Council of the European Union

Brussels, 7 April 2022
(OR. en)

7827/22

Interinstitutional File: 2021/0431(COD)

CODEC 423
UK 58
PHARM 57
SAN 200
MI 248
COMPET 212
PE 31

INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta - Outcome of the European Parliament's first reading (Strasbourg, 4-7 April 2022)

I. INTRODUCTION

A number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this file at first reading.

After the plenary approved the request of the Committee on the Environment, Public Health and Food Safety to proceed according to the Rule 163 (urgent procedure) on 5 April 2022, the EPP, S&D, ID, Greens/EFA and The Left groups jointly presented a compromise amendment (amendment number 1) to the abovementioned proposal for a Directive and the EPP, S&D, Greens/EFA and The Left groups jointly presented an amendment to the draft legislative resolution containing the statement by the Commission (amendment number 2). These amendments had been agreed during the informal contacts referred to above. No other amendments were tabled.

II. VOTE

When it voted on 7 April 2022, the plenary adopted the compromise amendment (amendment number 1) to the abovementioned proposal for a Directive, as well as amendment number 2 to the draft legislative resolution. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto[1].

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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[1] The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics.*** The symbol " ▌ " indicates deleted text.

ANNEX
(7.4.2022)

Medicinal products made available in the UK with respect to Northern Ireland, Cyprus, Ireland and Malta ***I

European Parliament legislative resolution of 7 April 2022 on the proposal for a directive of the European Parliament and of the Council amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta (COM(2021)0997 – C9-0475/2021 – 2021/0431(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2021)0997),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0475/2021),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 24 February 2022[2],

– after consulting the Committee of the Regions,

– having regard to the undertaking given by the Council representative by letter of 30 March 2022 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rules 59 and 163 of its Rules of Procedure,

1. Adopts its position at first reading hereinafter set out;

2. Takes note of the statement by the Commission annexed to this resolution;

[2] Not yet published in the Official Journal.

3. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P9_TC1-COD(2021)0431

Position of the European Parliament adopted at first reading on 7April 2022 with a view to the adoption of Directive (EU) 2022/… of the European Parliament and of the Council amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[3],

Acting in accordance with the ordinary legislative procedure[4],

[3] Opinion of 24 February 2022 (not yet published in the Official Journal).
[4] Position of the European Parliament of 7 April 2022.

Whereas:

(1) The Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community[5] (the 'Withdrawal Agreement') was concluded on behalf of the Union by Council Decision (EU) 2020/135[6] and entered into force on 1 February 2020. The transition period referred to in Article 126 of the Withdrawal Agreement, during which Union law continued to apply to and in the United Kingdom in accordance with Article 127 of the Withdrawal Agreement, ended on 31 December 2020. On 25 January 2021, the Commission issued a Notice[7] on the application of the Union's pharmaceutical *acquis* in markets historically dependent on medicinal products supply from or through Great Britain, namely Cyprus, Ireland, Malta and Northern Ireland, from the end of that transition period until 31 December 2021.

5 OJ L 29, 31.1.2020, p. 7.

6 Council Decision (EU) 2020/135 of 30 January 2020 on the conclusion of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 1).

7 Commission Notice - Application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period (2021/C 27/08) (OJ C 27, 25.1.2021, p. 11).

(2) In accordance with the Protocol on Ireland/Northern Ireland (the 'Protocol'), which forms an integral part of the Withdrawal Agreement***, the provisions of Union law listed in Annex 2 to the Protocol apply, under the conditions set out in that Annex, to and in the United Kingdom in respect of Northern Ireland. That list includes Article 13 of Directive 2001/20/EC[8] of the European Parliament and of the Council regarding the manufacture and import of investigational medicinal products, Directive 2001/83/EC[9] of the European Parliament and of the Council and Regulation (EC) No 726/2004[10] of the European Parliament and of the Council. Therefore,*** medicinal products placed on the market in Northern Ireland are to comply with ***those provisions of*** Union law.

