Council of the European Union

Brussels, 28 March 2025
(OR. en)

7200/25

LIMITE

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Interinstitutional Files:
2023/0131(COD)
2023/0132(COD)

WORKING DOCUMENT

From:	Presidency
To:	Delegations
No. prev. doc.:	16051/24, 5539/25
Subject:	Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 *- Exchange of views*

Delegations will find in Annex the revised Articles on final provisions and Brexit to be discussed at the meeting of the Working Party on 3 April 2025.

Changes compared to the Commission proposals are indicated in ~~strikethrough~~ for deletions and **bold/underline** for new text made in document 16051/24. In addition, changes compared to document 5539/25 are highlighted in grey and recital 75 of the Directive was added to this document.

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REGULATION

CHAPTER XII
GENERAL PROVISIONS

Article 171
Penalties at national level

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

2. Member States shall inform the Commission immediately of any litigation instituted for infringement of this Regulation.

Article 172
Union penalties

1. The Commission may impose financial penalties in the form of fines or periodic penalty payments on the marketing authorisations holder granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations.

2. The Commission may, insofar as specifically provided for in the delegated acts referred to in paragraph 10, point (b), impose the financial penalties referred to in paragraph 1 on a legal entity or legal entities other than the marketing authorisation holder provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:
   (a) exerted a decisive influence over the marketing authorisation holder; or
   (b) were involved in, or could have addressed, such failure to comply with the obligation by the marketing authorisation holder.

3. Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to comply with any of the obligations, referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.

4. In determining whether to impose a financial penalty and in determining its appropriate amount, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness and take into consideration, where relevant, the seriousness and the effects of the failure to comply with the obligations.

5. For the purposes of paragraph 1, the Commission shall take into account:
   (a) any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts;
   (b) any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.

6. Where the Commission finds that the marketing authorisation holder has failed, intentionally or negligently, to comply with its obligations, as referred to in paragraph 1, it may adopt a decision imposing a fine not exceeding 5 % of the marketing authorisation holder's Union turnover in the business year preceding the date of that decision.

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Where the marketing authorisation holder continues to fail to comply with its obligations referred to in paragraph 1, the Commission may adopt a decision imposing periodic penalty payments per day not exceeding 2,5 % of the marketing authorisation holder's average daily Union turnover in the business year preceding the date of that decision.

Periodic penalty payments may be imposed for a period running from the date of notification of the relevant Commission's decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in paragraph 1, has been brought to an end.

7. When conducting the investigation on a failure to comply with any of the obligations referred to in paragraph 1, the Commission may cooperate with competent authorities of the Member States and rely on resources provided by the Agency.

8. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders for the protection of their business secrets.

9. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. The Court of Justice of the European Union may cancel, reduce or increase the fine or periodic penalty payment imposed by the Commission.

10. The Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement this Regulation by laying down:
    (a) procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of the defence, access to file, legal representation and confidentiality;
    (b) further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;
    (c) rules on duration of procedure and limitation periods;

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(d) elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments, as well as the conditions and methods for their collection.

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ANNEX II
LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 172

(1) the obligation to submit complete and accurate particulars and documentation in an application for marketing authorisation submitted to the Agency or in response to obligations laid down in this Regulation to the extent that the failure to comply with the obligation concerns a material particular;

(2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal product for human use, as referred to in Article 12 (4), point (c) and in Article 13(1) fourth subparagraph;

(3) the obligation to comply with conditions or restrictions included in the marketing authorisation with regard to the safe and effective use of the medicinal product for human use as referred to in Article 12(4), points (b), (d), (e), (f) and (g) and in Article 13(1);

(4) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the medicinal products for human use to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 45(1);

(5) the obligation to supply any new information which may entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any country in which the medicinal product for human use is marketed, or to supply any information that may influence the evaluation of the risks and benefits of the product, as provided for in Article 45(2);

