YES	YES							

			administration, inserted into a plastic container, supplied in a box									
Rispolept Consta 50 mg	prolonged-release suspension for i.m. injection	Cilag AG, Schaffhausen, Switzerland for Janssen Pharmaceutica N.V., Beerse, Belgium	131.2 mg powder (microsphere) in a glass bottle, 2 mL of diluent in a syringe, 2 needles for suspension preparation and one needle for intramuscular administration, inserted in a plastic container, supplied in a box	YES	YES							
Rispolept tablets 1 mg	film coated tablets	Janssen-Cilag S.p.A., Borgo San Michele, Latina, Italy	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES	YES							
Rispolept tablets 2 mg	film coated tablets	Janssen-Cilag S.p.A., Borgo San Michele, Latina, Italy	60 (6x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES	YES							
Rispolept tablets 3 mg	film coated tablets	Janssen-Cilag S.p.A., Borgo San Michele, Latina, Italy	60 (6x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES	YES							
Rispolept tablets 4 mg	film coated tablets	Janssen-Cilag S.p.A., Borgo San Michele, Latina, Italy	60 (6x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES	YES							
Rispolux 1 mg	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/PE/PVDC/Al blister, supplied in a box	YES		YES		YES				
Rispolux 2 mg	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/PE/PVDC/Al blister, supplied in a box	YES		YES		YES				
Rispolux 3 mg	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/PE/PVDC/Al blister, supplied in a box	YES		YES		YES				
Rispolux 4 mg	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/PE/PVDC/Al blister, supplied in a box	YES		YES		YES				
Risset tablets 1 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in an orange PVC/PVDC/A1 blister, supplied in a box	YES		YES						
Risset tablets 2 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in an orange PVC/PVDC/A1 blister, supplied in a box	YES		YES						
Risset tablets 3 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in an orange PVC/PVDC/A1 blister, supplied in a box	YES		YES						
Risset tablets 4 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in an orange PVC/PVDC/A1 blister, supplied in a box	YES		YES						
Rivotril 0.5 mg tablets	tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	50 tablets in an amber glass bottle with a plastic (PE) stopper, supplied in a box	YES	YES							
Rivotril 2 mg tablets	tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 tablets in an amber glass bottle with a plastic (PE) stopper, supplied in a box	YES	YES							
Roaccutane soft capsules 10 mg	soft capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) soft capsules in a blister (PVC/PE/PVDC//Al), supplied in a box	YES	YES							
Rocaltrol 0.25 µg capsules	soft capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 (5x20) capsules in PVC/AI blister, supplied in a box	YES	YES							

Rocaltrol 0.5 µg capsules	soft capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 (5x20) capsules in a PVC/Al blister, supplied in a box		YES	YES						
Rocephin 1 g i.m.	powder for preparation of solution for intramuscular injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	2 g of powder in a vial and 3.5 mL of diluent (Water for Injection) in an ampoule, supplied in a box		YES	YES						
Rocephin 1 g i.v.	powder for preparation of solution for intravenous injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	1 g of powder in a vial and 10mL of diluent (Water for Injection) in an ampoule, supplied in a box		YES	YES						
Rocephin 2g powder for infusion solution	powder for solution for infusion (for i.v. use)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One 50 mL glass vial for infusion containing powder, with rubber cap, supplied in a vial		YES	YES						
Roferon-A 3 MIU/0.5 mL	solution for injection (for single s.c. administration)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe containing 0.5 mL of solution, closed with protective cap and a needle (in a plastic container), supplied in a box		YES	YES						
Roferon-A 4.5 MIU/0.5 mL	solution for injection (for single s.c. administration)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe with 0.5 mL of solution closed with a protective cap and one needle (in a plastic container), supplied in a box		YES	YES						
Roferon-A 6 MIU/0.5 mL	solution for injection (for single s.c. administration)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe with 0.5 mL of solution closed with a protective cap and one needle (in a plastic container), supplied in a box		YES	YES						
Roferon-A 9 MIU/0.5 mL	solution for injection (for single s.c. administration)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe with 0.5 mL of solution closed with a protective cap and one needle (in a plastic container), supplied in a box		YES	YES						
ROJAZOL 200 mg pessary	pessary	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	7 (1 x7) pessaries in an Al/PE strip, supplied in a box	YES			YES					
ROJAZOL cream	cream	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 g of cream in an aluminium tube with a plastic stopper, supplied in a box	YES			YES					
ROJAZOL oral gel	oral gel	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	40 g of oral gel in an aluminium tube with a 5 mL plastic measuring spoon, supplied in a box	YES			YES					
Rosalgin granules	granules for vaginal solution	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	4 bags (2x2), each with 9.44 g of granulate, supplied in a box		YES		YES					
Rosalgin solution	vaginal solution	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	140 mL of solution in a plastic bottle with plastic applicator attachment, 5 bottles in a carton box		YES		YES					
ROWAchol capsules	capsules	ROWA PHARMACEUTICALS LTD., Newtown, Bantry, Co. Cork, Republic of Ireland	30 (3x10) capsules in a blister, supplied in a box		YES				YES	YES		
ROWAtinex capsules	capsules	ROWA PHARMACEUTICALS LTD., Newtown, Bantry, Co. Cork, Republic of Ireland	30 (3x10) capsules in a blister, supplied in a box		YES				YES	YES		
Rozamet 1% cream	cream	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of cream in an Al tube, supplied in a carton box	YES			YES					
RUDAKOL 135 mg coated tablets	coated tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 coated tablets in an amber glass bottle with an aluminium stopper, supplied in a box	YES			YES					

Rupurut chewing tablets	chewing tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 (2x10) chewing tablets in a blister, supplied in a box		YES	YES			YES		
Rutacid chewing tablets 500 mg	chewing tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (PVC/PVDC/AI), supplied in a box		YES		YES		YES		
Rytmonorm 150 mg film tablets	film coated tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) film coated tablets in a blister (PVC/AI or PP/AI), supplied in a box		YES	YES					
Rytmonorm 300 mg film tablets	film coated tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) film coated tablets in a blister (PVC/AI or PP/AI), supplied in a box		YES	YES					
Rytmonorm solution for injection	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	20 mL of injection solution in a glass ampoule, 5 ampoules supplied in a box		YES		YES				
Salazopyrin EN tablets 500 mg	gastric-resistant tablets	Pfizer Health AB, Uppsala, Sweden	100 tablets in a polyethylene bottle, supplied in a box		YES	YES					
Salofalk suppositories 250 mg	suppositories	dr. Falk Pharma GmbH, Freiburg, Germany	30 (6x5) suppositories in a strip (PVC/LDPE), supplied in a box		YES		YES				
Salofalk suppositories 500 mg	suppositories	dr. Falk Pharma GmbH, Freiburg, Germany	30 (6x5) suppositories in a strip (PVC/LDPE), supplied in a box		YES		YES				
Salofalk suspension for rectal administration 4 g/60 mL	suspension for rectal administration	dr. Falk Pharma GmbH, Freiburg, Germany	7 plastic containers each with 60 mL of suspension (with attachment for rectal administration) in a protective blister, supplied in a box		YES		YES				
Salofalk 250 mg tablets	gastric-resistant tablets	dr. Falk Pharma GmbH, Freiburg, Germany	100 (10x10) tablets in a PVC/PVDC//AI blister, supplied in a box		YES		YES				
Salofalk 500 mg tablets	gastric-resistant tablets	dr. Falk Pharma GmbH, Freiburg, Germany	100 (10x10) tablets in a PVC/PVDC//AI blister, supplied in a box		YES		YES				
Salviamin L8b.UH	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	250-mL of solution for infusion in a plastic bottle for infusion, 10 bottles and plastic bottle holders in a box	YES			YES				
Salviamin L8b.UH	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution for infusion in a glass infusion bottle, 10 bottles and plastic bottle holders in a box	YES			YES				
Salviamin LX6	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution for infusion in a glass infusion bottle, 10 bottles in a box	YES			YES				
Sandimmun 50 mg/mL concentrate for infusion	concentrate for intravenous infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	10 ampoules containing 5 mL of concentrate for infusion, supplied in a box		YES	YES					
Sandimmun Neoral 100 mg capsules	soft gelatinous capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	50 (10x5) capsules in an AI blister, supplied in a box		YES	YES					
Sandimmun Neoral capsules 25 mg	soft gelatinous capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	50 (10x5) capsules in an AI blister, supplied in a box		YES	YES					
Sandimmun Neoral capsules 50 mg	soft gelatinous capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	50 (10x5) capsules in an AI blister, supplied in a box		YES	YES					

Sandimmun Neoral 100 mg/mL oral solution	oral solution	Novartis Pharma S.A.S., Huningue Cedex, France	50 mL of solution in an amber glass bottle with a measuring kit (in a protective container), supplied in a box		YES	YES						
Sandostatin 0.05 mg injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 ampoules each with 1 mL of solution for injection, supplied in a box		YES	YES						
Sandostatin 0.1 mg injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 ampoules each with 1 mL of solution for injection, supplied in a box		YES	YES						
Sandostatin 0.5 mg injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 ampoules each with 1 mL of solution for injection, supplied in a box		YES	YES						
Sandostatin LAR 10 mg	powder and diluent for suspension for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial with powder, pre-filled syringe with 2.5 mL of diluent for suspension, and two needles (1.1x40 mm, 19 G x 1 1/2") in individual packages, inserted into protective plastic container, supplied in a carton box		YES	YES						
Sandostatin LAR 20 mg	powder and diluent for suspension for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial with powder, pre-filled syringe with 2.5 mL of diluent for suspension, two needles (1.1x40 mm, 19 G x 1 1/2") in individual packages, inserted into a protective plastic container, supplied in a carton box		YES	YES						
Sandostatin LAR 30 mg	powder and diluent for suspension for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial with powder, pre-filled syringe with 2.5 mL of diluent for suspension, two needles (1.1x40 mm, 19 G x 1 1/2") in individual packages, inserted into a protective plastic container, supplied in a carton box		YES	YES						
Sanval 10 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/AI blister, supplied in a box		YES	YES						
Sanval 10 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/AI blister, supplied in a box		YES	YES						
Sanval 5 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/AI blister, supplied in a box		YES	YES						
Saridon	tablets	Bayer Sante Familiale, 33 rue de L'industrie, 74240 Gaillard, France	10 (1x10) tablets in a PVC/AI blister, supplied in a box		YES	YES				YES		
Seldiar capsules	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 capsules in an amber glass bottle, supplied in a box		YES	YES						
Septolete	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (3x10) lozenges in a blister, supplied in a box		YES	YES				YES		
Septolete D	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) lozenges in a blister, supplied in a box		YES	YES				YES		
Septolete wild cherry	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	18 (2x9) lozenges in a blister (PVC/PVDC-AI), supplied in a box		YES	YES				YES		
Septolete lemon	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	18 (2x9) lozenges in a blister (PVC/PVDC-AI), supplied in a box		YES	YES				YES		

