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NOTE

From:	General Secretariat of the Council
To:	Delegations
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 - Presidency compromise proposal

Delegations will find attached the Presidency compromise proposal for the above-mentioned Commission proposal contained in ST 15188/21 + COR1. The changes are in line with the comments the Presidency has received from delegations.

Amendments are marked in **bold underline** and ~~strikethrough~~ as compared to the Commission proposal.

This document will be presented and discussed at the meeting of the WP UK on 4 February 2022 with a view to enabling further proceedings in the WP on Pharmaceuticals and Medical Devices.

2021/0431 (COD)

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

(1) (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,

Acting in accordance with the ordinary legislative procedure,

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[1] (the 'Withdrawal Agreement') was concluded on behalf of the Union by Council Decision (EU) 2020/135 [2] 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 (the 'transition period'), ended on 31 December 2020. On 25 January 2021, the Commission issued a Notice[3] on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain, namely Cyprus, Ireland, Malta and Northern Ireland, from the end of the transition period until 31 December 2021.

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1 OJ L 29, 31.1.2020, p. 7.

2 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).

3 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, which forms an integral part of the Withdrawal Agreement, **the provisions of Union law listed in Annex 2 to that Protocol apply, under the conditions set out in that Annex, to and in the United Kingdom in respect of Northern Ireland. This includes Article 13 of Directive 2001/20/EC regarding the manufacture and import of investigational medicinal producs, Directive 2001/83/EC as well as Regulation (EC) No 726/2004. Therefore,** medicinal products placed on the market in Northern Ireland are to comply with **these provisions of** Union law.

(3) Directives 2001/20/EC[4] and 2001/83/EC[5] of the European Parliament and of the Council 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 supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland, and the supply chains for these markets have not yet been fully adapted to comply with Union law. In order to prevent shortages of medicines 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 the medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from 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 possession of a manufacturing and import authorisation. In order 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, the 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. 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.

(6) Regulation (EC) No 726/2004 of the European Parliament and of the Council[6] lays down Union procedures for the authorisation of medicinal products. Upon authorisation in the Union, medicinal products are available to patients in Northern Ireland. However, it is possible that for some of the medicinal products the competent authorities of the United Kingdom in respect of parts of the United Kingdom other than Northern Ireland issue a marketing authorisation, while there is no marketing

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4 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).

5 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).

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

authorisation granted yet 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 as set out in Regulation (EC) No 726/2004, those temporary authorisations should be limited in time and should cease 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 may only be granted to an applicant established in the Union or in Northern Ireland. A number of operators have not yet been able to comply with this requirement and it is not likely that they will be able to do so by 31 December 2021. To ensure access to certain medicines in Northern Ireland, it is crucial that the holders of marketing authorisations issued by the national 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 medicines in Cyprus, Ireland, Malta and Northern Ireland, it is necessary to allow the national competent authorities of Cyprus, Ireland, Malta and Northern Ireland to grant marketing authorisations in the context of the mutual recognition and decentralised procedures 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 marketing authorisation wishing to obtain a marketing authorisation for the United Kingdom in respect of Northern Ireland as well as 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 decentralised procedure or the mutual recognition procedure. Where medicinal products are also authorised in parts of the United Kingdom other than Northern Ireland, the requirement to comply with this obligation may hamper the continuous access to medicines for patients in Northern Ireland. To avoid this, 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 decentralised procedures or in accordance with the national marketing authorisation procedure applicable in relation to the United Kingdom in respect of Northern Ireland. In the latter case, the marketing authorisation should be granted in compliance with Union law, including the requirements on the 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 have to undergo quality control testing in the Union. Article 20, point (b), of that Directive allows the importers placing 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 medicines supply from other parts of the United Kingdom and the related risks of shortages of medicines 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 equivalent quality standards to those laid down in Union law, thus ensuring an equivalent level of protection of human health. Given that 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 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 needs to hold a manufacturing authorisation issued 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 that operators withdraw from or significantly reduce medicines supply to Cyprus, Ireland, Malta and Northern Ireland, it is necessary to exceptionally derogate from that requirement under certain conditions and to allow imports of medicinal products from parts of the United Kingdom other than Northern Ireland into Cyprus, Ireland, Malta and Northern Ireland by wholesale distributors that do not hold a manufacturing authorisation otherwise required for import, while ensuring an equivalent level of protection of human health.

(11) In addition, in the situation where a medicinal product is 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 (quality control testing) to guarantee the quality of 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) Article 48 of Directive 2001/83/EC, read in conjunction with its Article 49 and with the Protocol, is understood as requiring that the marketing authorisation holder to have at its disposal a qualified person is established in and operating from the Union or Northern Ireland. To ensure a continuous access to certain medicines to patients in Northern Ireland, it is appropriate to allow the qualified person responsible 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 needs to be established in and operate from the Union or Northern Ireland. A number of operators have not yet been able to comply with this requirement, it is not likely that they will be able to do so by 31 December 2021. To ensure that access to certain medicines for patients in Northern Ireland is not hampered, it is appropriate to allow the qualified person responsible for pharmacovigilance to be established in parts of the United Kingdom other than Northern Ireland.