(6) the obligation to keep product information up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made public on the European medicines web-portal, as provided for in Article 45(3);

(7) the obligation to provide, at the request of the Agency, any data demonstrating that the benefit-risk balance remains favourable, as provided for in Article 45(4);

(8) the obligation to place the medicinal product for human use on the market in accordance with the content of the summary of product characteristics and the labelling and package leaflet as contained in the marketing authorisation;

(8a) the obligation to make products available and supplied for use in patients in all Member States, as referred to in Article 5(1a), in case of a consistent failure, based on submissions of non-accessibility from at least two Member States;

(9) the obligation to comply with the conditions referred to in Article 18(1) and Article 19;

(10) the obligation to notify the Agency of the dates of actual marketing and of the date when the medicinal product for human use ceases to be on the market, and to provide to the Agency data relating to the volume of sales and the volume of prescriptions of the medicinal product for human use, as provided in Article 16(4);

(11) the obligation to operate a comprehensive pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including the operation of a quality system, maintenance of a pharmacovigilance system master file and performance of regular audits, in accordance with Article 99 in conjunction with Article 99 of [revised Directive 2001/83/EC];

(12) the obligation to submit, at the request of the Agency, a copy of the pharmacovigilance system master file, as provided for in Article 45(4);

(13) the obligation to operate a risk management system as provided for in Article 22 and Article 99(2) in conjunction with Article 99(4) of [revised Directive 2001/83/EC];

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(14) the obligation to record and report suspected adverse reactions for medicinal products for human use, in accordance with Article 106 (1) in conjunction with Article 105 of [revised Directive 2001/83/EC];

(15) the obligation to submit periodic safety update reports, in accordance with Article 106(2) in conjunction with of [revised Directive 2001/83/EC];

(16) the obligation to conduct post-marketing studies, including post-authorisation safety studies and post-authorisation efficacy studies, and to submit them for review, as provided for in Article 20;

(17) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Articles 104 of [revised Directive 2001/83/EC];

(18) the obligation to comply with the time limits for initiating or completing measures specified in the Agency's decision on deferral following the initial marketing authorisation of the medicinal product for human use concerned and in accordance with the definitive opinion referred to in Article 81(2);

(19) the obligation to submit to the Agency an updated version of the paediatric investigation plan in accordance with the agreed timing as provided for in Article 74(2) and Article 74(3);

(20) the obligation to place the medicinal product for human use on the market within two years of the date on which the paediatric indication is authorised, as provided for in Article 59 of [revised Directive 2001/83/EC];

(21) the obligation to notify the Agency the intention to discontinue the placing on the market of the product no less than six months before the discontinuation as provided for in Article 60 of [revised Directive 2001/83/EC];

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(22) the obligation to transfer the marketing authorisation or to allow a third party to use documentation contained in the file of the medicinal product, as provided for in Article 60 of [revised Directive 2001/83/EC];

(23) the obligation to notify the Agency of the intention to discontinue the conduct of an agreed paediatric investigation plan and provide the reasons for such discontinuation no less than six months before the discontinuation as provided in Article 88;

(24) the obligation to submit paediatric studies to the Agency or to the Member States, including the obligation to enter information on third country clinical trials into the European database, as provided for in Articles 91;

(25) the obligation to submit to the Agency a paediatric investigation plan with a request for agreement or an application for a waiver from it, not later than upon completion of the human pharmaco-kinetic studies in adults, except in duly justified cases, as provided for in Article 76(1).

CHAPTER XIII
DELEGATED AND IMPLEMENTING ACTS

Article 173

Standing Committee on Medicinal Products for Human Use and examination procedure

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use established by Article 214 of [revised Directive 2001/83/EC]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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3. Where the opinion of the Committee is to be obtained by written procedure and reference is made to this paragraph, that procedure shall be terminated without result only when, within the time-limit for delivery of the opinion, the chair of the Committee so decides.

4. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of procedure are adapted to the need to make medicinal products swiftly available to patients.