Septolete Plus lozenges	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES		YES		
Septolete green apple	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	18 (2x9) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES		YES		
Serdolect 12 mg film coated tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (4x7) tablets in a blister (PVC/PVdC/Al), supplied in a box		YES	YES			YES		
Serdolect 16 mg film coated tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (4x7) tablets in a blister (PVC/PVdC/Al), supplied in a box		YES	YES			YES		
Serdolect 20 mg film coated tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (4x7) tablets in a blister (PVC/PVdC/Al), supplied in a box		YES	YES			YES		
Serdolect 4 mg film coated tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	31 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box		YES	YES			YES		
Seretide 100 discus	inhalation powder	Glaxo Wellcome Operations, Greenford, Great Britain	60 doses of powder in an aluminium blister (with protective foil) in a plastic housing, supplied in a box		YES	YES			YES		
Seretide 125 Inhaler	inhalation aerosol	Glaxo Wellcome Production, Evreux, France	One metal container (120 doses) with metering valve in plastic atomizer for oral administration, supplied in a box		YES	YES			YES		
Seretide 250 diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Great Britain	60 doses of powder in an aluminium blister (with protective foil) in a plastic housing, supplied in a box		YES	YES			YES		
Seretide 250 Inhaler	inhalation aerosol	Glaxo Wellcome Production, Evreux, France	One metal container (120 doses) with metering valve in plastic atomizer for oral administration, supplied in a box		YES	YES			YES		
Seretide 50 Inhaler	inhalation aerosol	Glaxo Wellcome Production, Evreux, France	One metal container (120 doses) with metering valve in plastic atomizer for oral administration, supplied in a box		YES	YES			YES		
Seretide 500 diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Great Britain	60 doses of powder in an aluminium blister (with protective foil) in a plastic housing, supplied in a box		YES	YES			YES		
Serevent Discus	inhalation powder	Glaxo Wellcome Production, Evreux, France	60 doses of powder in an aluminium blister, in a plastic housing, supplied in a box		YES	YES					
Serevent Inhaler	inhalation aerosol (suspension)	GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznań, Polish Glaxo Wellcome Production, 23 Rue Lavoisier, Evreux, France	120 doses in a metal (aluminum) bottle with metering valve in plastic nebulizer, supplied in a box		YES	YES					
SEROQUEL tablets 100 mg	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	60 tablets (6x10) in a blister, supplied in a box		YES	YES			YES		
SEROQUEL tablets 200 mg	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	60 tablets (6x10) in a blister, supplied in a box		YES	YES			YES		
SEROQUEL tablets 25 mg	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	60 tablets (6x10) in a blister, supplied in a box		YES	YES			YES		

Seroquel tablets 300 mg	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	60 (6x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES			YES		
Seroxat 20 mg tablets	film coated tablets	Belupo lijekovi i kozmetika d.d., Koprivnica, Republic of Croatia in cooperation with GlaxoSmithKline, Great Britain	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Seroxat 30 mg tablets	film coated tablets	Belupo lijekovi i kozmetika d.d., Koprivnica, Republic of Croatia in cooperation with GlaxoSmithKline, Great Britain	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Seroxat oral suspension	oral suspension	Belupo lijekovi i kozmetika d.d., Koprivnica, Republic of Croatia in cooperation with GlaxoSmithKline, Great Britain	150 mL of suspension in an amber glass bottle, supplied in a box	YES			YES				
Setronon injection 4 mg/2 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 5 ampoules containing 2 mL of solution	YES			YES				
Setronon injection 8 mg/4 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 5 ampoules containing 4 mL of solution	YES			YES				
Setronon tablets 4 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES			YES				
Setronon tablets 8 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES			YES				
Sevorane	inhalate, solution	Abbott Laboratories Ltd., Queenborough, Great Britain	Brown polyethylene bottle with 250 mL of solution and a temper-evident stopper, supplied in a box		YES	YES					
Sevredol 10 mg film coated tablets	film coated tablets	Bard Pharmaceuticals Ltd., Milton Road, Cambridge, Great Britain	56 (4x14) tablets in a PVC/PVdC/AI blister, supplied in a box		YES	YES					
Sevredol 10 mg film coated tablets	film coated tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 (3x10) tablets in a PVC/PVdC/AI blister, supplied in a box		YES	YES					
Sevredol 20 mg film coated tablets	film coated tablets	Bard Pharmaceuticals Ltd., Milton Road, Cambridge, Great Britain	56 (4x14) tablets in a PVC/PVdC/AI blister, supplied in a box		YES	YES					
Sevredol 20 mg film coated tablets	film coated tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	31 (3x10) tablets in a PVC/PVdC/AI blister, supplied in a box		YES	YES					
Silapen 1000 oral suspension	oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	150 mL of suspension in an amber glass bottle, supplied in a box	YES			YES				
Silapen 1000 tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 tablets in a plastic bottle, supplied in a box	YES			YES				
Silapen 1500 tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES				
Silymarin capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) capsules in a PVC/AI blister, supplied in a box	YES					YES	YES	
Simcard 10	film coated tablets	Cipla Ltd., MIDC Industrial Area, Kurkumbh, Pune, Maharashtra State, India	20 (2x10) tablets in a blister (white PVC/PVdC/AI), supplied in a box		YES		YES				

Simcard 20	film coated tablets	Cipla Ltd., MIDC Industrial Area, Kurkumbh, Pune, Maharashtra State, India	20 (2x10) tablets in a blister (white PVC/PVDC/AI), supplied in a box		YES	YES						
Simcard 40	film coated tablets	Cipla Ltd., MIDC Industrial Area, Kurkumbh, Pune, Maharashtra State, India	28 (2x14) tablets in a blister (white PVC/PVDC/AI), supplied in a box		YES	YES						
Simdax 2.5 mg/mL concentrate for solution for infusion	concentrate for solution for infusion	Orion Corporation ORION PHARMA, Espoo, Finland	One glass vial with 5 mL of solution concentrate, supplied in a box		YES	YES			YES			
Simulect 10 mg	powder and solvent for preparation of solution for injection or infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial containing medicinal product (powder) and ampoule with 5mL of diluent (Water for Injection), supplied in a box		YES	YES						
Simulect 20 mg	powder and solvent for preparation of solution for injection or infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial containing medicinal product (powder) and ampoule with 5mL of diluent (Water for Injection), supplied in a box		YES	YES						
Simvastatin Lek 10 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia, LEK S.A., Warszawa, Poland and Salutas Pharma GmbH, Barleben, Germany	28 (2x14) tablets in a PVC/AI blister, supplied in a box		YES	YES			YES			
Simvastatin Lek 20 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia, LEK S.A., Warszawa, Poland and Salutas Pharma GmbH, Barleben, Germany	28 (2x14) tablets in a PVC/AI blister, supplied in a box		YES	YES			YES			
Simvastatin Lek 40 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia, LEK S.A., Warszawa, Poland and Salutas Pharma GmbH, Barleben, Germany	28 (2x14) tablets in a PVC/AI blister, supplied in a box		YES	YES			YES			
Simvax 10 mg film coated tablets	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/PVDC/AI) blister, supplied in a box	YES		YES						
Simvax 10 mg film coated tablets	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	28 (1x28) film coated tablets in a PVC/PVDC/AI blister, supplied in a box	YES		YES						
Simvax 20 mg film coated tablets	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/PVDC/AI) blister, supplied in a box	YES		YES						
Simvax 40 mg film coated tablets	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/PVDC/AI) blister, supplied in a box	YES		YES						
Sinecod 50 film coated tablets	film coated tablets	Novartis Saglik, Turkey za Novartis Consumer Health S.A., Switzerland	10 (1x10) tablets in a blister, supplied in a box		YES	YES						
Sinecod oral drops	oral drops, solution	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	20 mL of solution in a plastic bottle with dropper attachment, supplied in a box		YES	YES						
Sinecod syrup	syrup	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	200 mL of syrup in an amber glass bottle and a plastic measuring vessel, supplied in a box		YES	YES						
Sinemet CR tablets	controlled-release tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	100 tablets in an amber glass bottle, supplied in a box		YES	YES						
Sinemet tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	100 (10x10) tablets in a blister, supplied in a box		YES	YES						

SINERSUL forte tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in a PVC/AI blister, supplied in a box	YES			YES					
SINERSUL syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of syrup in an amber glass bottle with aluminum cap and a 5-mL plastic spoon, supplied in a box	YES			YES					
SINERSUL tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/AI), supplied in a box	YES			YES					
Singulair 10 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a PA/PVC/AI blister, supplied in a box		YES	YES						
Singulair junior 5 mg chewing tablets	chewing tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a PA/PVC/AI blister, supplied in a box		YES	YES						
Singulair mini 4 mg oral granules	granules for oral solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 aluminum bags each containing 500 mg of granules, supplied in a box		YES	YES						
Singulair mini 4 mg chewing tablets	chewing tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a PA/PVC/AI blister, supplied in a box		YES	YES						
Siofor 500	film coated tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	39 (3x10) tablets in a PVC/AI blister, supplied in a box		YES		YES					
Siofor 850	film coated tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	30 (2x15) tablets in a PVC/AI blister, supplied in a box		YES		YES					
Iceland lichen syrup	syrup	Trešnjevka laboratorij d.o.o., Jukićeva 32, Zagreb, Republic of Croatia	220 mL of syrup in an amber glass bottle with aluminum cap, supplied in a box	YES					YES	YES		
Skinoren cream	cream	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	30 g of cream in an aluminium tube, supplied in a box		YES	YES						
Skinoren cream	cream	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	30 g of cream in an aluminium tube, supplied in a box		YES	YES						
Skopryl 10 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	36 (3x10) tablets in a PVC/AI blister, supplied in a box		YES		YES					
Skopryl 20 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	37 (3x10) tablets in a PVC/AI blister, supplied in a box		YES		YES					
Compound sodium lactate solution (Hartmann's solution)	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	1000 mL of infusion solution in a plastic bottle (10 bottles in a box)		YES		YES					
Compound sodium lactate solution (Hartmann's solution)	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES		YES					
Smecta	powder for preparation of oral suspension	Beaufor Ipsen Industrie, Dreux, France	30 bags (LDPE/AI/paper) each with 3.76 g of powder for oral suspension, supplied in a box		YES		YES			YES		
Smecta	powder for oral suspension	Beaufor Ipsen Industrie, Dreux, France	10 bags (LDPE/AI/paper) each containing 3.76 g of powder for oral suspension, supplied in a box		YES		YES			YES		
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 100 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag		YES		YES		YES			

			containing oxygen absorber, and one bag with solution for packaging airtightness control								
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 500 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control	YES	YES	YES	YES				
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 250 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control	YES	YES	YES	YES				
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	Glass infusion bottle with 500 mL of emulsion (with rubber stopper, aluminum ring and plastic protective cap), 10 bottles in a carton box	YES	YES	YES	YES				
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	Glass infusion bottle with 250 mL emulsion (with rubber stopper, aluminum ring and plastic protective cap), 10 bottles in a carton box	YES	YES	YES	YES				
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	Glass infusion bottle with 100 mL of emulsion (with rubber stopper, aluminum ring and plastic protective cap), 10 bottles in a carton box	YES	YES	YES	YES				
SOLPADEINE capsules	capsules	Glaxo Wellcome Production, Mayenne, France	12 (1x12) capsules in a PVC/AI blister, supplied in a box	YES	YES	YES	YES				
SOLPADEINE effervescent tablets	effervescent tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 (3x4) effervescent tablets in multilayer strip packing (paper/PE/AI/PE), supplied in a box	YES	YES	YES	YES				
SOLPADEINE tablets	tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 (1x12) tablets in PVC/AI blister, supplied in a box	YES	YES	YES	YES				
Solu-Cortef injection 100 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (2 mL) in the upper part, supplied in a box	YES	YES						
Soludeks 1	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 20 mL of solution for injection (with rubber stopper and aluminum cap), supplied in a box	YES		YES					
Soludeks 40	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass nfusion bottles each containing 500 mL of infusion solution and plastic holders for infusion bottles, supplied in a box	YES		YES					
Soludeks 70	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	11 glass nfusion bottles each containing 500 mL of infusion solution and plastic holders for infusion bottles, supplied in a box	YES		YES					
SOLU-MEDROL injection 1000 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (15.60 mL for reconstitution of lyophilisate), supplied in a box	YES	YES	YES					
SOLU-MEDROL injection 125 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (2 mL) in the upper part, supplied in a box	YES	YES	YES					

