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*(Legislative acts)*

# REGULATIONS

## REGULATION (EU) 2023/1182 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**of 14 June 2023**

**on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), 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 ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

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 (the 'Withdrawal Agreement') was concluded on behalf of the Union by Council Decision (EU) 2020/135 ([3]) and entered into force on 1 February 2020. The transition period referred to in Article 126 of the Withdrawal Agreement, during which Union law continued to apply to and in the United Kingdom in accordance with Article 127 of the Withdrawal Agreement, ended on 31 December 2020.

(2) The Protocol on Ireland/Northern Ireland (the 'Protocol') forms an integral part of the Withdrawal Agreement.

([1]) Opinion of 27 April 2023 (not yet published in the Official Journal).
([2]) Position of the European Parliament of 9 May 2023 (not yet published in the Official Journal) and decision of the Council of 30 May 2023.
([3]) 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) The provisions of Union law listed in Annex 2 to the Protocol apply, under the conditions set out in that Annex, to and in the United Kingdom in respect of Northern Ireland. That list includes Directive 2001/83/EC of the European Parliament and of the Council ([4]) and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([5]). Therefore, medicinal products placed on the market in Northern Ireland are required to comply with those provisions of Union law.

(4) Directive 2001/83/EC lays down rules for medicinal products for human use and Regulation (EC) No 726/2004 lays down Union procedures for the authorisation of medicinal products for human use.

(5) In order to take account of the specific situation of Northern Ireland, it is appropriate to adopt specific rules relating to the placing on the market in Northern Ireland of medicinal products for human use.

(6) It is appropriate to clarify that the provisions of Union law listed in Annex 2 to the Protocol should apply in respect of medicinal products for human use intended to be placed on the market in Northern Ireland, unless specific rules are laid down in this Regulation. Where specific rules of this Regulation apply, and there is an inconsistency between those specific rules of this Regulation and the provisions of Union law listed in Annex 2 to the Protocol, those specific rules of this Regulation should take precedence.

(7) Furthermore, it is important to ensure that the application of the specific rules laid down in this Regulation does not lead to an increased risk to public health in the internal market.

(8) The specific rules should include a prohibition against displaying the safety features referred to in Directive 2001/83/EC on the outer packaging or, where there is no outer packaging, on the immediate packaging of medicinal products for human use intended to be placed on the market in Northern Ireland and a prohibition against placing on the market in Northern Ireland new and innovative medicinal products that have been granted a marketing authorisation in accordance with Regulation (EC) No 726/2004. Furthermore, the specific rules should include certain labelling requirements for medicinal products for human use intended to be placed on the market in Northern Ireland. As a consequence, Commission Delegated Regulation (EU) 2016/161 ([6]) should not apply to medicinal products for human use intended to be placed on the market in Northern Ireland.

(9) In respect of new and innovative medicinal products, the competent authorities of the United Kingdom should be able to authorise the placing of those medicinal products on the market in Northern Ireland provided that certain conditions are fulfilled, namely that the authorisation is granted in accordance with the law of the United Kingdom and that the medicinal products are placed on the market in Northern Ireland under the terms of the authorisation granted by the competent authorities of the United Kingdom, that those medicinal products comply with certain labelling requirements, and that written guarantees have been provided by the United Kingdom to the Commission.

(10) Furthermore, appropriate safeguards for the Union should be put in place in order to ensure that the application of the specific rules does not increase risks to public health in the internal market. Such safeguards should include continuous monitoring by the competent authority of the United Kingdom of the placing on the market in Northern Ireland of medicinal products for human use subject to specific rules laid down in this Regulation and a total prohibition against the movement to or placing on the market in a Member State of medicinal products subject to the specific rules laid down in this Regulation.

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([4]) 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).

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

([6]) Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

(11) The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of suspending the application of some or all of the specific rules laid down in this Regulation where there is evidence that the United Kingdom is not taking appropriate measures to tackle serious or repeated infringements of those specific rules. In such an event, it is appropriate to provide for a formal information and consultation mechanism with clear time limits within which the Commission should act. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([7]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(12) Where the specific rules for the placing on the market in Northern Ireland of medicinal products for human use are suspended, the relevant provisions of Union law listed in Annex 2 to the Protocol should apply again to such medicinal products.

(13) In order to ensure an effective and swift reaction to any increased risk for public health, this Regulation should provide for the possibility for the Commission to adopt delegated acts in accordance with an urgency procedure.

