Council of the European Union

Brussels, 17 December 2021
(OR. en)

15188/21

Interinstitutional File:
2021/0431(COD)

LIMITE

UK 270
PHARM 226
SAN 766
MI 967
COMPET 927

PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	17 December 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2021) 997 final
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

Delegations will find attached document COM(2021) 997 final.

Encl.: COM(2021) 997 final

EUROPEAN
COMMISSION

Brussels, 17.12.2021
COM(2021) 997 final

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

(Text with EEA relevance)

1. EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Pursuant to the Protocol on Ireland / Northern Ireland ("the Protocol") 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[1] ("the Withdrawal Agreement"), medicines placed on the market in Northern Ireland must be covered by a valid marketing authorisation issued by the Commission (EU-wide authorisations) or the United Kingdom (UK) in respect of Northern Ireland. These national authorisations shall be in compliance with the obligations of the EU acquis for medicinal products.

During these last years, the UK as well as the small markets of the European Union (i.e. Malta, Ireland and Cyprus) that are dependent on supply of medicinal products from the United Kingdom have raised issues with respect to the ability of economic operators to comply with all provisions of the acquis for **medicines** after the end of the transition period provided for in the Withdrawal Agreement (de facto mostly for generics and over-the-counter medicines). There are two possible national authorisation routes: purely UK national authorisations ("Northern Ireland-only authorisations"), which concern medicines that are made available in Northern Ireland only, and UK national authorisations issued under Union law procedures involving at least another Member State (Mutual Recognition or Decentralised Procedures[2]).

The Commission Notice of 25 January 2021[3] provides for a grace period of one year (until end-December 2021) for maintaining batch testing and manufacturing / logistics in parts of the United Kingdom other than Northern Ireland to ensure undisrupted supply of medicines to Northern Ireland, Cyprus, Ireland and Malta.[4]

Despite the transition period, it still proves very difficult for certain operators currently based in parts of the United Kingdom other than Northern Ireland to adapt and move relevant regulatory compliance functions (namely, the marketing authorisation holder, quality control (batch) testing, the qualified persons responsible

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1 OJ L 29, 31.1.2020, p. 7.

2 Under these procedures, a Member State takes the lead in the assessment ("Reference Member State") and issues the first authorisation, on the basis of which identical national authorisations are then issued by the other Concerned Member States. Pursuant to the Protocol, Northern Ireland participates in these two procedures but the UK cannot have the leading role.

3 Commission Notice of 25 January 2021 on the 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, OJ C 27, 25.1.2021, p. 11.

4 The current flexibilities allow: (i) wholesale distributors in Northern Ireland, Cyprus, Ireland and Malta to place medicinal products imported from other parts of the United Kingdom than Northern Ireland without the manufacturing authorisation required for imports from third countries; (ii) batch testing normally required to be carried out in the Union (or Northern Ireland pursuant to the Protocol) before placing medicinal products on the market to take place in other parts of United Kingdom than Northern Ireland; (iii) derogations relating to the placement of the unique identifier for medicines for human use.

for batch testing pharmacovigilance) to Northern Ireland or the EU in respect of nationally authorised products, as required by the Protocol. The main reasons are the too high adjustment costs relative to the small size of the Northern Irish market and the complex logistics involved, for which no viable alternative logistical hubs in Northern Ireland have been identified.

By the same token, most industry players currently based in parts of the United Kingdom other than Northern Ireland are not prepared to make the necessary regulatory changes to continue to serve the EU Member States (Cyprus, Ireland, Malta) that have been traditionally dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland. Medicines for these markets are still mainly distributed by wholesalers with logistical hubs in parts of the United Kingdom other than Northern Ireland. The common English leaflet in United Kingdom in respect of Northern Ireland, Cyprus, Ireland and Malta is also one of the element that industry wants to preserve.

The objectives of this proposal are to address the issues related to the human medicinal products, to prevent shortages of medicines and ensure adequate level of public health protection in Northern Ireland, Cyprus, Ireland and Malta.

This proposal allows exceptionally that:

– A marketing authorisation holder may be established in parts of the United Kingdom other than Northern Ireland;

The manufacturing authorisation holder may be located in parts of the United Kingdom other than Northern Ireland;

The batch testing may be carried out in parts of the United Kingdom other than Northern Ireland;

The qualified person for batch testing and pharmacovigilance may be located in parts of the United Kingdom other than Northern Ireland;

An EU wholesaler located in Northern Ireland, Cyprus, Ireland, or Malta may purchase and obtain medicines from a third country (parts of the United Kingdom other than Northern Ireland) without holding a manufacturing import authorisation and without re-testing the products.