SOLU-MEDROL injection 250 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (4 mL) in the upper part, supplied in a box		YES	YES						
SOLU-MEDROL injection 40 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (1mL) in the upper part, supplied in a box		YES	YES						
SOLU-MEDROL injection 500 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (7.8 mL for reconstitution of lyophilisate), supplied in a box		YES	YES						
SOMAVERT injection 10 mg	powder and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle of 6 mL with powder and a glass bottle with 8 mL of water for injection 30 bottles with powder and 30 bottles with solvent, supplied in a box		YES	YES		YES	YES			
SOMAVERT injection 15 mg	powder and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle of 6 mL with powder and a glass bottle with 8 mL of water for injection 30 bottles with powder and 30 bottles with solvent, supplied in a box		YES	YES		YES	YES			
SOMAVERT injection 20 mg	powder and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle of 6 mL with powder and a glass bottle with 8 mL of water for injection 30 bottles with powder and 30 bottles with solvent, supplied in a box		YES	YES		YES	YES			
SOMAVERT injection 20 mg	powder and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle of 6 mL with powder and a glass bottle with 8 mL of water for injection 1 bottle with powder and 1 bottle with solvent, supplied in a box		YES	YES		YES	YES			
Sonalia 50 mg	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	28 (2x14) tablets in a PVC/Al blister, supplied in a box	YES		YES						
Sortis 10 mg tablets	film coated tablets	Gödecke GmbH, Mooswaldalle 1, Freiburg, Germany; Heinrich Mack Naef. GmbH&Co.KG, Heinrich Mack Strasse 35, Illertissen, Germany; Pfizer Italia S.r.l., Strada statale 156, km 50, Borgo san Michele, Latina, Italy	14 (2x7) tablets in a (PA/Al/PVC//Al) blister, supplied in a box		YES	YES						
Sortis 20 mg tablets	film coated tablets	Gödecke GmbH, Mooswaldalle 1, Freiburg, Germany; Heinrich Mack Naef. GmbH&Co.KG, Heinrich Mack Strasse 35, Illertissen, Germany; Pfizer Italia S.r.l., Strada statale 156, km 50, Borgo san Michele, Latina, Italy	15 (2x7) tablets in a (PA/Al/PVC//Al) blister, supplied in a box		YES	YES						
Sortis 40 mg tablets	film coated tablets	Gödecke GmbH, Mooswaldalle 1, Freiburg, Germany; Heinrich Mack Naef. GmbH&Co.KG, Heinrich Mack Strasse 35, Illertissen, Germany; Pfizer Italia S.r.l., Strada statale 156, km 50, Borgo san Michele, Latina, Italy	16 (2x7) tablets in a (PA/Al/PVC//Al) blister, supplied in a box		YES	YES						
Sortis 80 mg tablets	film coated tablets	Gödecke GmbH, Mooswaldalle 1, Freiburg, Germany; Heinrich Mack Naef. GmbH&Co.KG, Heinrich Mack Strasse 35, Illertissen, Germany; Pfizer Italia S.r.l., Strada statale 156, km 50, Borgo san Michele, Latina, Italy	17 (2x7) tablets in a (PA/Al/PVC//Al) blister, supplied in a box		YES	YES						
Spasmex 0.2 mg/5 mL injection	solution for injection	Lek farmaceutska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) amber glass ampoules with 5 mL of solution for injection in a plastic container, supplied in a box		YES	YES						

Spasmex forte 5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES		YES					
Spiriva 18 micrograms, inhalation powder, hard capsule	inhalation powder, hard capsules	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	30 capsules (3 blisters with 10 (2x5) capsules) in a blister (Al/PVC/Al) and an inhaler (HandiHaler), supplied in a box		YES	YES			YES			
Stalevo 100 mg/25 mg/200 mg	film coated tablets	Orion Corporation ORION PHARMA, Espoo, Finland	100 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES			YES			
Stalevo 150 mg/37.5 mg/200 mg	film coated tablets	Orion Corporation ORION PHARMA, Espoo, Finland	100 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES			YES			
Stalevo 50 mg/12.5 mg/200 mg	film coated tablets	Orion Corporation ORION PHARMA, Espoo, Finland	100 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES			YES			
STAMARIL, attenuated vaccine against yellow fever, 1 dose	powder and diluent for suspension for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	One glass vial with a single dose of lyophilized vaccine and a pre-filled glass syringe with fixed needle containing 0.5mL of diluent, supplied in a box		YES							YES
Starcitin tablets 10 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES					
Starcitin tablets 20 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES					
Starcitin tablets 40 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister, supplied in a box	YES			YES					
Statex 20	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 20 tablets (blister, 2x10 tbl.)	YES			YES					
Stediril-d sugar coated tablets	sugar coated tablets	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland	21 (1x21) tablets in PVC/Al blister, supplied in a carton box		YES	YES						
Stediril-m sugar coated tablets	sugar coated tablets	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland or Haupt Pharma Munster GmbH, Munster, SR Germany	21 (1x21) tablets in PVC/Al blister, supplied in a carton box		YES	YES						
Stediril-m sugar coated tablets	sugar coated tablets	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland or Haupt Pharma Munster GmbH, Munster, SR Germany	21 (1x21) tablets in PVC/Al blister, supplied in a carton box		YES	YES						
Stocrin 100 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 capsules in a HDPE bottle with a PP stopper, supplied in a box		YES	YES		YES	YES			
STOCRIN 200 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	90 tablets in a plastic (HDPE) bottle with a temper-evident stopper, supplied in a box		YES	YES		YES	YES			
Stocrin 200 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	90 capsules in a HDPE bottle with a PP stopper, supplied in a box		YES	YES		YES	YES			
STOCRIN 50 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES	YES			
Stocrin 50 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 capsules in a HDPE bottle with a PP stopper, supplied in a box		YES	YES		YES	YES			

STOCRIN 600 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES	YES				
STOMATIDIN solution	solution	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	200 mL of solution in an amber glass bottle with aluminum cap, supplied in a carton box		YES		YES			YES			
STRATTERA 10 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	7 (1x7) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES	YES				
STRATTERA 18 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	7 (1x7) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES	YES				
STRATTERA 25 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (2x14) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES	YES				
STRATTERA 40 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (2x14) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES	YES				
STRATTERA 60 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (2x14) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES	YES				
STREPSILS sugar-free lozenges, lemon flavour	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	16 lozenges (2x8) in a blister, supplied in a box		YES		YES			YES			
Strepsils sugar-free lozenges, lemon flavour	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	16 (2x8) lozenges in a blister, supplied in a box		YES		YES			YES			
Strepsils lozenges - honey and lemon	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES			YES			
Strepsils honey and lemon lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) lozenges in PVC/PVDC-Al blister, supplied in a tin box		YES		YES			YES			
Strepsils honey and lemon lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) lozenges in a blister, supplied in a tin box		YES		YES			YES			
Strepsils lozenges - menthol and eucalyptus	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES			YES			
Strepsils lozenges - menthol and eucalyptus	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES			YES			
Strepsils lozenges - orange with vitamin C	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES			YES			
Strepsils lozenges - orange with vitamin C	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES			YES			
Strepsils original lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES			YES			
Strepsils original lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES			YES			
Strepsils Plus lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES			YES			

Strepsils Plus lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister (PVC/PVDC-AI), supplied in a box		YES		YES		YES		
Structolipid 20%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 500 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES		YES		
Structolipid 20%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 250 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES		YES		
Stugeron forte tablets	tablets	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	50 (5x10) tablets in a PVC/AI blister, supplied in a box		YES		YES				
Subutex 0.4 mg sublingual tablets	sublingual tablets	Reckitt Benckiser Healthcare (UK) Limited, East Yorkshire, Great Britain for Schering-Plough Corporation, USA	7 (1x7) tablets in a PVC/PVDC-AI blister, supplied in a box		YES	YES			YES		
Subutex sublingvalne tablets 2 mg	sublingual tablets	Reckitt Benckiser Healthcare (UK) Limited, East Yorkshire, Great Britain for Schering-Plough Corporation, USA	7 (1x7) tablets in a PVC/PVDC-AI blister, supplied in a box		YES	YES			YES		
Subutex sublingvalne tablets 8 mg	sublingual tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	7 tablets, supplied in a box		YES	YES			YES		
Subutex sublingvalne tablets 8 mg	sublingual tablets	Reckitt Benckiser Healthcare (UK) Limited, East Yorkshire, Great Britain for Schering-Plough Corporation, USA	7 (1x7) tablets in a PVC/PVDC-AI blister, supplied in a box		YES	YES			YES		
Sulfasol 4%	eye drops, solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 mL of solution in a PE bottle with dropper attachment and PP cap, supplied in a box		YES		YES				
Sulotrim 100/20 mg tablets	tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/AI blister, supplied in a box		YES		YES				
Sulotrim 400/80 mg tablets	tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Sulotrim Forte 800/160 mg tablets	tablets	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Sulotrim oral suspension	oral suspension	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of suspension in an amber glass bottle and a plastic measuring spoon, supplied in a box		YES		YES				
Sulpirid 100 mg/2 mL injection	solution for injection	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	2 mL of solution for injection in a glass ampoule, 6 ampoules in a box		YES		YES				
Sulpirid 200 mg capsules	capsules	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	12 capsules in a plastic bottle with closure, supplied in a box		YES		YES				
Sulpirid 50 mg capsules	capsules	Belupo, lijekovi I kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/AI blister, supplied in a box		YES		YES				

Sumamed forte syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One HDPE bottle with powder, one plastic spoon and one plastic syringe for dose delivery, supplied in a box	YES		YES						
Sumamed injection	powder for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES		YES						
Sumamed capsules	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 (1x6) capsules in a PVC/PVDC/AI blister, supplied in a box	YES		YES						
Sumamed S capsules 250 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 4 capsules (blister)	YES		YES						
Sumamed S tablets 500 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 2 film tablets (blister)	YES		YES						
Sumamed syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One HDPE bottle with powder, one plastic spoon and one plastic syringe for dose delivery, supplied in a box	YES		YES						
Sumamed syrup 1200	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One HDPE bottle with powder, one plastic spoon and one plastic syringe for dose delivery, supplied in a box	YES		YES						
Sumamed syrup 1200 XL	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One HDPE bottle with powder, one plastic spoon and one plastic syringe for dose delivery, supplied in a box	YES		YES						
Sumamed tablets 125 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 (1x6) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Sumamed tablets 500 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	4 (1x3) tablets in a PVC/AI blister, supplied in a box	YES		YES						
Supremin	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of syrup in an amber glass bottle with aluminum cap and a 5-mL polystyrene spoon, supplied in a box	YES		YES						
Sutent 12.5 mg capsules	capsules, hard	Pfizer Italia S.r.l., Marina del Tronto, Ascoli Piceno, Italy	30 capsules in a plastic (HDPE) bottle with a plastic stopper, supplied in a box		YES	YES		YES	YES			
Sutent 25 mg capsules	capsules, hard	Pfizer Italia S.r.l., Marina del Tronto, Ascoli Piceno, Italy	30 capsules in a plastic (HDPE) bottle with a plastic stopper, supplied in a box		YES	YES		YES	YES			
Sutent 50 mg capsules	capsules, hard	Pfizer Italia S.r.l., Marina del Tronto, Ascoli Piceno, Italy	30 capsules in a plastic (HDPE) bottle with a plastic stopper, supplied in a box		YES	YES		YES	YES			
Symbicort Turbuhaler 160/4.5 µg	inhalation powder	AstraZeneca Södertälje, Sweden or AstraZeneca GmbH, Plankstadt, Germany	120 doses in a plastic inhaler with mouthpiece, supplied in a box		YES	YES						
Symbicort Turbuhaler 160/4.5 µg	inhalation powder	AstraZeneca AB, S-151-85 Södertälje, Sweden; AstraZeneca GmbH, D-68721 Plankstadt, Germany	60 doses in a plastic inhaler with a mouthpiece, supplied in a box		YES	YES						
Symbicort Turbuhaler 320/9 µg	inhalation powder	AstraZeneca AB, S-151-85 Södertälje, Sweden; AstraZeneca GmbH, D-68721 Plankstadt, Germany	60 doses in a plastic inhaler with a mouthpiece, supplied in a box		YES	YES						
Symbicort Turbuhaler 80/4.5 µg	inhalation powder	AstraZeneca AB, S-151-85 Södertälje, Sweden; AstraZeneca GmbH, D-68721 Plankstadt, Germany	60 doses in a plastic inhaler with a mouthpiece, supplied in a box		YES	YES						

