



Brussels, 27.2.2023
COM(2023) 122 final

2023/0064 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on specific rules relating to medicinal products for human use intended to be placed on
the market of Northern Ireland**

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• **Reasons for and objectives of the proposal**

In accordance with 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)¹, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland (“the Protocol”) in conjunction with Annex 2 to that Protocol, Regulation (EC) No 726/2004² and Directive 2001/83/EC³ as well as the Commission acts based on them, apply to and in the United Kingdom (UK) in respect of Northern Ireland.

Medicines placed on the market in Northern Ireland must therefore be covered by a valid marketing authorisation issued by the Commission (EU-wide authorisation) or by the UK in respect of Northern Ireland in accordance with the abovementioned acts.

Despite the transition period provided for in the Withdrawal Agreement, it proved difficult for certain economic operators based in parts of the UK other than Northern Ireland to adapt and move relevant regulatory compliance functions (namely, the marketing authorisation holder, quality control (batch) testing, the qualified persons responsible for batch testing and release and for pharmacovigilance) to Northern Ireland or the Union in respect of nationally authorised medicines, as required by the Protocol.

To ensure the uninterrupted supply of medicines covered by UK national authorisations from Great Britain to Northern Ireland, as well as to other markets that have been historically dependent on supplies from the UK market, the Union adopted Directive (EU) 2022/642⁴, which introduced derogations from certain obligations concerning certain medicinal products for human use made available in the UK in respect of Northern Ireland (and in Cyprus, Ireland and Malta). These derogations allowed economic operators to maintain batch testing and release and manufacturing / regulatory functions in parts of the UK other than Northern Ireland.

Directive (EU) 2022/642 also introduced a bridging solution on novel medicines that under Union law are authorised through the centralised procedure provided by Regulation (EC) No 726/2004. That solution allows the competent authorities of the UK to authorise the supply to patients in Northern Ireland of a novel medicine for which a marketing authorisation has been issued by the competent authority of the UK, while there is no marketing authorisation granted yet for the same medicine in

¹ OJ L 29, 31.1.2020, p. 7.

² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance) OJ L 136, 30.4.2004.

³ 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.

⁴ Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta (Text with EEA relevance) OJ L 118, 20.4.2022.

the Union. This possibility was granted on a temporary basis, until a marketing authorisation is granted or refused in the Union, and in any case for a maximum period of six months.

The practical application of the above provisions on novel medicines has shown that any divergence between the terms of the marketing authorisations granted for the same medicine in the Union and in the UK would require manufacturers to provide separate packs and patient leaflets for Great Britain and Northern Ireland. This would represent a significant economic burden for the manufacturers concerned relative to the small size of the Northern Ireland market and could put at risk the uninterrupted supply of novel medicines to patients in Northern Ireland. Both the UK authorities and stakeholders have also raised concerns that the coexistence of potentially divergent marketing authorisations for Great Britain and Northern Ireland for the same medicine would create legal uncertainty as to the applicable rules for medicines that need to be made available at all times across the UK to the same cohorts of patients.

Additionally, medicines subject to prescription intended for the Northern Ireland market must carry safety features in accordance with Union law. To prevent the reintroduction of exported medicines into the EU single market, Article 22(a) of Commission Delegated Regulation (EU) 2016/161⁵ obliges wholesalers to decommission the unique identifier on all medicines they export outside the Union before they are exported. If the exported medicines are subsequently reimported into the Union, the requirements for importation under Directive 2001/83/EC must be met and a new unique identifier affixed and uploaded to the repositories system. These operations can only be performed by the holder of a manufacturing and importation authorisation. In December 2021, the Commission Delegated Regulation (EU) 2022/315⁶ amended Delegated Regulation (EU) 2016/161 with a view to introducing a derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the UK for a period of three years. This was to prevent supply disruptions in Northern Ireland as many medicines were purchased from the UK by wholesalers not holding a manufacturing and importation authorisation and therefore unable to meet the importation requirements laid down in Directive 2001/83/EC and Delegated Regulation (EU) 2016/161.

Despite the above-mentioned derogations, the UK and certain stakeholders based in the UK have raised concerns that the need for separate marketing authorisations for Great Britain and Northern Ireland in respect of novel medicines and the application of the Union unique identifier requirement for medicines subject to prescription impose unnecessary administrative burdens for medicines that are to be placed only on the Northern Ireland market and will not be made available in any Member State.