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8 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

9 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

10 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

(3) Directives 2001/20/EC and 2001/83/EC lay down the rules for medicinal products for human use and investigational medicinal products intended to be placed on the market in the Member States.

(4) Cyprus, Ireland, Malta and Northern Ireland have historically relied on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland, and the supply chains for those markets have not yet been fully adapted to comply with Union law. To prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, Directives 2001/20/EC and 2001/83/EC need to be amended to provide for derogations for medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland. In order to ensure uniform application of Union law in the Member States, the derogations applicable in Cyprus, Ireland and Malta should be of a temporary nature only.

(5) In accordance with Article 13(1) of Directive 2001/20/EC, read in conjunction with the Protocol, the import of investigational medicinal products from third countries into the Union or Northern Ireland is subject to the holding of a manufacturing and import authorisation. To ensure continued access to new, innovative or improved treatments for clinical trial participants in Northern Ireland, as well as in Cyprus, Ireland and Malta after 31 December 2021, such a manufacturing and import authorisation should not be required for investigational medicinal products imported into those markets from parts of the United Kingdom other than Northern Ireland provided that certain conditions are fulfilled. To ensure uniform application of Union law in the Member States, the derogations applicable in Cyprus, Ireland and Malta should be of a temporary nature only.

(6) Regulation (EC) No 726/2004 lays down Union procedures for the authorisation of medicinal products. Upon authorisation in the Union, medicinal products are available to patients in Northern Ireland. It is possible, however, that the competent authorities of the United Kingdom in respect of parts of the United Kingdom other than Northern Ireland issue a marketing authorisation for a medicinal product before a marketing authorisation has been granted for the same medicinal product in the Union. In such exceptional cases, and in order to ensure that patients in Northern Ireland have access to those medicinal products at the same time as patients in other parts of the United Kingdom, the competent authorities of the United Kingdom in respect of Northern Ireland should be able to supply those medicinal products to patients in Northern Ireland temporarily and until a marketing authorisation is granted or refused in the Union. In order to ensure the full effectiveness of the centralised procedure for granting marketing authorisations set out in Regulation (EC) No 726/2004, those temporary authorisations should be limited in time and should cease to be valid when the Commission takes a decision to grant or refuse the authorisation to market that medicinal product.

(7) In accordance with Article 8(2) of Directive 2001/83/EC, read in conjunction with the Protocol, a marketing authorisation is only able to be granted to an applicant established in the Union or in Northern Ireland. A number of operators were not able to comply with that requirement by 31 December 2021. To ensure access to certain medicinal products in Northern Ireland, it is crucial that the holders of marketing authorisations granted by the competent authorities of the United Kingdom in respect of Northern Ireland are allowed to be established in parts of the United Kingdom other than Northern Ireland. Similarly, to ensure access to certain medicinal products in Cyprus, Ireland, Malta and Northern Ireland, it is necessary to allow the competent authorities of Cyprus, Ireland, Malta and Northern Ireland to grant marketing authorisations in the context of the mutual recognition or the decentralised procedure to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

(8) It follows from Articles 17 and 18 of Directive 2001/83/EC, read in conjunction with the Protocol, that applicants for a marketing authorisation wishing to obtain both a marketing authorisation for the United Kingdom in respect of Northern Ireland as well as a marketing authorisation for one or more Member States need to include the United Kingdom in respect of Northern Ireland in the scope of their marketing authorisation application in accordance with the mutual recognition or the decentralised procedure. Where medicinal products are also authorised in parts of the United Kingdom other than Northern Ireland, the requirement to comply with that obligation could hamper the continuous access to medicinal products for patients in Northern Ireland. To avoid that issue, it is necessary to allow applicants in such situations the possibility to apply for a marketing authorisation for the United Kingdom in respect of Northern Ireland either in accordance with the mutual recognition or the decentralised procedure, or in accordance with the national marketing authorisation procedure applicable in relation to the United Kingdom in respect of Northern Ireland. In the case of such a national marketing authorisation procedure, the marketing authorisation should be granted in compliance with Union law, including the requirements on quality, safety and efficacy of medicinal products.