Symbicort Turbuhaler 80/4.5 µg	inhalation powder	AstraZeneca Södertälje, Sweden or AstraZeneca GmbH, Plankstadt, Germany	120 doses in a plastic inhaler with mouthpiece, supplied in a box		YES	YES						
Synagis 100 mg powder and diluent for injections	lyophilisate and diluent for preparation of solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	Box with one bottle with 100 mg of preparation, 1 mL of solvent in an ampoule and a leaflet		YES	YES		YES				
Synagis 50 mg powder and diluent for injections	lyophilisate and diluent for preparation of solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	Box with one bottle with 50 mg of preparation and 1 mL of solvent in an ampoule		YES	YES		YES				
Synopen injection	solution for injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia in cooperation with Novartis, Basel, Switzerland	2 mL of solution for injection in an ampoule, 10 ampoules in a box	YES		YES						
Synopen ointment	ointment	Pliva Croatia Ltd., Zagreb, Republic of Croatia in cooperation with Novartis, Basel, Switzerland	20 grams of ointment in an Al tube, supplied in a box	YES		YES						
Syntocinon 5 IU injection	solution for intramuscular/intravenous injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Box with 10 ampoules with 1 mL of solution		YES	YES						
Syntocinon aerosol	nasal aerosol	Novartis Pharma S.A.S., Huningue Cedex, France for Novartis Pharma AG, Basel, Switzerland	Bottle with 5 mL of solution with a spray attachment, supplied in a box		YES	YES						
Tabex forte syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of syrup in an amber glass bottle and a 5-mL plastic measuring spoon, supplied in a box	YES		YES		YES				
Tabex syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of syrup in an amber glass bottle and a 5-mL plastic measuring spoon, supplied in a box	YES		YES		YES				
TachoComb 2.5x3.0x0.5 cm	spongy absorbent wound dressing	Nycomed Austria GmbH, St. Peter-Strasse 25, Linz, Austria	One collagen sponge for wound dressing (2.5x3.0x0.5 cm) in a double package (plastic foil/alufoil) and a silicagel bag, supplied in a box		YES							YES
TachoComb 9.5x4.8x0.5 cm	spongy absorbent wound dressing	Nycomed Austria GmbH, St. Peter-Strasse 25, Linz, Austria	One collagen sponge for wound dressing (9.5x4.8x0.5 cm) in a double package (plastic foil/alufoil) and a silicagel bag, supplied in a box		YES							YES
TachoSil 2.5x3.0x0.5 cm	spongy absorbent wound dressing	Nycomed Austria GmbH, St. Peter Strasse 25, Linz, Austria	One collagen sponge for wound dressing (2.5x3.0x0.5 cm) in a double package (blister) and a silicagel bag, supplied in a box		YES							YES
TachoSil 9.5x4.8x0.5 cm	spongy absorbent wound dressing	Nycomed Austria GmbH, St. Peter Strasse 25, Linz, Austria	One collagen sponge for wound dressing (9.5x4.8x0.5 cm) in a double package (blister) and a silicagel bag, supplied in a box		YES							YES
Tadenan	capsules, soft	Laboratoires Fournier S.A., Fontaine Les Dijon, France	60 (6x10) soft capsules in a blister (PVC/AI), supplied in a box		YES	YES				YES		
Tafen 50 µg nasal spray	nasal spray, suspension	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of suspension (200 inhalation doses) in a brown glass bottle with a plastic atomizer pump and plastic protective cap, supplied in a box		YES		YES					
Tafen Novolizer 200 µg inhalation powder	inhalation powder	Lek d.d., Ljubljana, Republic of Slovenia in cooperation with Sofotec GmbH & Co.KG, Germany	One cartridge with 2.18 g of powder on average (1 cartridge contains 200 doses of powder), supplied in a box		YES		YES					
Tafen Novolizer 200 µg powder for inhalation	inhalation powder	Lek d.d., Ljubljana, Republic of Slovenia in cooperation with Sofotec GmbH & Co.KG,	One inhaler and one cartridge with approx. 2.18 g of powder (the cartridge contains 200 doses of		YES		YES					

		Germany	powder), supplied in a box								
Tagren 250 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	40 (3x10) tablets in a PVC/AI blister, supplied in a box	YES	YES						
Tamiflu 12 mg/mL powder for oral suspension	powder for preparation of oral suspension	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 g of powder for oral suspension in a glass bottle with a plastic temper-evident stopper, a plastic measuring cup for solvent, a plastic attachment affixed to the bottle and a plastic syringe for application of oral suspension, supplied in a box	YES	YES		YES	YES			
Tamiflu 75 mg hard capsules	hard capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 (1x10) capsules in a blister, supplied in a box	YES	YES		YES	YES			
Tamosin 0.4 mg extended-release capsules, hard	prolonged-release capsules, hard	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/PVDC//AI blister, supplied in a box	YES		YES					
Tanakan 40 mg/mL oral solution	oral solution	Beaufor Ipsen Industrie, Dreux, France	30 mL of solution in an amber glass bottle with a plastic stopper and 1 mL measuring plastic syringe with a protective casing, supplied in a box	YES					YES	YES	
Tanakan film coated tablets	film coated tablets	Beaufor Ipsen Industrie, Dreux, France	90 (6x15) film coated tablets in a PVC/AI blister, supplied in a box	YES					YES	YES	
Tantum Lemon lozenges	lozenges	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	10 individually paper-wrapped lozenges in a protective PE/paper/AI wrapping, 20 (2x10) lozenges in a box	YES	YES				YES		
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	1000 mL of solution in a plastic bottle with temper-proof closure and metering pump, supplied in a box	YES	YES				YES		
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	1000 mL of solution in a plastic bottle with temper-proof closure, supplied in a box	YES	YES				YES		
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	150 mL of solution in a plastic bottle with temper-proof closure and atomizer pump, supplied in a box	YES	YES				YES		
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	150 mL of solution in a plastic bottle with temper-proof closure cap, supplied in a box	YES	YES				YES		
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	60 mL of solution in a glass bottle with a temper-evident stopper, supplied in a box	YES	YES				YES		
Tantum Verde lozenges	lozenges	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	11 individually paper-wrapped lozenges in a protective PE/paper/AI wrapping, 20 (2x10) lozenges in a box	YES	YES				YES		
Tantum Verde spray 0.15%	oromucosal spray	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	30 mL of solution in a plastic bottle with a spray attachment, supplied in a box	YES	YES				YES		
Tantum Verde spray 0.30%	oromucosal spray	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	15 mL of solution in a plastic bottle with nebulizer attachment, supplied in a box	YES	YES				YES		
TANYZ 0.4 mg	prolonged release capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 (6x10) capsules in a PVC/PE/PVDC/AI blister, supplied in a box	YES	YES	YES	YES	YES			

TANYZ 0.4 mg	prolonged-release capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) capsules in a PVC/PE/PVDC/Al blister, supplied in a box		YES		YES	YES	YES			
Tarceva 100 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES	YES			YES			
Tarceva 150 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES	YES			YES			
Tarceva 25 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES	YES			YES			
Target 10	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	7 capsules in an amber glass bottle, supplied in a box	YES			YES			YES		
Target Plus capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 capsules in an amber glass bottle, supplied in a box	YES			YES					
Targocid 200 mg	powder for preparation of solution for injection	Gruppo Lepetit S.p.A, Anagni, Italy	Vial with powder and ampoule with diluent supplied in a box		YES	YES						
Targocid 400 mg	powder for preparation of solution for injection	Gruppo Lepetit S.p.A, Anagni, Italy	Vial with powder and ampoule with diluent supplied in a box		YES	YES						
Tarka	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 capsules (2x14) in a PVC/Al blister, supplied in a box		YES	YES						
Tarka 180 mg/2 mg tablets	modified-release tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) modified-release tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES						
TARKA 240 mg/2 mg tablets	modified-release tablets	Abbott GmbH & Co.KG., Ludwigshafen, Germany	28 (2x14) modified-release tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES						
TARKA 240 mg/4 mg tablets	modified-release tablets	Abbott GmbH & Co.KG., Ludwigshafen, Germany	28 (2x14) modified-release tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES						
Tavanic 250 mg tablets	film tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	10 tablets in a blister, supplied in a box		YES	YES			YES			
Tavanic 500 mg tablets	film tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	10 tablets in a blister, supplied in a box		YES	YES			YES			
Tavanic i.v. 500 mg	solution for intravenous infusion	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	100 mL of solution in a glass bottle, supplied in a box		YES	YES			YES			
Taxol injection 100 mg / 16.7 mL	concentrate for solution for infusion	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	One glass vial with 16.7 mL of solution concentrate, supplied in a carton box		YES	YES			YES			
Taxol injection 30 mg / 5 mL	concentrate for solution for infusion	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	One glass vial with 5 mL of solution concentrate, supplied in a carton box		YES	YES			YES			
Taxol injection 300 mg / 50 mL	concentrate for solution for infusion	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	One glass vial with 50 mL of solution concentrate, supplied in a carton box		YES	YES			YES			
Taxotere 20 mg	concentrate for solution for infusion	Aventis Pharma Dagenham, Dagenham, Essex, Great Britain	One glass vial with 0.5 mL of concentrate and one glass vial containing 1.5 mL of diluent in a blister, supplied in a box		YES	YES						

Taxotere 80 mg	concentrate for solution for infusion	Aventis Pharma Dagenham, Dagenham, Essex, Great Britain	One glass vial with 2 mL of concentrate and one glass vial with 6mL of diluent in a blister, supplied in a box		YES	YES						
Tazocin 4.5 g injection for intravenous use	powder for preparation of solution for injection or infusion	Wyeth Lederle S.p.A., Catania, Italy; Wyeth Laboratories, New Lane, Havant, Great Britain	Clear glass 72-mL bottle with 4.5 g of lyophilisate equipped with a grey bromobutyl stopper and flip-off cap of aluminum and plastic coloured pink, supplied in a box		YES	YES						
Telebrix 35	solution for injection	Guerbet, Cedex, France	Vial with 50 mL of solution, supplied in a box		YES	YES						
Telfast 120 mg	film coated tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	10 tablets in a blister, supplied in a box		YES	YES						
Telfast 180 mg	film coated tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	10 tablets in a blister, supplied in a box		YES	YES						
Telfast 30 mg	film coated tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	60 (4x15) tablets in a blister, supplied in a box		YES	YES						
Temodal capsules 100 mg	capsules, hard	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	5 capsules in a glass bottle with a plastic stopper, supplied in a box		YES	YES						
Temodal capsules 20 mg	capsules, hard	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	5 capsules in a glass bottle with a plastic stopper, supplied in a box		YES	YES						
Temodal capsules 250 mg	capsules, hard	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	5 capsules in a glass bottle with a plastic stopper, supplied in a box		YES	YES						
Temodal capsules 5 mg	capsules, hard	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	5 capsules in a glass bottle with a plastic stopper, supplied in a box		YES	YES						
Tenicef 0.5 g injection	powder for preparation of solution for i.v. and i.m. injection	Pliva Krakow, Krakow, Poland	5 (10 mL) glass bottles with powder, supplied in a box		YES	YES						
Tenicef 1g injection	powder for preparation of solution for i.v. and i.m. injection	Pliva Krakow, Krakow, Poland	5 (15 mL) glass bottles with powder, supplied in a box		YES	YES						
Tenicef 2g injection	powder for preparation of injection/infusion solution for i.v. use	Pliva Krakow, Krakow, Poland	5 (15 mL) glass bottles with powder, supplied in a box		YES	YES						
Tenormin 100 mg tablets	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	28 (2x14) film coated tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES						
Tenormin 50 mg tablets	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	29 (2x14) film coated tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES						
Tenox 10 mg tablets	tablets	Krka d.d., Novo Mesto, Republic of Slovenia; Krka Farma d.o.o., DPC Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES		YES						