(14) To avoid shortages of medicines 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 are relying 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. Given that 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 shall 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 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 if the Commission is lacking information to assess whether an essentially equivalent level of protection is guaranteed, the Commission should enter in consultations with the United Kingdom, to find a mutually agreed remedy to that situation. If such remedy is not found within a prescribed period, the Commission should, as a last resort, be empowered to adopt delegated acts suspending the application of one or more provisions of 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 products to which they intend to apply or have applied the derogations as set out in this Directive. In order to make the information easily searchable, that list should contain the same information as included in the package leaflet or summary of product characteristics of the medicinal products concerned.

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

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

1. 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 paragraph the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Malta, Cyprus and Ireland shall allow investigational medicinal products to be

imported from parts of the United Kingdom other than Northern Ireland without a manufacturing and import authorisation, provided that the following conditions are fulfilled:

(a) the 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 clinical trial participants in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to clinical trial participants in Northern Ireland."

Article 2

Directive 2001/83/EC is amended as follows:

(1) the following Article 5a 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 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 6 months. Notwithstanding the specified validity, the temporary authorisation shall cease when the medicinal product concerned has been granted a marketing authorisation in accordance with Article 10 of Regulation (EC) No 726/2004, or when such marketing authorisation has been refused in accordance with that Article.";

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

"2a. By way of derogation from paragraph 2, a marketing authorisation may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland to an applicant 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 IV 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 … [*OP: please insert the date - 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 expire at the latest on 31 December 2026.";

(3) the following Article 18a 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 validity period 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 … *OP: please insert the date - 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 and 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 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 established 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 which is established in the Union on … [*OP: Please insert the date of the entry into force of this amending Directive*].";

(5) in Article 40, the following paragraph 1a 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) who are not in possession of a relevant manufacturing authorisation, provided that 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, 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 equivalent quality standards as those laid down in Article 51(1);

(c) the marketing authorisation for the medicinal product concerned has been issued 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 the imports that meet the conditions laid down in the first subparagraph.";

(6) in Article 40, the following paragraph 3a 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, if 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 if they are accompanied by the control reports referred to in Article 51(1), third subparagraph."

(7) in Article 48, the following paragraph 3 is added:

"3. When the marketing 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 in and operate from 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 which is established in the Union on … [*OP: Please insert the date of the entry into force of this amending Directive*]."

(8) 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 in and operate from 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 is established in the Union on … [*OP: Please insert the date of the entry into force of this amending Directive*]."

(9) the following Article 111c 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 Articles 8(2a), 8(2b), 20 second paragraph, 40(1a), 40(3a), 48(3), 104(3) and 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 person and their obligations, quality control testing, batch release and pharmacovigilance as laid down in United Kingdom law;

(b) whether the United Kingdom competent authorities ensure the effective enforcement within their territory of the rules referred to in point (a), among others, by means of 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 rulesis no longer essentially equivalent to that guaranteed within the Union, or where sufficient information is not available to the Commission 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 6 months following that written notification, the Commission shall enter into consultations with the United Kingdom with a view to remedying the situation giving rise to the written notification made pursuant to the first subparagraph. In duly justified cases, the Commission may extend that period by 3 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 first 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 the provisions in relation to which the delegated act pursuant to in paragraph 3 has been adopted 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.

~~6. Article 121a (3) – (6) shall apply to the power to adopt delegated acts referred to in paragraphs 3 and 5.~~

(9a) in Article 121a(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 [*OP: Please insert the date of the entry into force of this amending Directive*].";**

(9b) in Article 121a, the paragraphs 3 and 6 are replaced by the following:

"3. The delegation of power referred to in Article 14(1), Article 22b, Article 23b, Article 46a, Article 47, Article 52b, Article 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.

6. A delegated act adopted pursuant to Article 14(1), Article 22b, Article 23b, Article 46a, Article 47, Article 52b, Article 54a**, Article 111c(3) and (5),** and 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 126c 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 for justified public health reasons authorise 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 granted before [*date of entry into force of this Amending Directive*] pursuant to Article 126a which authorise the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.

Authorisations granted, extended or maintained in force pursuant to the first and 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 the paragraph 1 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 Directive 2001/83/EC and 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 127c and 127d are inserted:

"Article 127c

The derogations set out in Articles 8(2a), 8(2b), 18a, 20 second paragraph, 40(1a), 40(3a), 48(3), 104(3a) and 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 Directive 2001/83/EC.

Article 127d

1. By [*30 days after the entry into force of this 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 ~~or~~ 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 6-monthly basis."

Article 3

1. Member States shall adopt and publish, ~~by [30 June 2022] at the latest,~~ 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 forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 January 2022.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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 third day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*