Article 174

Implementing measures related to authorisation and pharmacovigilance activities

1. In order to harmonise electronic transmissions provided for in this Regulation, the Commission may adopt implementing measures covering the format and content of electronic transmissions by marketing authorisation holders.

   Those measures shall take account of the work on international harmonisation carried out in the area and shall, where necessary, be revised to take account of technical and scientific progress. Those measures shall be adopted in accordance with the examination procedure referred to in Article 173(2).

2. In order to harmonise the performance of the pharmacovigilance activities provided for in this Regulation, the Commission shall adopt implementing measures as provided for in Article 214 of [revised Directive 2001/83/EC] covering the following areas:
   (a) the content and maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder;
   (b) the minimum requirements for the quality system for the performance of pharmacovigilance activities by the Agency;
   (c) the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;
   (d) the minimum requirements for the monitoring of data included in the Eudravigilance database to determine whether there are new risks or whether risks have changed;
   (e) the format and content of electronic transmission of suspected adverse reactions by Member States and marketing authorisation holders;

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(f) the format and content of electronic periodic safety update reports and risk management plans;

(g) the format of protocols, abstracts and final study reports of the post-authorisation safety studies.

Those measures shall take account of the work on international harmonisation carried out in the area of pharmacovigilance and shall, where necessary, be revised to take account of technical and scientific progress. Those measures shall be adopted in accordance with the examination procedure referred to in Article 173(2).

Article 175

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 3(5), 19(8), 21, 47(4), 49(2), 63(2), 67(4), 75(3), 81(4) and 172(10) shall be conferred on the Commission for a period of five years from [date of entry into force]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 3(5), 19(8), 21, 47(4), 49(2), 63(2), 67(4), 75(3), 81(4) and 172(10) 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.

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4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 21, 19(8), 47(4), 49(2) and 175 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 to 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 three months at the initiative of the European Parliament or of the Council.

CHAPTER XV
FINAL PROVISIONS

Article 179
Repeals

1. Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006 are repealed. References to the repealed Regulations shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex V.

2. Commission Implementing Regulation (EU) No 198/2013[1] is repealed.

[1] Commission Implementing Regulation (EU) No 198/2013 of 7 March 2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring (OJ L 65, 8.3.2013, p. 17).

Article 180

Transitional provisions

1. The provisions of Article 117 ~~of this Regulation~~ shall also apply to marketing authorisations of medicinal products for human use granted in accordance with Regulation (EC) No 726/2004 and in accordance with Directive 2001/83/EC before [*Note to the OP: Please insert the date = date of entry into application of this Regulation*].

2. The procedures concerning the applications for marketing authorisations for medicinal products for human use that have been validated, in accordance with Article 5 of Regulation (EC) No 726/2004, before [*Note to the OP: Please insert the date = date of entry into application of this Regulation*] and that were pending on [*Note to the OP: Please insert the date = the day before the date of application of this Regulation*] shall be completed in accordance with Article 10 of Regulation (EC) No 726/2004.

3. Procedures concerning imposed post-authorisation studies that were initiated in accordance with Article 10a of Regulation (EC) No 726/2004, before [*Note to the OP: Please insert the date = date of entry into application of this Regulation*] and that were pending on [*Note to the OP: Please insert the date = the day before the date of application of this Regulation*] shall be completed in accordance with Article 20 of this Regulation.

4. By way of derogation, the periods of regulatory protection referred to in Article 29 shall not apply to reference medicinal products for which an application for marketing authorisation has been submitted before [*Note to the OP: Please insert the date of application of this Regulation*]. Article 14(11) of Regulation (EC) No 726/2004 shall continue to apply to them.