Tenox 5 mg tablets	tablets	Krka d.d., Novo Mesto, Republic of Slovenia; Krka Farma d.o.o., DPC Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES		YES						
Teolin retard 125 mg tablets	prolonged-release tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	40 tablets in a glass bottle, supplied in a carton box		YES	YES						
Teolin retard 300 mg tablets	prolonged-release tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	40 (4x10) tablets in a PVC/AI blister, supplied in a carton box		YES	YES						
Teotard 200 mg prolonged-release capsules	prolonged-release capsules, hard	Krka d.d., Novo mesto, Šmarješka cesta 6, Republic of Slovenia in cooperation with Astellas Pharma GmbH, Germany	40 (4x10) capsules in a blister (PVC/AI), supplied in a box		YES	YES						
Teotard capsules prolonged-release 350 mg	prolonged-release capsules, hard	Krka d.d., Novo mesto, Šmarješka cesta 6, Republic of Slovenia in cooperation with Astellas Pharma GmbH, Germany	40 (4x10) capsules in a blister (PVC/AI), supplied in a box		YES	YES						
Tertensif	film coated tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	30 (1x30) tablets in a PVC/Alu blister, supplied in a box		YES	YES						
Tertensif SR	sustained-release film tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	Box with 30 tablets (2x15) in a blister		YES	YES						
Tetanus antitoxin (equine) 1500 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 ampoule with 1500 IU of preparation	YES							YES	
Tetanus antitoxin (equine) 1500 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 ampoules each with 1500 IU of preparation	YES							YES	
Tetanus antitoxin (equine) 3000 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 ampoules each with 3000 IU of preparation	YES							YES	
Tetanus antitoxin (equine) 3000 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 ampoule with 3000 IU of preparation	YES							YES	
TETRAAct - Hib, combined diphtheria, tetanus, pertussis and Haemophilus influenzae type B vaccine	lyophilisate and suspension for preparation of suspension for i.m. and deep subcutaneous use	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with 1 bottle containing lyophilisate and 1 glass syringe with 0.5 mL of suspension		YES						YES	
TETRAXIM diphtheria, tetanus, pertussis (acellular) and poliomyelitis (inactivated) vaccine, absorbed	suspension for injections	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Glass syringe with a needle containing 0.5 mL of suspension for injections		YES						YES	
TEVETEN 600 mg	film coated tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands	30 (2x14) film coated tablets in a blister (PVC/Aclar//AI), supplied in a box		YES	YES						
TEVETEN 600 mg	film coated tablets	Solvay Pharmaceuticals B.V., C.J. van Houtenlaan 36, 1381 CP Weesp, the Netherlands	28 (2x14) tablets in a blister (PVC/Aclar/AI), supplied in a box		YES	YES					YES	
Teveten plus	film coated tablets	Solvay Pharmaceuticals GmbH, Hannover, Germany Solvay Pharmaceuticals B.V., Weesp, the Netherlands	28 (2x14) tablets in a nontransparent PVC/Aclar/Alu blister, supplied in a box		YES	YES					YES	

Thyrogen 0.9 mg powder for solution for injection	powder for solution for injection	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	Clear type I glass 5-mL vials with siliconized butyl stopper with tamper proof flip-off cap, supplied in a box		YES	YES		YES	YES				YES
TIAREN	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	40 (4x10) capsules in blister (PVC/AI), supplied in a box	YES			YES						
Tienam i.v. Infusion	powder for preparation of solution for infusion	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Netherlands	5 (115 mL) glass bottles with powder for solution for infusion, supplied in a box		YES	YES							
Timalen 0.25% eye drops	eye drops	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 5 mL of solution in a plastic bottle with a dropper	YES			YES						
Timalen 0.5% eye drops	eye drops	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 5 mL of solution in a plastic bottle with a dropper	YES			YES						
TINIDIL	sublingual tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	40 (4x10) lozenges in an orange blister (PVC/PVDC//AI), supplied in a box	YES			YES						
TIRAMAT 100 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (3x20) tablets in a blister (PVC/PE/PVDC//AI), supplied in a box	YES			YES						
TIRAMAT 200 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (5x12) tablets in a blister (PVC/PE/PVDC//AI), supplied in a box	YES			YES						
TIRAMAT 25 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (2x30) tablets in a blister (PVC/PE/PVDC-AI), supplied in a box	YES			YES						
TIRAMAT 50 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (2x30) tablets in a blister (PVC/PE/PVDC-AI), supplied in a box	YES			YES						
Tissucol kit 1.0 mL	Iyophilisates for preparation of two-component fibrin adhesives	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	5 glass bottles: Tissucol lyophilisate, 1 mL of aprotinin solution, Trombin 4 Iyophilisate, trombin 500 lyophilisate, 1 mL of calcium chloride solution; application kit (Duploject)		YES								YES
Tissucol kit 2.0 mL	Iyophilisates for preparation of two-component fibrin adhesive	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	5 glass bottles: Tissucol lyophilisate, 2 mL of aprotinin solution, Trombin 4 Iyophilisate, trombin 500 lyophilisate, 2 mL of calcium chloride solution; application kit (Duploject)		YES								YES
Tissucol kit 5.0 mL	Iyophilisates for preparation of two-component fibrin adhesive	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	5 glass bottles: Tissucol lyophilisate, 5 mL of aprotinin solution, Trombin 4 Iyophilisate, trombin 500 lyophilisate, 5 mL of calcium chloride solution; application kit (Duploject)		YES								YES
TOBRADEX eye drops, suspension	eye drops, suspension	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of suspension in a polyethylene bottle with a drop tainer and an LDPE dropper with a PP temper-evident screw cap, supplied in a box		YES	YES							
TOBRADEX eye ointment	eye ointment	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	3.5 g of ointment in an aluminum tube, supplied in a box		YES	YES							
Tobrex eye drops	eye drops, solution	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of solution in a plastic bottle with a dropper, supplied in a box		YES	YES							
Tobrex eye ointment	eye ointment	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	3.5 g of ointment in an aluminum tube, supplied in a box		YES	YES							

TONOCARDIN 2 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES		YES						
TONOCARDIN 4 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	23 (2x10 tablets in PVC/PVDC/Al blister, supplied in a box	YES		YES						
Topamax 100 mg tablets	film coated tablets	Cilag AG, Schaffhausen, Switzerland	60 (6x10) tablets in a blister, supplied in a box		YES	YES						
Topamax 200 mg tablets	film coated tablets	Cilag AG, Schaffhausen, Switzerland	60 (6x10) tablets in a blister, supplied in a box		YES	YES						
Topamax 25 mg tablets	film coated tablets	Cilag AG, Schaffhausen, Switzerland	60 (6x10) tablets in a blister, supplied in a box		YES	YES						
Topamax 50 mg tablets	film coated tablets	Cilag AG, Schaffhausen, Switzerland	60 (6x10) tablets in a blister, supplied in a box		YES	YES						
Torecan suppositories 6.5 mg	suppositories	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Novartis Pharma Ltd., Switzerland	6 (1x6) suppositories in a strip (Al/LDPE), supplied in a box		YES	YES						
Torecan solution for injection 6.5 mg/1 mL	solution for injection (for i.m., i.v. and s.c.use)	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Novartis Pharma Ltd., Switzerland	1-mL of solution for injection in a glass ampoule; 50 (5x10) ampoules in a blister, supplied in a box		YES	YES						
Torendo 1-mg film coated tablets	film coated tablets	Krka, d.d., Novo mesto, Republic of Slovenia or Krka-Farma d.o.o., Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES		YES						
Torendo 2-mg film coated tablets	film coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES		YES						
Torendo 3-mg film coated tablets	film coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES		YES						
Torendo 4-mg film coated tablets	film coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES		YES						
Torendo oral solution 1 mg/1 mL	oral solution	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 mL of solution in an amber glass bottle with plastic (PP) cap and 3 mL metered-dose syringe, supplied in a box		YES	YES						
Torendo Q-Tab 0.5-mg orodispersible tablets	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES		YES						
Torendo Q-Tab 1-mg orodispersible tablets	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES		YES						
Torendo Q-Tab 2-mg orodispersible tablets 2 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES		YES						
Tractocile 7.5 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Ferring GmbH, Wittland 1, Kiel, Germany; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	5 mL of concentrate in a glass bottle, supplied in a box		YES	YES						
Tractocile 7.5 mg/mL, solution for injection	solution for injection	Ferring GmbH, Wittland 1, Kiel, Germany; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	0.9-mL of solution in a glass bottle, supplied in a box		YES	YES						

TRALIN tablets 100 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC/AI blister, supplied in a box	YES		YES						
TRALIN tablets 50 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC/AI blister, supplied in a box	YES		YES						
Tramadol injection 100 mg/2 mL	solution for injection	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	5 ampoules each with 2 mL of solution, supplied in a box	YES		YES						
Tramadol injection 50 mg/mL	solution for injection	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	5 ampoules each with 1 mL of solution, supplied in a box	YES		YES						
Tramadol kapi 100 mg/mL	oral drops, solution	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	10 mL of solution in an amber glass bottle with dropper attachment and plastic cap, supplied in a box	YES		YES						
Tramadol capsules 50 mg	capsules	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) capsules in a blister (PVC/AI), supplied in a box	YES		YES						
Tramadol suppositories 100 mg	suppositories	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	5 suppositories in an AI/PE pack, supplied in a box	YES		YES						
Tramal 100 mg solution for injection	solution for injection	Grünenthal GmbH, Stolberg, Germany	5 ampoules with 2 mL of solution, supplied in a box		YES	YES						
Tramal 50 mg solution for injection	solution for injection	Grünenthal GmbH, Stolberg, Germany	5 ampoules with 1 mL of solution, supplied in a box		YES	YES						
Tramal suppositories	suppositories	Grünenthal GmbH, Stolberg, Germany	5 suppositories in a strip, supplied in a box		YES	YES						
Tramal drops 96 mL	solution, oral drops	Grünenthal GmbH, Stolberg, Germany	96 mL of solution in an amber glass bottle with a metering pump, supplied in a box		YES	YES						
Tramal kapi, solution for oral drops	solution, oral drops	Grünenthal GmbH, Stolberg, Germany	10 mL of solution in an amber glass bottle, supplied in a box		YES	YES						
Tramal capsules	capsules	Grünenthal GmbH, Stolberg, Germany	20 (2x10) capsules in a blister, supplied in a box		YES	YES						
Tramal retard tablets 100 mg	film coated tablets with prolonged-release	Grünenthal GmbH, Stolberg, Germany	Box with 30 tablets in a blister		YES	YES						
Tramal retard tablets 150 mg	film coated tablets with prolonged-release	Grünenthal GmbH, Stolberg, Germany	Box with 30 tablets in a blister		YES	YES						
Tramal 200 mg retard tablets	prolonged-release film coated tablets	Grünenthal GmbH, Stolberg, Germany	30 tablets in a blister, supplied in a box		YES	YES						
Tramundin retard	prolonged release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	50 (5x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Transtec 35 µg/h	transdermal patch	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	One transdermal patch in a multilayer bag (paper/PE/Al/surlin), 4 patches in a carton box		YES	YES			YES			
Transtec 35 µg/h	transdermal patch	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	One transdermal patch in a multilayer bag (paper/PE/Al/surlin), 16 patches in a carton box		YES	YES			YES			