(9) In accordance with Article 51(1), point (b), of Directive 2001/83/EC, medicinal products imported into the Union are to undergo quality control testing in the Union. Article 20, point (b), of that Directive allows the importers which place medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland on the market in Cyprus, Ireland, Malta or Northern Ireland, or wholesale distributors placing such medicinal products on those markets, to have, in justifiable cases, certain controls carried out in parts of the United Kingdom other than Northern Ireland. Taking into account the historical dependence of Cyprus, Ireland, Malta and Northern Ireland on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland and the related risks of shortages of medicinal products in those jurisdictions, a justifiable case within the meaning of Article 20, point (b), of Directive 2001/83/EC should be considered to occur when each batch of the medicinal product concerned is released by a qualified person on a site in the Union or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards equivalent to those laid down in Union law, thereby ensuring an equivalent level of protection of human health. Since Article 20, point (b), of Directive 2001/83/EC only provides for batch testing to be carried out in a third country on a case-by-case basis, it is necessary to lay down conditions harmonising the implementation of that provision with regard to medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland.

(10) It follows from Article 40(3) of Directive 2001/83/EC, read in conjunction with the Protocol, that importers of medicinal products from third countries into a Member State are to hold a manufacturing authorisation granted by the Member State where the importer is established or, in the case of importers established in Northern Ireland, by the United Kingdom in respect of Northern Ireland. To avoid a situation in which operators withdraw from or significantly reduce medicinal products supply to Cyprus, Ireland, Malta and Northern Ireland, it is necessary to derogate exceptionally from that requirement under certain conditions and to allow imports of medicinal products from or through parts of the United Kingdom other than Northern Ireland into Cyprus, Ireland, Malta and Northern Ireland by wholesale distributors that do not hold the relevant manufacturing authorisation, while ensuring an equivalent level of protection of human health.

(11) In a situation where medicinal products are exported from a Member State to parts of the United Kingdom other than Northern Ireland, and subsequently imported into Cyprus, Ireland, Malta or Northern Ireland, it should be possible to waive specific controls, namely quality control testing, intended to guarantee the quality of those medicinal products imported from third countries, provided that appropriate arrangements have been made by the Union to ensure that the necessary controls are carried out in the exporting country.

(12) It follows from Article 48 of Directive 2001/83/EC, read in conjunction with Article 49 of that Directive and with the Protocol, that the manufacturing authorisation holder is to have at its disposal a qualified person who resides and operates in the Union or Northern Ireland. To ensure a continuous access to certain medicinal products to patients in Northern Ireland, it is appropriate to allow the qualified person to reside and operate in parts of the United Kingdom other than Northern Ireland.

(13) It follows from Article 104(3) of Directive 2001/83/EC, read in conjunction with the Protocol, that the qualified person responsible for pharmacovigilance is to reside and operate in the Union or Northern Ireland. A number of operators were not able to comply with that requirement by 31 December 2021. To ensure that access to certain medicinal products for patients in Northern Ireland is not hampered, it is appropriate to allow the qualified person responsible for pharmacovigilance to reside and operate in parts of the United Kingdom other than Northern Ireland.