5. Orphan designations granted before *[Note to the OP: Please insert the date of application of this Regulation],* entered in and not removed from the Community Register of Orphan Medicinal Products in accordance with Article 5, paragraphs 8 and 12, respectively, of Regulation (EC) No 141/2000 and not granted a marketing authorisation in accordance with Article 7(3) of Regulation (EC) No 141/2000 corresponding to the orphan designation shall be considered to comply with this Regulation and shall be entered in the Register of Designated Orphan Medicinal Products.

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6. Orphan designations granted before *[Note to the OP: Please insert the date of application of this Regulation]* which are either removed from the Community Register of Orphan Medicinal Products in accordance with Article 5(12) of Regulation (EC) No 141/2000 or granted a marketing authorisation in accordance with Article 7(3) of Regulation (EC) No 141/2000 shall not be considered as orphan designations and shall not be entered in the Register of Designated Orphan Medicinal Products.

7. The 7-year validity of an orphan designation referred to in Article 66 of this Regulation for orphan medicinal products granted before *[Note to the OP: Please insert the date of application of this Regulation],* entered in and not removed from the Community Register of Orphan Medicinal Products in accordance with Article 5 (8) and (12), respectively, of Regulation (EC) No 141/2000 and not granted a marketing authorisation in accordance with those Article 7(3) of Regulation (EC) No 141/2000 corresponding to the orphan designation shall begin to run from *[Note to the OP: Please insert the date of application of this Regulation]*.

8. The procedures concerning orphan designations which were initiated in accordance with Article 5, paragraphs 1, 11 or 12 of Regulation (EC) No 141/2000 before *[Note to the OP: Please insert the date of application of this Regulation]* and were pending on *[OP please insert the date = the day before the date of application]*, shall be completed in accordance with Article 5, paragraphs 1, 11 or 12 of Regulation (EC) No 141/2000 as applicable on [*OP please insert the date = the day before the date of application]*.

9. When a paediatric investigation plan, a waiver or a deferral has been granted in accordance with Regulation (EC) No 1901/2006 before [*Note to the OP: Please insert the date of application of this Regulation*], it shall be considered to comply with this Regulation.

   The procedures concerning the application for a paediatric investigation plan, a waiver or a deferral submitted before [date of entry into application], shall be completed in accordance with Regulation (EC) No 1901/2006.

10. Regulations (EC) No 2141/96, (EC) No 2049/2005, (EC) No 507/2006 and (EC) No 658/2007 shall remain in force and continue to apply unless and until repealed.

11. Regulation (EC) No 1234/2008 shall continue to apply unless and until repealed as regards medicinal products for human use that are covered by Regulation (EC) No 726/2004 and Directive 2001/83/EC and that are not excluded from the scope of Regulation (EC) No 1234/2008 pursuant to Article 23b, paragraphs 4 and 5 of Directive 2001/83/EC.

12. Commission Regulation (EC) No 847/2000[2] shall continue to apply unless and until repealed as regards orphan medicinal products that are covered by this Regulation.

13. By way of derogation from Article [*Duration of application of Chapter III*] vouchers granted until [*Note to OP: insert the date of 15 years after the date of entry into force of this Regulation*] or until the date when the Commission has granted a total of 10 vouchers in accordance with Chapter III, whichever date is the earliest, shall continue to be valid according to the conditions set out in Chapter III.

Article 181

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*Note to the OP: Please insert the date of ~~18~~ **24** months after its entry into force. The date should be identical to the date for the application of the Directive*].

[2] Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority' (OJ L 103, 28.4.2000, p. 5).

However, Article 67 shall apply from [*Note to the OP: Please insert the date of 2 years after the date of adoption/entry into force/application of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels,

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

PUBLIC

DIRECTIVE

Chapter XVI

General provisions

Article 200

Competent authorities of the Member States

1. Member States shall designate the competent authorities to carry out tasks under this Directive.

2. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].

3. The competent authorities of the Member States shall cooperate with each other and with the Agency and the Commission in the performance of their tasks under this Directive and [revised Regulation (EC) No 726/2004] to ensure proper application and due enforcement. The competent authorities of the Member States shall ~~transmit~~ **communicate** to each other all ~~necessary~~ **appropriate** information **within a reasonable timeframe**.