Transtec 52.5 µg/h	transdermal patch	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	One transdermal patch in a multilayer bag (paper/PE/Al/surlin), 4 patches in a carton box		YES	YES			YES		
Transtec 70 µg/h	transdermal patch	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	One transdermal patch in a multilayer bag (paper/PE/Al/surlin), 4 patches in a carton box		YES	YES			YES		
Travatan 40 µg/mL eyel drops, solution	eye drops	Alcon Couvreur N.V., Rijksweg 14, Puurs, Belgium; Alcon Cusi S.A., Camil Fabra 58, El Masnou, Barcelona, Spain	2.5 mL of solution in a polypropylene bottle with dropper attachment, in foil, supplied in a box		YES	YES					
Travocort cream	cream	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	15 g of cream in an Al tube		YES	YES					
Trental 400 mg tablets	modified-release film-coated tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	20 (2x10) tablets in a blister, supplied in a box		YES	YES					
Tricor 145 mg	film coated tablets	Laboratoires Fournier S.A., Fontaine Les Dijon, France	33 (3x10) film coated tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES		YES	YES		
Tricor 160 mg	film coated tablets	Laboratoires Fournier S.A., Fontaine Les Dijon, France	34 (3x10) film coated tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES		YES	YES		
Triderm cream	cream	Schering-Plough Labo N.V. Industriepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Triderm ointment	ointment	Schering-Plough Farma, Lda, Casal do Colaride, Aguvalva Cacem, Portugal	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Trileptal 150 mg film coated tablets	film coated tablets	Novartis Farma S.p.A., Torre Annunziata (Napoli), Italy	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES			YES		
Trileptal 300 mg film coated tablets	film coated tablets	Novartis Farma S.p.A., Torre Annunziata (Napoli), Italy	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES			YES		
Trileptal 60 mg/mL oral suspension	oral suspension	Novartis Pharma S.A.S., Huningue Cedex, France	250-mL of oral suspension in an amber glass bottle with plastic temper-proof closure, 10-mL plastic syringe for administration of oral suspension and a plastic bottle attachment, supplied in a box		YES	YES			YES		
Trileptal 600 mg film coated tablets	film coated tablets	Novartis Farma S.p.A., Torre Annunziata (Napoli), Italy	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES			YES		
Trinitrosan 5 mg	concentrate for solution for infusion	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	1-mL of concentrate for the solution for infusion in a glass ampoule, 5 ampoules in a box		YES	YES					
Trinovum tablets	tablets	Cilag AG, Schaffhausen, Switzerland	21 (1x21) tablets (7 white, 7 pink and 7 orange) in a blister (PVC/Al), supplied in a box		YES	YES					
Triquilar	coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	21 coated tablets (6 red-brown, 5 white and 10 dar yellow) in blister (PVC/Al), supplied in a box		YES	YES					
Trisequens	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark	28 (12 blue, 10 white, 6 red) tablets in a plastic calendar dial pack (dispenser with marked days of the week), supplied in a box		YES	YES					

Tritace 1.25	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Tritace 2.5	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Tritace 5	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Tritazide 2.5 mg/12.5 mg	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a green blister (PVC/AI), supplied in a box		YES	YES						
Tritazide 5 mg/25 mg	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a green blister (PVC/AI), supplied in a box		YES	YES						
Trusopt eye drops	eye drops	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	5 mL of solution in a plastic container OCUMETER PLUS, supplied in a box		YES	YES						
Tuberkulin PPD RT 23 SSI 10 T.U./0.1 mL	solution for intradermal use	Statens Serum Institut, Copenhagen, Denmark	Box with 1 glass bottle containing 1.5 mL of tuberculin of 10 T.U./0.1 mL		YES						YES	
Tuberkulin PPD RT 23 SSI 2 T.U./0.1 mL	solution for intradermal use	Statens Serum Institut, Copenhagen, Denmark	Box with 1 glass bottle containing 1.5 mL of tuberculin of 2 T.U./0.1 mL		YES						YES	
Tuberkulin PPD RT 23 SSI 2 T.U./0.1 mL	solution for intradermal use	Statens Serum Institut, Copenhagen, Denmark	Box with 1 glass bottle containing 5 mL of tuberculin of 2 T.U./0.1 mL		YES						YES	
Tulip 10 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Tulip 10 mg film coated tablets	film-tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	60 tablets (6x10) in a blister, supplied in a box		YES	YES						
Tulip 20 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Tulip 20 mg film coated tablets	film-tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	60 tablets (6x10) in a blister, supplied in a box		YES	YES						
Tulip 40 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister (AI/PVC//PVC//AI), supplied in a box		YES	YES						
Tusidil sugar coated tablets	sugar coated tablets	AD JAKA 80 Radoviš, Radoviš, FYROM	20 (1x20) sugar-coated tablets in a A-PVC blister, supplied in a box		YES	YES						
Tusidil syrup for children	syrup	AD JAKA 80 Radoviš, Radoviš, FYROM	60 mL of syrup in an amber glass bottle, supplied in a box		YES	YES						
Tusifan syrup 1 mg/mL	syrup	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	150 mL of syrup in a dark brown plastic bottle, supplied in a box	YES		YES			YES			
Tusifan syrup 3 mg/mL	syrup	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	150 mL of syrup in a dark brown plastic bottle, supplied in a box	YES		YES			YES			
TWINRIX Adult	suspension for injection	GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, Rixensart, Belgium	Pre-filled glass syringe containing a single dose of the vaccine (1 mL of suspension) with plunge stopper and needle, supplied in a carton box		YES						YES	

TWINRIX Paediatric	suspension for injection	GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, Rixensart, Belgium	Pre-filled glass syringe containing a single dose of the vaccine (0.5 mL of suspension) with plunge stopper and needle, supplied in a carton box		YES								YES	
TYPHIM Vi, typhoid polysaccharide vaccine, purified	solution for intramuscular and subcutaneous use	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with 1 glass syringe containing 1 dose of vaccine (0.5 mL) and a needle with a needle protection		YES								YES	
Ulfamid tablets 20 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES							
Ulfamid tablets 40 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) tablets in a blister, supplied in a box		YES		YES							
Ultop capsules 20 mg	gastric-resistant capsules, hard	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 capsules in a plastic (HDPE) bottle with plastic PP cap and desiccant, supplied in a box		YES		YES							
Ultop capsules 20 mg	gastric-resistant capsules, hard	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 capsules in a plastic (HDPE) bottle with plastic (PP) closure and desiccant, supplied in a box		YES		YES							
Ultop capsules 40 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 capsules in a plastic bottle (with desiccant), supplied in a box		YES		YES							
Ultop powder for solution for infusion 40 mg	powder for solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	Colourless glass bottle with lyophilisate (closed with a rubber stopper and Al ring), supplied in a box		YES		YES							
Ultop S capsules 10 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 capsules in a plastic bottle (with desiccant), supplied in a box		YES		YES							
Ultraproct suppositories	suppositories	Intendis Manufacturing SpA, Segrate, Milano, Italy	10 suppositories in a strip (Al/LDPE foil), supplied in a box		YES	YES								
Ultraproct ointment	rectal ointment	Intendis Manufacturing SpA, Segrate, Milano, Italy	30 g of ointment in an aluminium tube with a plastic applicator, supplied in a box		YES	YES								
Ultravist 240 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 50 mL of solution, supplied in a box		YES	YES								
Ultravist 300 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 100 mL of solution, supplied in a box		YES	YES								
Ultravist 300 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 50 mL of solution, supplied in a box		YES	YES								
Ultravist 300 solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 ampoules each containing 20 mL of solution, supplied in a box		YES	YES								
Ultravist 370 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 100 mL of solution, supplied in a box		YES	YES								
Ultravist 370 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	200 mL in a glass bottle for infusion, 10 bottles in a box		YES	YES								

Ultravist 370 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	500 mL of solution in a glass infusion bottle, 8 bottles in a box		YES	YES						
Ultravist 370 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 50 mL of solution, supplied in a box		YES	YES						
Ultravist 370 solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 ampoules each containing 30 mL of solution, supplied in a box		YES	YES						
Ulzol	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (2x7) capsules in a blister, supplied in a box	YES		YES						
UPFEN 200 mg film coated tablets	film coated tablets	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	20 (2x10) film coated tablets in a PVC-Al blister, supplied in a box		YES	YES			YES			
UPFEN 200 mg effervescent tablets	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	2 plastic tubes each with 10 effervescent tablets, supplied in a box (desiccant in the plastic cap)		YES	YES			YES			
UPSARIN plus vitamin C	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	10 effervescent tablets in a polypropylene tube (desiccant in polyethylene cap), supplied in a box		YES	YES			YES			
Upsavit vitamin C 1000 mg	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	10 effervescent tablets in a polypropylene tube (desiccant in polyethylene cap), supplied in a box		YES	YES			YES			
Uromitexan injection	solution for intravenous injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	15 (3x5) ampoules with 4 mL of solution, supplied in a box		YES	YES						
Urosal M plus capsules	capsules, soft	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) capsules in a PVC/Al blister, supplied in a box	YES					YES	YES		
Ursofalk capsules	capsules	dr. Falk Pharma GmbH, Freiburg, Germany	100 (4 x 25) tablets in PVC/Al blister, supplied in a box		YES	YES						
Urutal 8 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Bottle with 100 tablets, supplied in a box	YES		YES						
Urutal forte 16 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (3x20) tablets in a PVC/PVDC/Al blister, supplied in a box	YES		YES						
UTROGESTAN 100 mg capsules	capsules, soft	Laboratoires Besins International, Montrouge, France; Besins International Belgique S.A., Drogenbos, Belgium	30 (2x15) capsules in a PVC/Al blister, supplied in a box		YES	YES						
Uvin H Forte tea blend	tea blend	Cedevita d.o.o., Zagreb, Republic of Croatia	Polypropylene bag with 50 g, supplied in a carton box	YES					YES	YES		
Uvin H Forte tea blend in filter bags	tea blend in filter bags	Cedevita d.o.o., Zagreb, Republic of Croatia	25 filter bags (microcrystal cellulose) each with 1.5 g of tea blend, supplied in a box	YES					YES	YES		
Uvin H Forte granules	granules	Cedevita d.o.o., Zagreb, Republic of Croatia	14 bags (paper/Al/PE) each containing 5 g of granules, supplied in a box	YES					YES	YES		

Vagifem	vaginal tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark	15 (3x5) applicators each with one vaginal tablet, in blister packs, supplied in a box		YES	YES						
Vagisan	vaginal tablets	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	7 vaginal tablets in a strip, supplied in a box		YES		YES					
Vaira 10 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (1x28) tablets in a blister, supplied in a box	YES			YES					
Vaira 5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (1x28) tablets in a blister, supplied in a box	YES			YES					
Valcyte 450 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	60 tablets in a plastic (HDPE) bottle, supplied in a carton box		YES	YES			YES			
Vaqta 25 IU/0.5 mL (purified, inactivated hepatitis A vaccine)	suspension for injections	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Box with 1 glass bottle containing 0.5 mL of suspension		YES						YES	
Vaqta 50 IU/1 mL (purified, inactivated hepatitis A vaccine)	suspension for injections	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Box with 1 glass bottle containing 0.5 mL of suspension		YES						YES	
Vasilip film coated tablets 10 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in a PVC/PE/PVDC//Al blister, supplied in a box		YES		YES					
Vasilip 10 mg film-coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister PVC/PE/PVDC/PE/PVC//Al), supplied in a box		YES		YES					
Vasilip film coated tablets 20 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (3x10) tablets in a PVC/PE/PVDC//Al blister, supplied in a box		YES		YES					
Vasilip 20 mg film-coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister PVC/PE/PVDC/PE/PVC//Al), supplied in a box		YES		YES					
Vasilip film coated tablets 40 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) tablets in a PVC/PE/PVDC//Al blister, supplied in a box		YES		YES					
Vasilip film coated tablets 40 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister PVC/PE/PVDC/PE/PVC//Al), supplied in a box		YES		YES					
Vasoflex 1 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 tablets in an amber glass bottle, supplied in a box		YES		YES					
VAXIGRIP - inactivated vaccine against influenza (fragmented)	suspension for injection	Sanofi Pasteur S.A., Lyon, France	Pre-filled glass syringe (glass type I) with a needle and a chlorobromobutyl or chlorobutyl stopper, containing single dose (0.5 mL) of suspension for injection, supplied in a box		YES						YES	
VAXIGRIP inactivated vaccine against influenza (fragmented)	suspension for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Pre-filled glass syringe with a needle containing a single dose (0.5 mL) of the suspension for injection, supplied in a box		YES						YES	
VAXIGRIP Pediatric use - inactivated vaccine against influenza (fragmented) for children	suspension for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Pre-filled glass syringe with needle containing a single dose (0.25 mL) of suspension for injection, supplied in a box		YES						YES	