(14) To avoid shortages of medicinal products in Cyprus and Malta, the competent authorities of Cyprus and Malta should be allowed, for public health reasons and for a certain period, to grant, maintain in force and extend marketing authorisations on the basis of Article 126a of Directive 2001/83/EC which rely on marketing authorisations granted by the competent authorities of parts of the United Kingdom other than Northern Ireland, even if the marketing authorisation holder is no longer established in the Union, provided that certain conditions are fulfilled. Since Union law no longer applies in parts of the United Kingdom other than Northern Ireland, it is necessary to provide that the competent authorities of Cyprus and Malta ensure that such authorisations comply with Union law. In order to ensure that the functioning of the Union market is not undermined, it is necessary to establish the conditions for enhanced supervision and enforcement of the rules relevant for the application of the derogations introduced by this Directive. The Commission should monitor developments in parts of the United Kingdom other than Northern Ireland that could affect the level of protection regarding the regulatory functions covered by this Directive. If the Commission finds that the level of protection of public health ensured by the United Kingdom by means of rules governing the production, distribution and use of medicinal products, as well as by means of the effective enforcement of those rules, is no longer essentially equivalent to that guaranteed within the Union, or if the Commission lacks information to assess whether an essentially equivalent level of protection is guaranteed, the Commission should enter into consultation with the United Kingdom to find a mutually agreed remedy to that situation. If no such remedy is found within the prescribed period, the Commission should, as a last resort, be empowered to adopt delegated acts suspending the application of one or more provisions introduced by this Directive.

(15) In order to ensure transparency, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland should publish a list of medicinal products to which they intend to apply or have applied the derogations set out in this Directive. In order to make that list easily searchable, it should contain the same information as that included in the package leaflet or summary of product characteristics of the medicinal products concerned.

(16) Since the objectives of this Directive cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

(17) Directives 2001/20/EC and 2001/83/EC should therefore be amended accordingly.

(18) In order to ensure legal continuity for operators active in the pharmaceutical sector and to guarantee the continuous access of patients in Cyprus, Ireland, Malta and Northern Ireland to medicinal products, this Directive should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union* and the measures adopted by the Member States to comply with it should apply retroactively from 1 January 2022,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In Article 13(1) of Directive 2001/20/EC, the following subparagraph is added:

‘By way of derogation from the first subparagraph, the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta shall allow investigational medicinal products to be imported from parts of the United Kingdom other than Northern Ireland without such an authorisation provided that all of the following conditions are fulfilled:

(a) the investigational medicinal products imported into Cyprus, Ireland, Malta or Northern Ireland have undergone certification of batch release either in the Union, as provided for in paragraph 3, point (a), or in parts of the United Kingdom other than Northern Ireland in compliance with the requirements set out in paragraph 3, point (b);

(b) the investigational medicinal products are only made available to subjects in the Member State into which those investigational medicinal products are imported, or, if imported into Northern Ireland, are only made available to subjects in Northern Ireland.’.

Article 2

Directive 2001/83/EC is amended as follows:

(1) the following Article is inserted:

‘Article 5a

By way of derogation from Article 6, the competent authorities of the United Kingdom in respect of Northern Ireland may temporarily authorise the supply to patients in Northern Ireland of a medicinal product belonging to the categories referred to in Article 3(1) and (2) of Regulation (EC) No 726/2004 provided that all of the following conditions are fulfilled:

(a) the medicinal product concerned has been granted a marketing authorisation by the competent authority of the United Kingdom for parts of the United Kingdom other than Northern Ireland;

(b) the medicinal product concerned is only made available to patients or end-consumers in the territory of Northern Ireland and is not made available in any Member State.

The maximum validity of the temporary authorisation shall be six months. Notwithstanding the specified validity, the temporary authorisation shall cease to be valid if the medicinal product concerned has been granted a marketing authorisation in accordance with Article 10 of Regulation (EC) No 726/2004, or if such marketing authorisation has been refused in accordance with that Article.’;

(2) in Article 8, the following paragraphs are inserted:

‘2a. By way of derogation from paragraph 2, marketing authorisations may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland to applicants established in parts of the United Kingdom other than Northern Ireland.