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

(15) It is appropriate to provide for a transitional period for the application of the specific rules laid down in this Regulation to medicinal products for human use which are already on the market in Northern Ireland.

(16) As a consequence of the adoption of this Regulation, Directive 2001/83/EC should be amended accordingly,

HAVE ADOPTED THIS REGULATION:

*Article 1*

**Subject matter and scope**

1. This Regulation lays down specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland in accordance with Article 6 of Directive 2001/83/EC.

2. This Regulation also lays down rules regarding the suspension of the application of the specific rules laid down in this Regulation.

3. The provisions of Union law listed in Annex 2 to the Protocol on Ireland/Northern Ireland (the 'Protocol') shall apply in respect of the placing on the market in Northern Ireland of medicinal products as referred to in paragraph 1 of this Article, unless specific rules are laid down in this Regulation.

*Article 2*

**Definitions**

For the purposes of this Regulation, the definitions laid down in Article 2 of Regulation (EC) No 726/2004, including the definitions laid down in Article 1 of Directive 2001/83/EC, apply.

([7]) OJ L 123, 12.5.2016, p. 1.

*Article 3*

**Specific rules for medicinal products as referred to in Article 1(1)**

1. The competent authorities of the United Kingdom in respect of Northern Ireland may allow medicinal products as referred to in Article 1(1) of this Regulation to be imported into Northern Ireland from other parts of the United Kingdom by holders of a wholesale distribution authorisation that are not in possession of a relevant manufacturing authorisation, provided that the conditions laid down in Article 40(1a), first subparagraph, points (a) to (d), of Directive 2001/83/EC are fulfilled.

2. The safety features referred to in Article 54, point (o), of Directive 2001/83/EC shall not appear on the outer packaging or, where there is no outer packaging, on the immediate packaging of medicinal products as referred to in Article 1(1) of this Regulation.

3. Where a medicinal product as referred to in Article 1(1) of this Regulation bears the safety features referred to in Article 54, point (o), of Directive 2001/83/EC, those features shall be fully removed or covered.

4. The qualified person referred to in Article 48 of Directive 2001/83/EC shall, in the case of a medicinal product as referred to in Article 1(1) of this Regulation, ensure that the safety features referred to in Article 54, point (o), of that Directive have not been affixed on the packaging of the medicinal product.

5. Holders of a wholesale distribution authorisation shall not be required to:

(a) verify medicinal products as referred to in Article 1(1) of this Regulation in accordance with Article 80, first paragraph, point (ca), of Directive 2001/83/EC;

(b) keep records as regards the information referred to in Article 80, first paragraph, point (e), last indent, of Directive 2001/83/EC.

6. For all supplies of medicinal products as referred to in Article 1(1) of this Regulation to a person authorised or entitled to supply medicinal products to the public, as referred to in Article 82 of Directive 2001/83/EC, as regards the United Kingdom in respect of Northern Ireland, the authorised wholesaler shall not be required to enclose a document that makes it possible to ascertain the batch number of the medicinal products in accordance with Article 82, first paragraph, last indent, of that Directive.

*Article 4*

**Specific rules for medicinal products as referred to in Article 1(1) of this Regulation belonging to the categories referred to in Article 3(1) and (2) of Regulation (EC) No 726/2004**

1. A medicinal product as referred to in Article 1(1) of this Regulation belonging to the categories referred to in Article 3(1) and (2) of Regulation (EC) No 726/2004 that has been granted a marketing authorisation in accordance with Article 10 of that Regulation shall not be placed on the market in Northern Ireland.

2. Notwithstanding paragraph 1 of this Article, a medicinal product as referred to in Article 1(1) of this Regulation belonging to the categories referred to in Article 3(1) and (2) of Regulation (EC) No 726/2004 may be placed on the market in Northern Ireland provided that all of the following conditions are fulfilled:

(a) the competent authorities of the United Kingdom have authorised the placing on the market of the medicinal product in accordance with the law of the United Kingdom and under the terms of the authorisation granted by them;

(b) the medicinal product concerned is labelled in accordance with Article 5 of this Regulation;

(c) written guarantees are provided by the United Kingdom to the Commission in accordance with Article 8 of this Regulation.

*Article 5*

**Specific rules for the labelling of medicinal products as referred to in Article 1(1)**

Medicinal products as referred to in Article 1(1) shall bear an individual label that complies with the following requirements:

(a) it shall be attached to the packaging of the medicinal product in a conspicuous place in such a way that it is easily visible, clearly legible, and indelible; it shall not in any way be hidden, obscured, detracted from, or interrupted by any other written or pictorial matter or any other intervening material;

(b) it shall state the words 'UK only'.