The Union has an agile system to authorise new and innovative medicinal products through the centralised procedure provided by Regulation (EC) No 726/2004. Those medicinal products will be available to patients in Northern Ireland. However, it is possible that for some of these products the competent authorities of the United Kingdom in respect of other parts of the United Kingdom than Northern Ireland issue a marketing authorisation, while there is no marketing authorisation granted yet for the same medicinal product in the Union. In such an exceptional case, the competent authorities of the United Kingdom in respect of Northern Ireland would 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. Those temporary authorisations should be time limited and cease in any case once a decision on the medicinal product is taken by the Commission to grant or refuse the authorisation to market that product.

In addition, 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 proposal provides that the applicant may choose between the mutual recognition/decentralised procedure and the national authorisation procedure in respect of Northern Ireland.

Likewise, the proposal provides that 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 the mutual recognition or decentralised procedure may 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 the national authorisation procedure.

For Cyprus, Ireland and Malta, derogations are temporary as it is expected that these markets will gradually be supplied through Member States. A transition period of 3 years therefore seems sufficient.

- **Consistency with existing policy provisions in the policy area**

A comprehensive Union medicinal products legislative framework is established, in particular Directive 2001/83/EC [5] and Directive 2001/20/EC[6], which are of relevance for this initiative that will complement and amend them.

This proposal is consistent with the objective to protect public health in the small markets of the Union and in Northern Ireland.

- **Consistency with other Union policies**

This proposal does not affect other Union policies, except for the health and internal market rules. As a consequence, the assessment of the consistency with other Union policies is not considered necessary.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

As the initiative amends Directive 2001/83/EC and Directive 2001/20/EC, the same legal basis – Article 114 TFEU – is considered the appropriate legal basis for this proposal as well.

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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 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).

- **Subsidiarity (for non-exclusive competence)**

This proposal provides exemptions to the provisions of the EU pharmaceutical legislation and can only be achieved by an amendment of the relevant basic acts at EU level.

The European Commission has explored the possibility given by the implementation of Article 5 of Directive 2001/83/EC to use non-compliant medicines under the compassionate use procedure for the purposes of medicines supply to Cyprus, Ireland and Malta.

Nevertheless, the competent authorities of the Member States concerned do not want to transfer the liability arising from these derogations to the healthcare professionals. Moreover, the compassionate use should be restricted to a limited number of medicinal products on a case-by-case basis under certain circumstances.

This proposal aims to provide derogations for medicinal products distributed to Northern Ireland, Cyprus, Ireland and Malta.

- **Proportionality**

The proposal covers the exemptions for regulatory functions that had not been transferred by industry to the EU or Northern Ireland before the end of the transition period provided for in the Withdrawal Agreement. This proposal is not going beyond what is absolutely necessary to ensure continued supply of medicinal products (for human use).

The proposal is restricted to medicinal products made exclusively available in Northern Ireland and the small markets of the Union that are dependent on the UK market for their medicine supplies.

- **Choice of the instrument**

As the initiative amends Directive 2001/83/EC and Directive 2001/20/EC, a proposal for a Directive of the European Parliament and Council is considered the appropriate instrument.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

Not applicable

- **Stakeholder consultations**

This initiative is proposed following bilateral discussion with the concerned national authorities and industry, wholesale distributors and pharmacists, who have expressed strong concern due to the risk of shortages of medicines supplies.

- **Impact assessment**

  The proposal is exempted from the impact assessment due to the urgency of the situation, to ensure public health through the continued supply of medicinal products in Northern Ireland and the small markets of the Union that are dependent on the UK for their supplies.

- **Regulatory fitness and simplification**

  By waiving certain regulatory requirements for the importation of medicinal products, provided certain conditions are fulfilled, the proposal reduces compliance costs in particular as regards the SMEs.

- **Fundamental rights**

  The proposed Directive contributes to achieving a high level of human health protection as set out in Article 35 of the EU Charter of Fundamental Rights.

4. BUDGETARY IMPLICATIONS

No budgetary implications are foreseen.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

  The initiative applies to UK in respect of Northern Ireland that must implement it and must notify to the Commission the implementation planning associated with this initiative. The Member States concerned as well must take the necessary measures to implement the initiative. The Commission will further monitor its implementation via the supervision and control mechanism set therein, with the support of the competent authorities of the Member States.

- **Explanatory documents (for directives)**

  The Member States concerned shall transpose this proposal within the set timeframe and take the necessary measures to comply with this Directive.

- **Detailed explanation of the specific provisions of the proposal**

  Not applicable for this proposal.

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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)

2. 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, medicinal products placed on the market in Northern Ireland are to comply with 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 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

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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).

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,

3. 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.

(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. 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.

4. Done at Brussels,

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