4. The competent authority of the Member State may process personal health data from sources other than clinical studies to support their public health tasks and, in particular, the evaluation and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.

   Processing of personal data under this Directive shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.

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Article 201

Cooperation with other authorities

1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States shall consult the relevant authorities established under that Regulation.

2. Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.

Article 202

Member States exchange of information of manufacturing or wholesale distribution authorisations of medicinal products

1. Member States shall take all appropriate measures to ensure that the competent authorities of the Member States concerned communicate to each other such information as is appropriate to guarantee that the requirements placed on the authorisations referred to in Articles 142 and 163, on the certificates referred to in Article 188(13) or on the marketing authorisations are fulfilled.

2. Upon reasoned request, Member States shall send electronically the report referred to in ~~with~~ Article 188 to the competent authorities of another Member State or to the Agency.

3. The conclusions reached in accordance with Articles 188(13) or 188(14) shall be valid throughout the Union.

4. However, in exceptional cases, if a Member State is unable, for reasons relating to public health, to accept the conclusions reached following an inspection under Article 188(1), that Member State shall without undue delay inform the Commission and the Agency. The Agency shall inform the Member States concerned.

PUBLIC

5. When the Commission is informed of these divergences of opinion, it may, after consulting the Member States concerned, ask the inspector who performed the original inspection to perform a new inspection; the inspector may be accompanied by two other inspectors from Member States that are not parties to the disagreement.

Article 203

Information on prohibition of supply or other action on a marketing authorisation

1. Each Member State shall take all the appropriate measures to ensure that decisions granting marketing authorisation, refusing or revoking a marketing authorisation, ~~cancelling~~ **withdrawing** a decision refusing or revoking a marketing authorisation, prohibiting supply, or withdrawing a product from the market, together with the reasons on which such decisions are based, are brought to the attention of the Agency without undue delay.

2. ~~In addition to the notification made pursuant to Article 116 of [revised Regulation (EC) No 726/2004], the marketing authorisation holder shall declare without undue delay if such notified action is based on any of the grounds set out in Articles 195 or 196(1).~~ **The marketing authorisation holder shall notify the national competent authority without undue delay of any action they take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall declare if such notified action is based on any of the grounds set out in Articles 195 or 196(1) and specify the grounds for such action.**

2a. **The marketing authorisation holder shall make the notification electronically and in the formats made available by the Agency. The Agency shall consult the Member States when drawing up the formats.**

3. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 in cases where the action is taken in a third country and where such action is based on any of the grounds set out Articles 195 or 196(1).

4. The marketing authorisation holder shall furthermore notify the Agency where the action referred to in paragraphs 2 or 3 is based on any of the grounds referred to in Articles 195 or 196(1).

5. The Agency shall forward notifications received in accordance with paragraph 4 to all Member States without undue delay.

6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that may affect the protection of public health in third countries is without undue delay brought to the attention of the World Health Organization, with a copy to the Agency.

7. Each year, the Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or that have been withdrawn from the market, including the reasons for such action.

Article 204

Notification of decisions related to marketing authorisations

1. Every decision referred to in this Directive that is taken by the competent authority of a Member State shall state in detail the reasons on which it is based.

2. Such decision shall be notified to the party concerned, together with information as to the redress available to them under the laws in force and of the time limit allowed for access to such redress.

3. Decisions to grant or revoke a marketing authorisation shall be made publicly available.

PUBLIC

Article 205

Authorisation of a medicinal product on public health grounds

1. In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with Chapter III, a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product.

2. When a Member State avails itself of this possibility, it shall adopt the necessary measures in order to ensure that the requirements of this Directive are complied with, in particular those referred to in Chapters IV, VI, IX, XIII and XIV, and Article 206. Member States may decide that Article 74, paragraphs 1 to 3, shall not apply to medicinal products authorised under paragraph 1.