The Commission and the Government of the UK have thus reached a comprehensive set of joint solutions to address these concerns, while protecting the integrity of both the Union's and the UK's internal markets.

⁵ 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 (Text with EEA relevance) OJ L 32, 9.2.2016.

⁶ Commission Delegated Regulation (EU) 2022/315 of 17 December 2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom (Text with EEA relevance) OJ L 55, 28.2.2022.

These joint solutions mark a new way forward to implement the Protocol to ensure legal clarity, predictability and prosperity for the people and businesses in Northern Ireland while at the same time preventing any risks to public health in the internal market.

This Proposal reflects these joint solutions, to provide that:

- New and innovative medicines lawfully placed on the market in Northern Ireland are to be only covered by a valid marketing authorisation issued by the UK according to the law of the UK. The placing on the market of these medicines will therefore not anymore be regulated by EU-wide authorisations granted by the Commission.
- The EU safety features that must be displayed on packs of medicines subject to prescription in the Union should not appear on packs of medicines made available to patients in Northern Ireland.

These solutions are accompanied by safeguards to ensure that all medicines placed on the market in Northern Ireland will not be made available in any Member State. These include labelling UK packs with a specific label: “UK only”, continuous monitoring by the UK competent authorities as well as the possibility for the Commission to unilaterally suspend the application of the new rules in case of UK non-compliance with its obligations.

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

A comprehensive Union medicinal products legislative framework is established, including Regulation (EC) 726/2004 and Directive 2001/83/EC, which are of relevance for this initiative that will complement and amend them.

- **Consistency with other Union policies**

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

2. **LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY**

- **Legal basis**

Article 114 of the Treaty on the Functioning of the European Union, which is the same legal basis for the existing Union legislation in the area of medicinal products.

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

This Proposal provides for specific rules for the placing on the market in Northern Ireland of medicinal products for human use.

- **Proportionality**

This Proposal lays down a comprehensive framework of conditions, specific rules and safeguards. It lays down specific rules for the placing on the market in Northern Ireland of medicines for human use. It empowers the Commission to adopt the necessary delegated acts for the suspension of specific rules if there is evidence that the UK does not take appropriate measures to tackle serious or repeated infringements of the specific rules. The act also provides for a number of safeguard mechanisms to ensure that the integrity of the Union’s internal market is protected.

- **Choice of the instrument**

As the initiative concerns the adoption of specific rules in an area to which several Union acts apply, a proposal for a Regulation of the European Parliament and Council is considered to be the appropriate instrument.

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

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

Not applicable

- **Stakeholder consultations**

This initiative is proposed following bilateral discussions with the UK and industry associations and other relevant stakeholders. No open public consultation will be carried out.

- **Collection and use of expertise**

Not applicable

- **Impact assessment**

The proposal is exempted from the impact assessment due to the urgency of the situation.

- **Regulatory fitness and simplification**

Not applicable

- **Fundamental rights**

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

4. BUDGETARY IMPLICATIONS

There are no implications for the Union budget.

5. OTHER ELEMENTS

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

Not applicable

- **Explanatory documents (for directives)**

Not applicable

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

Not applicable

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (the Withdrawal Agreement) was concluded on behalf of the Union by Council Decision (EU) 2020/135³ 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.
- (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, but it is not limited to, Directive 2001/83/EC of the European Parliament and of the Council⁴ and Regulation (EC) No 726/2004 of the

¹ OJ C , , p. .

² OJ C , , p. .

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).

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).

European Parliament and of the Council⁵. 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 the 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 of Northern Ireland of medicinal products for human use.
- (6) It is appropriate to clarify that the provisions listed in Annex 2 to the Protocol apply in respect of medicinal products for human use intended to be placed on the market in Northern Ireland unless specific provisions are laid down by this Regulation. Where the specific provisions of this Regulation apply, and in the event of any inconsistencies between those specific provisions and the provisions listed in Annex 2 to the Protocol, those specific provisions should take precedence.
- (7) Furthermore, it is important to lay down rules which 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 the prohibition to display 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 the prohibition to place 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) 2016/161⁶ 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 products, the competent authorities of the United Kingdom should authorise the placing of these products on the market in Northern Ireland once certain conditions are fulfilled, including that the authorisation is granted in accordance with the law of the United Kingdom and that the 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 these products comply with certain labelling requirements, and lastly that the written guarantees have been provided by the United Kingdom to the European Commission.
- (10) At the same time, 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

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

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).

from the competent authority of the United Kingdom on 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 on 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.