Velafax tablets 37.5 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES		YES						
Velafax tablets 75 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES		YES						
Velafax XL capsules 150 mg	prolonged-release capsules, hard	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) capsules in a transparent blister (PVC/AI), supplied in a box	YES		YES						
Velafax XL capsules 75 mg	prolonged-release capsules, hard	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) capsules in a transparent blister (PVC/AI), supplied in a box	YES		YES						
Velcade powder for solution for injection	powder for solution for injection	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	10-mL glass vial containing 38.5 mg of powder for solution for injection, supplied in a box		YES	YES			YES			
Venofer 100 mg/5 mL solution for intravenous injection	solution for injection	Vifor International Inc., St. Gallen, Switzerland for Lek farmaceutska družba d.d. Ljubljana, Republic of Slovenia	5 ampoules each with 5 mL of solution, supplied in a box		YES	YES						
VENTAVIS 10 µg/mL solution for atomizer	solution for atomizer	Schering AG, Berlin, Germany and BERLIMED S.A., Alcala de Henares, Madrid, Spain	3-mL glass ampoule containing 2 mL of solution for nebulizer, 100 ampoules in a box		YES	YES			YES			
Ventolin inhalation solution	nebulisation solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 mL of solution in an amber glass bottle with plastic cap, supplied in a box	YES		YES						
Ventolin syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of syrup in an amber glass bottle with aluminum cap and plastic measuring spoon, supplied in a box	YES		YES						
Ventolin tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (2x30) tablets in a blister (PVC/AI), supplied in a box	YES		YES						
Vepesid injection 100 mg/5 mL	solution for injection (for preparation of i.v. infusion)	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	5 mL of solution in a glass bottle, supplied in a box (10 boxes in a collective carton packaging)		YES	YES						
Vepesid capsules 100 mg	capsules	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	10 capsules in an amber glass bottle, supplied in a box		YES	YES						
Vepesid capsules 50 mg	capsules	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	20 capsules in an amber glass bottle, supplied in a box		YES	YES						
Verbinaf 125 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES		YES						
Verbinaf 250 mg ablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES		YES						
Vermox 100 mg/5 mL oral suspension	oral suspension	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 mL of suspension in an amber glass bottle with a 5 mL plastic measuring spoon, supplied in a box		YES	YES						
Vermox tablets 100 mg	tablets	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	6 (1x6) tablets in a strip (AI/PE), supplied in a box		YES	YES						
Verolax Senna	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	23 (2x10) tablets in a PVC/PVD//AI blister, supplied in a box		YES				YES	YES		

Vesanoid soft capsules 10 mg	soft capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 soft capsules in a brown plastic bottle, supplied in a box		YES	YES						
VFEND 200 mg powder for solution for infusion	powder for solution for infusion	Pfizer PGM, Poce-sur-Cisse, France	One glass vial with rubber cap and aluminum ring, containing powder, supplied in a box		YES	YES			YES			
VFEND 40 mg/mL powder for oral suspension	powder for oral suspension	Pfizer PGM, Poce-sur-Cisse, France	45 g of powder for oral suspension in a plastic bottle with a temper-evident stopper, a plastic measuring cup for solvent (23 mL), a plastic attachment for bottle neck and a plastic syringe for administration of oral suspension, supplied in a box		YES	YES			YES			
VFEND tablets 200 mg	film coated tablets	Heinrich Mack Nachf. GmbH & Co., Illertissen, Germany	28 (2x14) tablets in a blister (PVC/AI), supplied in a box		YES	YES			YES			
VFEND tablets 50 mg	film coated tablets	Heinrich Mack Nachf. GmbH & Co., Illertissen, Germany	28 (2x14) tablets in a blister (PVC/AI), supplied in a box		YES	YES			YES			
Viagra tablets 100 mg	film coated tablets	Pfizer PGM, Poce-sur-Cisse, France	One (1x1) film coated tablet in a blister (PVC/AI), supplied in a box		YES	YES			YES			
Viagra tablets 25 mg	film coated tablets	Pfizer PGM, Poce-sur-Cisse, France	One (1x1) film coated tablet in a blister (PVC/AI) supplied in a box		YES	YES			YES			
Viagra tablets 50 mg	film coated tablets	Pfizer PGM, Poce-sur-Cisse, France	One (1x1) film coated tablet in a blister (PVC/AI) supplied in a box		YES	YES			YES			
Videx capsules 125 mg	gastric-resistant capsules, hard	Bristol-Myers Squibb, Meymac, France	30 (3x10) capsules in a PVC/PE/ACLAR/AI blister, supplied in a carton box		YES	YES		YES	YES			
Videx capsules 250 mg	gastric-resistant capsules, hard	Bristol-Myers Squibb, Meymac, France	30 (3x10) capsules in a PVC/PE/ACLAR/AI blister, supplied in a carton box		YES	YES		YES	YES			
Videx capsules 400 mg	gastric-resistant capsules, hard	Bristol-Myers Squibb, Meymac, France	30 (3x10) capsules in a PVC/PE/ACLAR/AI blister, supplied in a carton box		YES	YES		YES	YES			
Vilpin 10 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in an orange PVC/PVDC//AI, supplied in a box	YES			YES					
Vilpin 5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (orange PVC/PVDC//AI), supplied in a box	YES			YES					
Vincristine injection 1 mg	solution for injection (for intravenous use)	Pfizer (Perth) Pty Limited, Bentley WA, Australija	1-mL of solution for injection in a plastic bottle, 5 bottles in a box		YES	YES						
VIRACEPT 250 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	270 film-coated tablets in a plastic (HDPE) bottle with child resistant closure, supplied in a box		YES	YES			YES			
Viramune tablets 200 mg	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany and Boehringer Ingelheim Elias A.E., Atika, Greece	60 (6x10) tablets in a blister (PVC/AI), supplied in a box		YES	YES			YES			
Virolex cream	cream	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 g of cream in a tube, supplied in a box		YES		YES					

Virolex lyophilisate for preparation of infusion solution	lyophilisate for preparation of solution for infusion	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Glaxo SmithKline	5 glass bottles each with 250 mg of lyophilisate, supplied in a box		YES	YES						
Virolex eye ointment	eye ointment	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	4.5 g of ointment in a tube, supplied in a box		YES	YES						
Virolex tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES	YES						
Visipaque 270 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Gass bottle (with rubber stopper, aluminum ring and plastic protective cap) containing 50 mL of solution, 10 ampoules in a box		YES	YES						
Visipaque 270 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Gass bottle (with rubber stopper, aluminum ring and plastic protective cap) containing 100 mL of solution, 10 ampoules in a box		YES	YES						
Visipaque 270 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 50 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES						
Visipaque 270 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 100 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES						
Visipaque 320 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 100 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES						
Visipaque 320 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Glass bottle (with rubber stopper, aluminum ring and plastic cap) containing 200 mL of solution, 6 bottles in a box		YES	YES						
Visipaque 320 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Glass bottle (with rubber stopper, aluminum ring and plastic protective cap) containing 100 mL of solution, 10 ampoules in a box		YES	YES						
Visipaque 320 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Glass bottle (with rubber stopper, aluminum ring and plastic protective cap) containing 50 mL of solution, 10 ampoules in a box		YES	YES						
Visipaque 320 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 500 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 6 bottles in a box		YES	YES						
Visipaque 320 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 200 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES						

Visipaque 320 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 50 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box	YES	YES							
Visipaque 320 mg/L	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 20 mL of solution, with a plastic twist-off cap, 10 bottles in a box	YES	YES							
Vistagan Liquifilm 0.5 % eye drops	eye drops, solution	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	5 mL of solution in a plastic bottle with a dropper, supplied in a box	YES	YES							
Visudyne	powder for solution for infusion	Novartis Pharma S.A.S., Huningue Cedex, France	One glass vial containing powder with rubber stopper and aluminum ring, supplied in a box	YES	YES		YES					
Vitamin B12 Krka solution for injection 100 µg/1 mL	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 ampoules with 1 mL of solution, supplied in a box	YES	YES							
Vitamin B12 Krka solution for injection 500 µg/1 mL	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 ampoules with 1 mL of solution, supplied in a box	YES	YES							
Vitopril 10 mg	tablets	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	30 (3x10) tablets in a PVC/PVdC/Alu blister, supplied in a box	YES	YES							
Vitopril 20 mg	tablets	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	31 (3x10) tablets in a PVC/PVdC/Alu blister, supplied in a box	YES	YES							
Vitopril 5 mg	tablets	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	32 (3x10) tablets in a PVC/PVdC/Alu blister, supplied in a box	YES	YES							
Vizol eyel drops solution	eye drops, solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 mL of nasal drops in a clear plastic (PE) bottle with a dropper attachment, supplied in a box	YES		YES		YES				
Water for Injection, Alkaloid	diluent for parenteral use	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	50 colourless glass ampoules with 5 mL of water for injection, supplied in a box		YES	YES						
Water for Injections Viaflo	diluent for parenteral use	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabiningo, Spain; Baxter Healthcare S.A., Republic of Ireland	20 plastic Viaflo bags with 500 mL of infusion solution, in a protective bag, supplied in a box		YES	YES						
Water for Injection, Viaflo	diluent for parenteral use	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabiningo, Spain; Baxter Healthcare S.A., Republic of Ireland	30 plastic Viaflo bags with 250 mL of water for injection in a protective bag, supplied in a box		YES	YES						
Voltaren Emulgel 1 %	gel	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland Novartis Pharma Produktions GmbH, Offlinger Strasse 44, Wehr, Germany	50 g of gel in an aluminium tube, supplied in a box		YES	YES			YES			
Voltaren forte	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 20 tablets (blister, 2x10 tbl.)	YES		YES						
Voltaren injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 ampoules each with 3 mL of solution for injection, supplied in a box	YES		YES						

Voltaren rapid	coated tablets	Pliva Croatia Ltd., Zagreb, Republic of Croatia in cooperation with Novartis Pharma AG, Basel, Switzerland	10 (1x10) film coated tablets in a PVC//Al ili PVC/PE/PVDC//Al blister, supplied in a box	YES		YES						
Voluven 6% solution for infusion	solution for infusion	Fresenius Kabi Deutschland GmbH, Germany	500 mL of solution in a transparent plastic bag (Freeflex), 15 bags in a box		YES	YES		YES		YES		
Voluven 6% solution for infusion	solution for infusion	Fresenius Kabi Deutschland GmbH, Germany	500 mL of solution in a glass bottle, 10 bottles in a box		YES	YES		YES		YES		
Xalacom	eye drops, solution	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	2.5 mL of solution in a 5 mL plastic (LDPE) bottle with dropper attachment and plastic (HDPE) temper-proof closure, supplied in a box		YES	YES			YES			
Xalatan	eye drops, solution	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	2.5 mL eye drops, solution in a 5 mL plastic bottle with dropper attachment, supplied in a box		YES	YES						
Xanax SR 0.5 mg tablets	modified release tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	30 (3x10) tablets in a PA/Al//Al blister, supplied in a box		YES	YES						
Xanax SR 1 mg tablets	modified release tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	31 (3x10) tablets in a PA/Al//Al blister, supplied in a box		YES	YES						
Xanax SR tablets 2 mg	modified release tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	33 (3x10) tablets in a PVC/Al blister, supplied in a box		YES	YES						
Xanax tablets 0.25 mg	tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	31 (3x10) tablets in a PVC/Al blister, supplied in a box		YES	YES						
Xanax tablets 0.5 mg	tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	32 (3x10) tablets in a PVC/Al blister, supplied in a box		YES	YES						
XELODA 150 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	60 (6x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES			
XELODA 500 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	120 (12x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES			
Xenical	capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	42 (2x21) capsules in a blister, supplied in a box		YES	YES						
Xigris 20 mg powder for solution for infusion	powder for solution for infusion	Lilly Pharma Fertigung und Distribution GmbH & Co. KG, Giessen, Germany	One glass vial with 20 mg of medicinal product, supplied in a box		YES	YES						
Xigris 5 mg powder for solution for infusion	powder for solution for infusion	Lilly Pharma Fertigung und Distribution GmbH & Co. KG, Giessen, Germany	One glass vial with 5 mg of medicinal product, supplied in a box		YES	YES						
Xolair 150 mg	powder and diluent for solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	One glass vial with powder and one glass ampoule with 2 mL of Water for Injection, supplied in a box		YES	YES			YES			
Xolair 75 mg	powder and diluent for solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	One glass vial with powder and a glass ampoule with 2 mL of Water for Injection, supplied in a box		YES	YES			YES			