3. Before granting such a marketing authorisation, a Member State:
   (a) shall notify the marketing authorisation holder, in the Member State in which the medicinal product concerned is authorised, of the proposal to grant a marketing authorisation under this Article in respect of the medicinal product concerned;
   (b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 43(5) and of the marketing authorisation in force in respect of the medicinal product concerned. If so requested, the competent authority in that Member State shall supply, within 30 days of receipt of the request, a copy of the assessment report and the marketing authorisation in respect of the medicinal product concerned.

4. The Commission shall set up a publicly available register of medicinal products authorised under paragraph 1. Member States shall notify the Commission if any medicinal product is authorised, or ceases to be authorised, under paragraph 1, including the name or corporate name and permanent address of the marketing authorisation holder. The Commission shall amend the register of medicinal products accordingly and make this register available on their website.

PUBLIC

Article 206

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify without delay of any subsequent amendment affecting them.

   Those penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance.

2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:
   (a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;
   (aa) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, brokering, import and export of medicinal products as well as sale at distance of medicinal products to the public;
   (b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;
   (c) non-compliance with the provisions laid down in this Directive on the use of excipients;
   (d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;
   (e) non-compliance with the provisions laid down in this Directive on advertising.

3. Where relevant, the penalties shall take into account the risk to public health presented by the falsification of medicinal products.

Article 207

Collection of unused or expired medicinal products

Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.

PUBLIC

Article 208

Declaration of interests

1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry that could affect their impartiality. These persons shall make an annual declaration of their financial interests.

2. In addition, the Member States shall ensure that the competent authority makes publicly available its rules of procedure and those of its **medicinal products' authorisation** committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, ~~details of votes and explanations of votes,~~ including minority opinions.

Chapter XVIII
Final provisions

Article 213

Amendment to the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 215 amending Annexes I to VI in order to adapt them to scientific and technical progress and amend Article 22 with regard to the ERA requirements set out in paragraphs 2, 3, 4 and 6 of that Article.

Article 214

Standing Committee on Medicinal Products for Human Use

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where the opinion of the Committee is to be obtained by written procedure and reference is made to this paragraph, that procedure shall be terminated without result only when, within the time limit for delivery of the opinion, the chair of the Committee so decides.

4. The rules of procedure of the Standing Committee on Medicinal Products shall be made publicly available.

5. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of procedure are adapted to the need to make medicinal products swiftly available to patients and take account of the tasks incumbent upon it under Chapter III and the procedure set out in Article 42.

REGULATION

RECITALS

(50) On the basis of the opinion of the Agency the Commission should adopt a decision on the application by means of implementing acts. In justified cases, the Commission may return the opinion for further examination or deviate in its decision from the opinion of the Agency. Taking into account the need to make medicinal products swiftly available to patients, it should be acknowledged that the chairperson of the Standing Committee on Medicinal Products for human use will use the available mechanisms under Regulation (EU) 182/2011 of the European Parliament and of the Council[3] and notably the possibility to obtain the committee's opinion by written procedure and within expeditious deadlines which, in principle, will not exceed ~~10~~ **15** calendar days.

[3] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

DIRECTIVE

Article 215

Exercise of the delegations

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 shall be conferred on the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

   The power to adopt delegated acts referred to in Article 210, paragraphs 3 and 5, shall be conferred on the Commission for an indeterminate period of time from [OP please insert the date = the date of the entry into force of this Directive].

3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), 27(3), 28, paragraphs 2 and 3, 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 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.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

PUBLIC

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 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.

Article 216

Report

By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it.

Article 217

Repeals

1. Directive 2001/83/EC is repealed with effect from [OP please insert the date = 18 months after the date of entering into force of this Directive].

2. Directive 2009/35/EC is repealed with effect from [OP please insert the date = 18 months after the date of entering into force of this Directive].