2b. By way of derogation from paragraph 2, marketing authorisations may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, by the competent authorities of Cyprus, Ireland and Malta, in accordance with the mutual recognition or the decentralised procedure laid down in Chapter 4 of this Title, to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

The competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta may extend marketing authorisations already granted prior to … [insert the date of entry into force of this amending Directive] to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

The marketing authorisations granted or extended by the competent authorities of Cyprus, Ireland or Malta in accordance with the first and second subparagraph shall cease to be valid at the latest on 31 December 2026.’;

(3) the following Article is inserted:

‘Article 18a

1. By way of derogation from Article 17(1), second subparagraph, Article 17(2) and Article 18, if an application for marketing authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an application for marketing authorisation is submitted in the United Kingdom in respect of Northern Ireland for a medicinal product which is already being examined or has already been authorised in a Member State, the application regarding the United Kingdom in respect of Northern Ireland shall not have to be submitted in accordance with Articles 28 to 39 provided that all of the following conditions are fulfilled:

(a) the marketing authorisation for the United Kingdom in respect of Northern Ireland is granted by the competent authority for the United Kingdom in respect of Northern Ireland in compliance with Union law, and such compliance with Union law is ensured during the period of validity of that marketing authorisation;

(b) the medicinal products authorised by the competent authority for the United Kingdom in respect of Northern Ireland are made available to patients or end-consumers only in the territory of Northern Ireland, and they are not made available in any Member State.

2. The marketing authorisation holder of a medicinal product for which a marketing authorisation has already been granted for the United Kingdom in respect of Northern Ireland in accordance with Articles 28 to 39 before … [insert the date of entry into force of this amending Directive] shall be allowed to withdraw the marketing authorisation for the United Kingdom in respect of Northern Ireland from the mutual recognition or the decentralised procedure and to submit an application for a marketing authorisation for that medicinal product to the competent authorities of the United Kingdom with respect to Northern Ireland in accordance with paragraph 1.';

(4) in Article 20, the following paragraph is added:

'With regard to quality control testing carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in Article 127d other than those authorised by the Commission, the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta may consider that there is a justifiable case within the meaning of point (b) of the first paragraph, without carrying out a case-by-case assessment provided that:

(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51;

(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;

(c) where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on … [insert the date of the entry into force of this amending Directive].';

(5) Article 40 is amended as follows:

(a) the following paragraph is inserted:

‘1a. By way of derogation from paragraph 1 of this Article, the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta shall allow medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by holders of a wholesale distribution authorisation as referred to in Article 77(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:

(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 51(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 20, first paragraph, point (b);

(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 51(1) or, for medicinal products authorised by the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland, in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51(1);

(c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;

(d) medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to patients or end-consumers in Northern Ireland;

(e) the medicinal products bear the safety features referred to in Article 54, point (o).

Article 80, first subparagraph, point (b), shall not apply to imports that fulfil the conditions laid down in the first subparagraph of this paragraph.';

(b) the following paragraph is inserted:

‘3a. For batches of medicinal products which are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Northern Ireland or, until 31 December 2024, into Cyprus, Ireland or Malta, the controls upon importation referred to Article 51(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 51(1), third subparagraph.’;

(6) in Article 48, the following paragraph is added:

‘3. Where the manufacturing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person referred to in paragraph 1 may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the manufacturing authorisation holder already has at its disposal a qualified person who resides and operates in the Union on … [insert the date of the entry into force of this amending Directive].’;

(7) in Article 104(3), the following subparagraph is added:

‘By way of derogation from the second subparagraph, where the marketing authorisation is granted by the competent authority of United Kingdom in respect of Northern Ireland, the qualified person referred to in point (a) of the first subparagraph may reside and operate in parts of the United Kingdom other than Northern Ireland. This subparagraph shall not apply where the marketing authorisation holder already has at its disposal a qualified person who resides and operates in the Union on … [insert the date of the entry into force of this amending Directive].’;

(8) the following Article is inserted:

‘Article 111c

1. The Commission shall continuously monitor developments in the United Kingdom that could affect the level of protection regarding the regulatory functions referred to in Article 8(2a) and (2b), Article 20, second paragraph, Article 40(1a) and (3a), Article 48(3), Article 104(3) and Article 126c that are carried out in parts of the United Kingdom other than Northern Ireland taking into account, in particular, the following elements:

(a) the rules governing the granting of marketing authorisations, the obligations of the marketing authorisation holder, the granting of manufacturing authorisations, the obligations of the manufacturing authorisation holder, the qualified persons and their obligations, quality control testing, batch release and pharmacovigilance as laid down in United Kingdom law;

(b) whether the competent authorities of the United Kingdom ensure the effective enforcement within their territory of the rules referred to in point (a), by means of, inter alia, inspections and audits of marketing authorisation holders, manufacturing authorisation holders and wholesale distributors located in their territories, and on-the-spot checks at their premises regarding the exercise of the regulatory functions referred to in point (a).

2. Where the Commission finds that the level of protection of public health ensured by the United Kingdom through rules governing the production, distribution and use of medicinal products as well as the effective enforcement of those rules is no longer essentially equivalent to that guaranteed within the Union, or where sufficient information is not available to the Commission to enable it to establish whether an essentially equivalent level of protection of public health is ensured by the United Kingdom, the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor.

For a period of six months following the written notification made pursuant to the first subparagraph, the Commission shall enter into consultations with the United Kingdom with a view to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months.

3. If the situation giving rise to the written notification made pursuant to paragraph 2, first subparagraph, is not remedied within the time-limit referred to in paragraph 2, second subparagraph, the Commission shall be empowered to adopt a delegated act specifying the provisions among those referred to in paragraph 1 whose application shall be suspended.

4. Where a delegated act pursuant to paragraph 3 has been adopted, the provisions referred to in the introductory sentence of paragraph 1 as specified in the delegated act shall cease to apply on the first day of the month following the entry into force of the delegated act.

5. Where the situation giving rise to the adoption of the delegated act pursuant to paragraph 3 has been remedied, the Commission shall adopt a delegated act specifying those suspended provisions that shall apply again. In that case, the provisions specified in the delegated act adopted pursuant to this paragraph shall apply again on the first day of the month following the entry into force of the delegated act referred to in this paragraph.***';***

(9) Article 121a is amended as follows:

(a) in paragraph 2, the following subparagraph is added:

***'The power to adopt delegated acts referred to in Article 111c(3) and (5) shall be conferred on the Commission for an indeterminate period of time from … [insert the date of the entry into force of this amending Directive.'*;**

(b) paragraph 3 is replaced by the following:

'3. The delegation of power referred to in Article 14(1), Articles 22b, 23b, 46a, 47, 52b, 54a, ***Article 111c(3) and (5),*** and Article 120 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.';

(c) paragraph 6 is replaced by the following:

‘6. A delegated act adopted pursuant to Article 14(1), Articles 22b, 23b, 46a, 47, 52b, 54a***, Article 111c(3) or (5),*** or Article 120 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.’;

(10) the following Article is inserted:

Article 126c

‘1. By way of derogation from Article 126a, until 31 December 2024, in the absence of a marketing authorisation or of a pending application for a marketing authorisation the competent authorities of Cyprus and Malta may authorise for justified public health reasons the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.

The competent authorities of Cyprus and Malta may also maintain in force or, until 31 December 2024, extend marketing authorisations that were granted pursuant to Article 126a before ...[insert date of entry into force of this amending Directive] which authorise the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.

Authorisations that are granted, extended or maintained in force pursuant to the first or second subparagraph shall not be valid after 31 December 2026.

2. By way of derogation from Article 8(2), the competent authorities of Malta and Cyprus may grant marketing authorisations as referred to in paragraph 1 of this Article to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

3. Where the competent authorities of Cyprus or Malta grant or extend a marketing authorisation as referred to in paragraph 1, they shall ensure compliance with the requirements of this Directive.