- (11) Furthermore, it is appropriate to empower the Commission to adopt delegated acts to suspend the application of some or all of the specific rules laid down in this Regulation where there is evidence that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of these specific rules. In such an event, it is appropriate to provide for a formal information and consultation mechanism with clear time periods within which the Commission should act.
- (12) In the case of the suspension of the specific rules for the placing on the market in Northern Ireland of the medicinal products, the relevant provisions 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) It is appropriate to provide for a transitional period for the application of specific rules laid down in this Regulation to medicinal products for human use which are already on the market in Northern Ireland.
- (15) As a consequence of the entry into force 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 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 the medicinal products referred to in paragraph 1 of this Article, unless specific provisions are laid down in this Regulation.

Article 2
Definitions

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

Article 3

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

1. The competent authorities of the United Kingdom in respect of Northern Ireland may allow medicinal products 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) 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 referred to in Article 1(1) of this Regulation.
3. Where a medicinal product referred to in Article 1(1) of this Regulation bears the safety feature referred to in Article 54, point (o), of Directive 2001/83/EC, it 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 medicinal products referred to in Article 1(1) of this Regulation, ensure that the safety features referred to in Article 54, point (o), of Directive 2001/83/EC 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 the medicinal products referred to in Article 1(1) of this Regulation in accordance with Article 80, point (ca), of Directive 2001/83/EC;
 - (b) keep records in accordance with Article 80, point (e), of Directive 2001/83/EC.
6. For all supplies of medicinal products 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 in accordance with the last indent of the first paragraph of that Article.

Article 4

Specific rules for medicinal products 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 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. A medicinal product 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 if all the following conditions are met:
 - (a) the competent authorities of the United Kingdom have authorised the placing on the market of the product in accordance with the law of the United Kingdom and under the terms of the authorisation granted by the competent authorities of the United Kingdom;
 - (b) the medicinal product concerned is labelled in accordance with Article 5;

- (c) written guarantees are provided by the United Kingdom to the European Commission in accordance with Article 8.

Article 5

Specific rules for labelling requirements for medicinal products referred to in Article 1(1)

Medicinal products referred to in Article 1(1) shall bear an individual label which shall comply with the following conditions:

- (a) it shall be attached to the packaging of the medicinal product in a conspicuous place in such a way as to be easily visible, clearly legible, and indelible; it shall not be 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 following words: ‘UK only’

Article 6

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

The competent authority of the United Kingdom shall continuously monitor the placing into the market in Northern Ireland of medicinal products 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 on the movement to or placing on the market in a Member State of medicinal products referred to in Article 1(1)

1. Medicinal products 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 dissuasive and proportionate sanctions in the case of non-compliance with the rules laid down in this Regulation.

Article 8

Written guarantees by the United Kingdom to the European Commission

The United Kingdom shall provide the European Commission with written guarantees that the placing on the market of the medicinal products referred to in Article 1(1) does not increase the risk to public health in the internal market and that those 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 special 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 in Articles 3, 4 and 5.
2. Where there is evidence that the United Kingdom does not take 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.

3. For a period of three months from the date of that written notification, 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.
4. If the situation giving rise to the written notification referred to in 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, in accordance with Articles 10 and 11 of this Regulation, specifying the provisions among those referred to in paragraph 1 whose application shall be temporary or permanently suspended.
5. Where a delegated act has been adopted in accordance with paragraph 3 of this Article, the provisions referred to in Articles 3, 4 or 5 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.
6. 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 specifying those suspended provisions of Articles 3, 4 or 5 that shall apply again.
7. 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.

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 of this Regulation. 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 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 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 safeguards requirements

Medicinal products that have been lawfully placed on the market in Northern Ireland before the date of application referred to in Article 14 of this Regulation, 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 or 5.

Article 13
Amendment to Directive 2001/83/EC

Article 5a of Directive 2001/83/EC is deleted 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.

In the case 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 these written guarantees.

The Commission shall publish a Notice in the Official Journal 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 Brussels,

For the European Parliament
The President

For the Council
The President