3. References to the repealed Directives 2001/83/EC and 2009/35/EC shall be construed as references to this Directive. References to the repealed Directive 2001/83/EC shall be read in accordance with the correlation table in Annex VIII.

PUBLIC

Article 218

Transitional provisions

1. The procedures concerning the applications for marketing authorisations for medicinal products validated in accordance with Article 19 of Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive] and that were pending on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive] shall be completed in accordance with **Directive 2001/83/EC**~~Article 29~~.

2. Procedures initiated on the basis of Articles 29, 30, 31, and 107i of Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive] and that were pending on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive] shall be completed in accordance with Articles 32 to 34 or Article 107k, as appropriate, of that Directive as applicable on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive].

3. This Directive shall also apply to medicinal products authorised in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].

   This Directive shall also apply to registrations of homeopathic medicinal products and traditional herbal medicinal products carried out in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].

PUBLIC

4. By way of derogation from Chapter VI, the medicinal products placed on the market in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive] may continue to be made available on the market until [OP please insert the date = five years after 18 months after the date of entering into force of this Directive], provided that they comply with the provision on labelling and package leaflet set out in Title V of Directive 2001/83/EC as applicable on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive].

5. By way **o**f derogation from Article 81, reference medicinal products for which the application for marketing authorisation has been submitted before [OP please insert the date = 18 months after the date of entering into force of this Directive] shall be subject to the provisions on data protection periods set out in Article 10 of Directive 2001/83/EC as applicable on [OP please insert the date = 18 months after the date of entering into force of this Directive] until [OP please insert the date = 18 months after the date of entering into force of this Directive].

6. By way of derogation from paragraph 3, the reporting obligations as referred to in Article 57, shall not apply with regards to medicinal products authorised in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].

6a. For medicinal products authorised before [OP please insert the date the date of entering into force of this Directive] and for which the validity expires after that date, the renewal of the marketing authorisation shall follow the procedures referred to in Article 46.

7. For medicinal products authorised before [OP please insert the date the date of entering into force of this Directive] and medicinal products for which the application for marketing authorisation was validated before [OP please insert the date = date of entering into application of this Directive]~~[entering into application], the~~ requirement to make the package leaflet available ~~in the package~~ electronically, pursuant to Article 63, paragraph 1 shall apply on [OP please insert the date = 3 years after the date of entering into force of this Directive]~~, unless a Member State chooses to apply the requirement earlier in its territory.~~

8. ~~Stocks of~~ M~~m~~edicinal products produced, packaged and labelled prior to [OP please insert the date the date of entering into force of this Directive] which do not comply with the requirement to make the package leaflet available ~~in the package~~ electronically, pursuant to Article 63, paragraph 1 may continue to be placed on the market, distributed, dispensed, sold and used until stocks of those medicinal products are exhausted.

Article 219

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive by [**24**~~18~~ months after the date of entering into force of this Directive]. They shall immediately communicate the text of those measures to the Commission. **Member States shall apply those provisions from [24 months after the date of entering into force of this Directive].**

2. When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

3. Member States shall communicate to the Commission the text of the main measures of national law that they adopt in the field covered by this Directive.

Article 220

Entry into force

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

PUBLIC

Article 221

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament For the Council

The President *The President*

PUBLIC

Chapter XVII

Specific provisions concerning Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland

Article 209

Provisions relevant to the United Kingdom in respect of Northern Ireland

~~1. By way of derogation from Article 5, 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, paragraphs 1 and 2 of [revised 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 13 of [revised Regulation (EC) No 726/2004], or if such marketing authorisation has been refused in accordance with that Article.~~

2. By way of derogation from Article 56(4), marketing authorisations may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland:
   (a) to applicants established in parts of the United Kingdom other than Northern Ireland;
   (b) to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4.