4. Before granting a marketing authorisation pursuant to paragraph 1, the competent authorities of Cyprus or Malta:

   (a) shall notify the marketing authorisation holder in parts of the United Kingdom other than Northern Ireland of the proposal to grant a marketing authorisation or to extend a marketing authorisation under this Article in respect of the medicinal product concerned;

   (b) may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing authorisation of the medicinal product concerned.';

(11) the following Articles are inserted:

‘Article 127c

The derogations set out in Article 8(2a) and(2b), Article 18a, Article 20, second paragraph, Article 40(1a) and (3a), Article 48(3), Article 104(3a) and Article 126c shall not affect the obligations of the marketing authorisation holder to ensure the quality, safety and efficacy of the medicinal product placed on the markets of Cyprus, Ireland, Malta or Northern Ireland laid down in this Directive.

Article 127d

1. By ... [insert 30 days after the entry into force of this amending Directive], the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland shall establish, notify to the Commission and publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Directive.

2. The competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland shall ensure that the list referred to in paragraph 1 is updated and managed in an independent manner, at least on a six-monthly basis.”.

Article 3

1. Member States shall adopt and publish ▌ the laws, regulations and administrative provisions necessary to comply with this Directive ***within a period of four months as from the date of its entry into force***. They shall immediately inform the Commission thereof.

   They shall apply those measures from 1 January 2022.

   When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at ...,

For the European Parliament *For the Council*

The President *The President*

Commission statement on medicines supply to Cyprus, Ireland and Malta

The withdrawal of the United Kingdom from the Union has posed particular challenges for those Member States (Cyprus, Ireland and Malta) that during many years were being supplied with medicines from or through parts of the United Kingdom.

The Commission recognises the progress that has been made by Cyprus, Ireland and Malta and industrial operators to implement the necessary changes to facilitate the ongoing supply of medicines following the United Kingdom's withdrawal from the EU.

In order to ensure a long-term security of supply of medicines, the Commission stresses the need for enhanced efforts of all concerned parties in fostering the adaptation of the supply chains to the situation after the United Kingdom's withdrawal.

The Commission is fully committed to accompanying Cyprus, Ireland and Malta in their efforts towards phasing out the temporary derogations provided for in Directive [XXX]* and Regulation [XXX]* within three years.

To that end, the Commission will, in accordance with Union law and in full respect of the distribution of competences between the Union and Member States in the area of medicines for human use, continuously follow developments in the concerned Member States and will closely accompany the competent authorities of Cyprus, Ireland and Malta in their efforts to decrease the dependency of their domestic markets on the supply with medicinal products from or through parts of the United Kingdom other than Northern Ireland.

The Commission will invite the competent authorities of Cyprus, Ireland and Malta to provide it, on a regular basis, with information on these efforts.

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* OJ: Please insert in the text the number of the Directive/Regulation contained in document 2021/0431(COD)/2021/0432(COD) and insert the number, name, date and OJ reference of that Directive/Regulation in the footnote.

Taking this information into account, the Commission will report in writing to the European Parliament and the Council within 18 months from the date of entry into force of Directive [XXX]* and Regulation [XXX]* on the progress accomplished in Cyprus, Ireland and Malta towards the complete phasing out of the derogations and the actions of the Commission to closely accompany the competent authorities of those Member States in that regard.

The Commission will remind the industrial operators concerned who still need to make changes to their supply chains that they urgently should make the necessary adaptations to ensure access to medicines in the smaller markets. In this context, the Commission will monitor the progress made by operators involved in the supply of medicines in these Member States regarding their ability to fulfil those requirements of Union law from which Directive [XXX]*and Regulation [XXX]* provide for temporary derogations.

In addition and beyond these immediate and necessary steps, as announced in the "Pharmaceutical Strategy for Europe"[11], the Commission will make proposals by the end of 2022 to revise the pharmaceutical legislation of the Union. These proposals will seek to provide longer-term structural solutions, in particular, to the issue of access to medicines, with special attention to enhancing security of supply and addressing risks of shortages in the smaller markets of the Union.

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11 Commission Communication "Pharmaceutical Strategy for Europe", COM(2020)0761 final, 25.11.2020.