Xorimax 125 mg film coated tablets	film coated tablets	Sandoz GmbH, Kundl, Austria	10 (1x10) film coted tablets in a PA/AI/PE//AI blister or an AI/PE strip, supplied in a box		YES		YES		YES		
Xorimax 250 mg film coated tablets	film coated tablets	Sandoz GmbH, Kundl, Austria	10 (1x10) film coted tablets in a PA/AI/PE//AI blister or an AI/PE strip, supplied in a box		YES		YES		YES		
Xorimax 500 mg film coated tablets	film coated tablets	Sandoz GmbH, Kundl, Austria	10 (1x10) film coted tablets in a PA/AI/PE//AI blister or an AI/PE strip, supplied in a box		YES		YES		YES		
XYZAL 0.5 mg/mL oral solution	oral solution	UCB Pharma S.p.A., Pianezza, Italy	200 mL of oral solution in a glass bottle with temper-proof closure and a 10-mL plastic nebulizer, supplied in a box		YES	YES			YES		
Xyzal 5 mg film coated tablets	film coated tablets	UCB Pharma S.p.A., Via Praglia 15, I-10044 Pianezza (TO), Italy	10 (1x10) tablets in a AI/AI blister, supplied in a box		YES	YES			YES		
Yasmin film tablets	film coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	21 (1x21) film-coated tablets in a blister, supplied in a box		YES	YES			YES		
Yasnal film coated tablets 10 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister (OPA/AI/PVC//AI), supplied in a box		YES		YES				
Yasnal film coated tablets 5 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister (PVC/AI/OPA//AI), supplied in a box		YES		YES				
Zaditen	eye drops, solution	EXCELVISION, Annonay, France	5 mL of solution in a white plastic (LDPE) bottle with a dropper and a plastic (HDPE) stopper with a safety ring, supplied in a box		YES	YES			YES		
Zaditen SDU	eye drops, solution	EXCELVISION, Annonay, France	20 (5x4) single-dose plastic (LDPE) containers with 0.4 mL of solution in a protective package (PVC/AI/PA-AI/papir), supplied in a box		YES	YES			YES		
Zalasta 10 mg tablets	tablets	Jadran-Galenski laboratorij d.d., Rijeka, Hrvatska in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/AI/PVC-AI blister, supplied in a box	YES			YES				
Zalasta 5 mg tablets	tablets	Jadran-Galenski laboratorij d.d., Rijeka, Hrvatska in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/AI/PVC-AI blister, supplied in a box	YES			YES				
Zalasta Q-Tab 10 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a OPA/AI/PVC//AI blister, supplied in a box	YES			YES				
Zalasta Q-Tab 15 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a OPA/AI/PVC//AI blister, supplied in a box	YES			YES				
Zalasta Q-Tab 20 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a OPA/AI/PVC//AI blister, supplied in a box	YES			YES				
Zalasta Q-Tab 5 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a OPA/AI/PVC//AI blister, supplied in a box	YES			YES				
Zaldiar 37.5 mg/325 mg	film coated tablets	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	10 tablets in a blister, supplied in a box		YES	YES					
Zan 10 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	7 capsules in a PVC/PVDC/AI blister, supplied in a box	YES			YES				

Zan 5 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	7 capsules in a PVC/PVDC/AI blister, supplied in a box	YES			YES					
Zeffix tablets	film coated tablets	Glaxo Operations UK Ltd. (trading as Glaxo Wellcome Operations), Hertfordshire, Great Britain, GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	28 (2x14) tablets in a blister (PVC/PA/AI), supplied in a box		YES	YES		YES	YES			
ZELDOX 20 mg capsules	capsules	Heinrich Mack Nachf. GmbH & Co. (Pfizer grupa), Illertissen, Germany	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
ZELDOX 40 mg capsules	capsules	Heinrich Mack Nachf. GmbH & Co. (Pfizer grupa), Illertissen, Germany	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
ZELDOX 60 mg capsules	capsules	Heinrich Mack Nachf. GmbH & Co. (Pfizer grupa), Illertissen, Germany	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
ZELDOX 80 mg capsules	capsules	Heinrich Mack Nachf. GmbH & Co. (Pfizer grupa), Illertissen, Germany	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
Zemplar 5 µg/mL solution for injection	solution for injection	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	5 glass ampoules each with 1 mL of solution, supplied in a carton box		YES	YES			YES			
Zenafluk capsules 100 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	7 capsules in a PVC/AI blister, supplied in a box	YES			YES					
Zenafluk capsules 150 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One capsule in a PVC/AI blister, supplied in a box	YES			YES					
Zenafluk capsules 200 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	7 capsules in a PVC/AI blister, supplied in a box	YES			YES					
Zenafluk capsules 50 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	7 capsules in a PVC/AI blister, supplied in a box	YES			YES					
Zenapax	concentrate for infusion solution	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	Bottle with 5 mL of concentrate, supplied in a box		YES	YES			YES			
Zerit capsules 30 mg	capsules	Bristol-Myers Squibb, Meymac, France	56 (4x14) capsules in a blister, supplied in a box		YES	YES						
Zerit capsules 40 mg	capsules	Bristol-Myers Squibb, Meymac, France	56 (4x14) capsules in a blister, supplied in a box		YES	YES						
Ziagen tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	60 (6x10) tablets in a blister, supplied in a box		YES	YES						
Zinnat suspension 125 mg/5mL	granules for oral suspension	Glaxo Wellcome Operations, Greenford, Great Britain	Granules for 100 mL of suspension in a glass bottle, with a plastic spoon and a measuring device, supplied in a box		YES	YES						
Zinnat 125 mg tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	10 tablets in a blister, supplied in a box		YES	YES						
Zinnat 250 mg tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	10 tablets in a blister, supplied in a box		YES	YES						

Zinnat 500 mg tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	10 tablets in a blister, supplied in a box		YES	YES						
Zipantola tablets 20 mg	gastric-resistant tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a OPA/AI/PVC//AI blister, supplied in a box	YES			YES					
Zipantola 40 mg tablets	gastric-resistant tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES			YES					
Zofran injection 4 mg	solution for intravenous injection	GlaxoSmithKline S.p.A., Parma, Italy	5 ampoules with 2 mL of solution, supplied in a box		YES	YES						
Zofran injection 8 mg	solution for intravenous injection	GlaxoSmithKline S.p.A., Parma, Italy	5 ampoules with 4 mL of solution, supplied in a box		YES	YES						
Zofran 4 mg tablets	tablets	Glaxo Wellcome S.A., Aranda de Duero, Spain; GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	10 tablets in a blister, supplied in a box		YES	YES						
Zofran 8 mg tablets	tablets	Glaxo Wellcome S.A., Aranda de Duero, Spain; GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	10 tablets in a blister, supplied in a box		YES	YES						
Zoledex 3.6 mg	subcutaneous implant	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	Implant for s.c. administration in a syringe with a safety system (SafeSystem TM), in a sterile protective casing, supplied in a carton box		YES	YES						
Zoledex LA 10.8 mg	subcutaneous implant	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	Implant for s.c. administration in a syringe with a safety system (SafeSystem TM), in a sterile protective casing, supplied in a carton box		YES	YES						
Zoloft tablets 100 mg	film coated tablets	Pfizer Italia S.r.l., Borgo San Michele, Latina, Italy	28 (2x14) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Zoloft tablets 50 mg	film coated tablets	Pfizer Italia S.r.l., Borgo San Michele, Latina, Italy	28 (2x14) tablets in a blister (PVC/AI), supplied in a box		YES	YES						
Zoltex 20 mg tablets	gastric-resistant tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (2x14) tablets in a blister (PA/AI/PVC//AI), supplied in a box	YES			YES					
Zoltex 40 mg tablets	gastric-resistant tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 (2x7) tablets in a PA/AI/PVC//AI blister, supplied in a box	YES			YES					
Zometa 4 mg/5 mL concentrate for solution for infusion	concentrate of solution for infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 mL of solution concentrate in a plastic bottle, supplied in a box		YES	YES						
Zomig Rapimelt	orodispersible tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	6 (1x6) tablets in a blister (PVC/AI-AI/paper), supplied in a box		YES	YES						
Zomig tablets 2.5 mg	film coated tablets	Astra Zeneca UK Limited, Great Britain	3 (1x3) tablet in a blister (Alu/PA-Alu/PVC), supplied in a box		YES	YES						
Zonadin 10 mg tablets	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES					

Zonadin 5 mg tablets	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES		YES					
Zorac 0.05% gel	gel	Pierre Fabre Medicament Production, France	15 g of gel in an aluminum tube, supplied in a box		YES	YES					
Zorac 0.1 % gel	gel	Pierre Fabre Medicament Production, France	15 g of gel in an aluminum tube, supplied in a box		YES	YES					
Zovirax	cream	Glaxo Operations UK Ltd, Durham, Great Britain	2 grams of cream in an aluminum tube with plastic cap, supplied in a box		YES	YES			YES		
Zyban	prolonged release tablets	GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Poland	60 (6x10) tablets in an Al/Al blister, supplied in a box		YES	YES					
Zyllt film coated tablets 75 mg	film coated tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetković bb, Jastrebarsko, Republic of Croatia	14 (2x7) tablets in a blister, supplied in a box	YES		YES					
Zyprexa 10 mg injection	powder for solution for injection	Lilly Pharma Fertigung und Distribution GmbH & Co. KG, Giessen, Germany	5-mL glass vial with powder for solution for injection, supplied in a box		YES	YES					
Zyprexa 10 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Zyprexa 15 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Zyprexa 2.5 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Zyprexa 5 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Zyprexa 7.5 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	56 (8x7) tablets in an Al/Al blister, supplied in a box		YES	YES					
Zyprexa Velotab 10 mg orodispersible tablets	orodispersible tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a blister, supplied in a box		YES	YES					
Zyprexa Velotab 5 mg orodispersible tablets	orodispersible tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a blister, supplied in a box		YES	YES					
Zyvoxid granules for oral suspension 20 mg/mL	granules for oral suspension	Pharmacia & Upjohn Company, Michigan, USA and Pfizer Manufacturing Belgium NV, Puurs, Belgium	66 g granules in an amber glass bottle of 240 mL with a plastic temperature-evident stopper and a plastic measuring spoon (2.5 mL/5 mL), supplied in a box		YES	YES			YES		
Zyvoxid 2 mg/mL solution for infusion	solution for infusion	Fresenius Kabi Norge, Halden, Norway	300 mL of solution in a plastic infusion bag, in a protective aluminium casing, 10 bags per box.		YES	YES			YES		
Zyvoxid tablets 600 mg	film coated tablets	Pharmacia & Upjohn Company, Michigan, USA and Pfizer Manufacturing Belgium NV, Puurs, Belgium	10 (1x10) tablets in a PVC/Al blister, supplied in a box		YES	YES			YES		