The competent authorities of the United Kingdom in respect of Northern Ireland may extend marketing authorisations already granted prior to 20 April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

3. By way of derogation from Article 33, paragraphs 1, 3 and 4 and Article 35(1), 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 that 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 Chapter III, Sections 3 and 4, 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.

4. 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 Chapter III, Sections 3 and 4, before 20 April 2022 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.

PUBLIC

5. With regard to quality control testing referred to in Article 8 carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in Article 211(9) other than those authorised by the Commission, the competent authorities of the United Kingdom in respect of Northern Ireland may consider that there is a justifiable case within the meaning of Article 8, point (b), 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 153;

   (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 20 April 2022.

6. By way of derogation from Article 142(1), the competent authorities of the United Kingdom in respect of Northern Ireland shall allow medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by a wholesale distribution authorisation holders as referred to in Article 163(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 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);

   (b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by 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 153(1);

PUBLIC

(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 67.~~

7. For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Northern Ireland, the controls upon importation referred to in Article 153(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 153(1), third subparagraph.

8. 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 Article 151(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 20 April 2022.

9. By way of derogation from the Article 99(5), where the marketing authorisation is granted by the competent authority of United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 99(4), point (a), may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the marketing authorisation holder already has at its disposal a qualified person who resides and operates in the Union ~~on~~ 20 April 2022.

10. The competent authorities of the United Kingdom in respect of Northern Ireland shall 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 Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis.

PUBLIC

Article 210

Regulatory functions carried out in the United Kingdom

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 99(4), Article 151(3), Article 211, paragraphs 1, 2, 5 and 6, Article 209, paragraphs 6 and 7, 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.

PUBLIC

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 amending or supplementing 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.

RECITAL

(75) 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. Following the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, to prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, specific **provisions** ~~derogations to this Directive~~ need to be included 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. **Only those provisons that were envisoned in the Directive 2001/83/EC to be applicable after 31 December 2004, should also be placed in this Directive.**

PUBLIC

Article 211

Provisions relevant to Cyprus, Ireland and Malta ~~and applicable until 31 December 2024~~

1. By way of derogation from Article 56(4), marketing authorisations may be granted in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4, to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

~~Until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta marketing authorisations already granted prior to 20 April 2022 may be extended 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**s or Article 8 (2b) of Directive 2001/83/EC** shall cease to be valid at the latest on 31 December 2026.

2. With regard to quality control testing referred to in Article 8 carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in paragraph 9, other than those authorised by the Commission, 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 Article 8, point (b), 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 153(1);
   (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 20 April 2022.

3. By way of derogation from Article 142(1), 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 wholesale distribution authorisation holders as referred to in Article 163(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 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);

(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by the competent authorities 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 153(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 67.~~

Article 166(1), point (b), shall not apply to imports that fulfil the conditions laid down in the first subparagraph.

4. ~~For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported until 31 December 2024 into Cyprus, Ireland or Malta, the controls upon importation referred to Article 153(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 153(1), third subparagraph.~~

PUBLIC

5. ~~By way of derogation from Article 205(1) 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 205(1) before 20 April 2022 and that 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 subparagraphs shall not be valid after 31 December 2026.

6. By way of derogation from Article 56(4), the competent authorities of Malta and Cyprus may grant marketing authorisations as referred to in paragraph 5 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

7. Where the competent authorities of Cyprus or Malta grant or extend a marketing authorisation as referred to in paragraph 5, they shall ensure compliance with the requirements of this Directive.

8. Before granting a marketing authorisation pursuant to paragraph 5, 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 paragraphs 5 to 8 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.

9. The competent authorities of Cyprus, Ireland, Malta shall 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 Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis.

Article 212

Derogations for medicinal products placed on the markets of Cyprus, Ireland, Malta or Northern Ireland

The ~~derogations~~ **provisions** ~~set out in~~ **of** Article 211, paragraphs 1 and 6, Article 8, Article 209, paragraphs 6 and 7, Article 153 (3), Article 99(4) and Article 211(5) 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.

PUBLIC