*Article 6*

**Monitoring of medicinal products as referred to in Article 1(1)**

The competent authority of the United Kingdom shall continuously monitor the placing on the market in Northern Ireland of medicinal products as referred to in Article 1(1) and the effective enforcement of the specific rules laid down in Articles 3, 4 and 5.

*Article 7*

**Prohibition against the movement to or placing on the market in a Member State of medicinal products as referred to in Article 1(1)**

1. Medicinal products as referred to in Article 1(1) shall not be moved from Northern Ireland to a Member State or be placed on the market in a Member State.

2. The Member States shall apply effective, proportionate and dissuasive penalties in the case of non-compliance with the specific rules laid down in this Regulation.

*Article 8*

**Written guarantees provided by the United Kingdom to the Commission**

The United Kingdom shall provide the Commission with written guarantees that the placing on the market of medicinal products as referred to in Article 1(1) does not increase the risk to public health in the internal market and that such medicinal products will not be moved to a Member State, including guarantees to the effect that:

(a) economic operators comply with the labelling requirements laid down in Article 5;

(b) effective monitoring, enforcement and controls of the specific rules laid down in Articles 3, 4 and 5 are in place and are carried out, by means of, *inter alia*, inspections and audits.

*Article 9*

**Suspension of the specific rules laid down in Articles 3, 4 and 5**

1. The Commission shall continuously monitor the application by the United Kingdom of the specific rules laid down in Articles 3, 4 and 5.

2. Where there is evidence that the United Kingdom is not taking appropriate measures to address serious or repeated infringements of the specific rules laid down in Articles 3, 4 and 5, the Commission shall inform the United Kingdom by means of written notification.

For a period of three months from the date of the written notification referred to in 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 a further three months.

3. If the situation giving rise to the written notification referred to in paragraph 2, first subparagraph, of this Article is not remedied within the period referred to in paragraph 2, second subparagraph, of this Article, the Commission is empowered to adopt a delegated act in accordance with Articles 10 and 11 to supplement this Regulation by specifying the specific rules among those referred to in paragraph 1 of this Article whose application is to be temporarily or permanently suspended.

4. Where a delegated act has been adopted in accordance with paragraph 3 of this Article, the specific rules of Articles 3, 4 and 5 as specified in that delegated act shall cease to apply on the first day of the month following the entry into force of that delegated act.

5. Where the situation giving rise to the adoption of the delegated act in accordance with paragraph 3 of this Article has been remedied, the Commission shall adopt a delegated act in accordance with Articles 10 and 11 to supplement this Regulation by specifying those suspended specific rules of Articles 3, 4 and 5 that are to apply again.

6. Where a delegated act has been adopted in accordance with paragraph 5 of this Article, the specific rules of Articles 3, 4 and 5 as specified in that delegated act shall apply again on the first day of the month following the entry into force of that delegated act.

*Article 10*

**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 Article 9 shall be conferred on the Commission for a period of five years from the date of application referred to in Article 14. 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 Article 9 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.

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 Article 9 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 11*

**Urgency procedure**

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 10(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

*Article 12*

**Transitional provisions for safeguard requirements**

Medicinal products that have been lawfully placed on the market in Northern Ireland before the date of application referred to in Article 14, and that are not repackaged or relabelled after that date, may be further made available on the market in Northern Ireland until their expiry date without being required to comply with the specific rules laid down in Articles 3, 4 and 5.

*Article 13*

**Amendment to Directive 2001/83/EC**

Article 5a of Directive 2001/83/EC is deleted with effect from the date of application referred to in Article 14 of this Regulation.

*Article 14*

**Entry into force and application**

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

It shall apply from 1 January 2025, provided that the United Kingdom has provided the written guarantees referred to in Article 8 and that the Commission has published prior to that date the notice referred to in the fifth paragraph of this Article.

In the event that those written guarantees are provided earlier than 1 January 2025 or later than that date, this Regulation shall apply from the first day of the month following the month during which the United Kingdom provides those written guarantees.

Within one month of reception of those written guarantees, the Commission shall provide a report to the European Parliament and to the Council with its assessment of those written guarantees.

The Commission shall publish a notice in the *Official Journal of the European Union* indicating the date from which this Regulation applies.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 14 June 2023.

| *For the European Parliament* | *For the Council* |
|---|---|
| *The President* | *The President* |
| R. METSOLA | J. ROSWALL |