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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta - Outcome of the European Parliament's first reading (Strasbourg, 4-7 April 2022)

I. INTRODUCTION

A number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this file at first reading.

After the plenary approved the request of the Committee on the Environment, Public Health and Food Safety to proceed according to the Rule 163 (urgent procedure) on 5 April 2022, the EPP, S&D, ID, Greens/EFA and The Left groups jointly presented a compromise amendment (amendment number 1) to the abovementioned proposal for a Regulation and the EPP, S&D, Greens/EFA and The Left groups jointly presented an amendment to the draft legislative resolution containing the statement by the Commission (amendment number 2). These amendments had been agreed during the informal contacts referred to above. No other amendments were tabled.

II. VOTE

When it voted on 7 April 2022, the plenary adopted the compromise amendment (amendment number 1) to the abovementioned proposal for a Regulation, as well as amendment number 2 to the draft legislative resolution. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto[1].

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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[1] The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics.*** The symbol " ▌ " indicates deleted text.

ANNEX
(7.4.2022)

Investigational medicinal products made available in the UK with respect to Northern Ireland, Cyprus, Ireland and Malta ***I

European Parliament legislative resolution of 7 April 2022 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta (COM(2021)0998 – C9-0476/2021 – 2021/0432(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2021)0998),

– having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0476/2021),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 24 February 2022[2],

– after consulting the Committee of the Regions,

– having regard to the undertaking given by the Council representative by letter of 30 March 2022 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rules 59 and 163 of its Rules of Procedure,

1. Adopts its position at first reading hereinafter set out;

2. Takes note of the statement by the Commission annexed to this resolution;

[2] Not yet published in the Official Journal.

3. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P9_TC1-COD(2021)0432

Position of the European Parliament adopted at first reading on 7 April 2022 with a view to the adoption of Regulation (EU) 2022/… of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta

(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[3],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[4],

[3] Opinion of 24 February 2022 (not yet published in the Official Journal).
[4] Position of the European Parliament of 7 April 2022.

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[5] (the 'Withdrawal Agreement') was concluded on behalf of the Union by Council Decision (EU) 2020/135[6] 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. On 25 January 2021, the Commission issued a Notice[7] on the application of the Union's pharmaceutical *acquis* in markets historically dependent on medicinal products supply from or through Great Britain, namely Cyprus, Ireland, Malta and Northern Ireland, after the end of that transition period. That Notice includes explanations of how the Commission was to apply the Union's pharmaceutical *acquis* in those markets with regard to investigational medicinal products. That Notice ceased to apply on 31 December 2021.

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5 OJ L 29, 31.1.2020, p. 7.

6 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).

7 Commission Notice – Application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period (2021/C 27/08) (OJ C 27, 25.1.2021, p. 11).

(2) In accordance with the Protocol on Ireland/Northern Ireland (the 'Protocol'), which forms an integral part of the Withdrawal Agreement***, 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 Chapter IX of Regulation (EU) No 536/2014 of the European Parliament and of the Council[8] regarding the manufacturing and import of investigational medicinal products and auxiliary medicinal products. Therefore,*** investigational medicinal products used in clinical trials in Northern Ireland are to comply with ***those provisions of*** Union law.

(3) Regulation (EU) No 536/2014 lays down the rules for investigational medicinal products intended to be used in clinical trials in the Union. That Regulation applies from 31 January 2022.

8 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

(4) In accordance with Article 61(1) of Regulation (EU) No 536/2014, read in conjunction with the Protocol, the import of investigational medicinal products from third countries into the Union or Northern Ireland is subject to the holding of a manufacturing and import authorisation. Cyprus, Ireland, Malta and Northern Ireland have historically relied on the supply of medicinal products, including investigational medicinal products, from or through parts of the United Kingdom other than Northern Ireland, and the supply chains for those markets have not yet been fully adapted to comply with Union law. To ensure that clinical trial participants in Northern Ireland, as well as in Cyprus, Ireland and Malta continue to have access to new, innovative or improved treatments, it is necessary to amend Regulation (EU) No 536/2014 to provide for a derogation from the requirement of the holding of a manufacturing and import authorisation for investigational medicinal products imported into those markets from parts of the United Kingdom other than Northern Ireland. To ensure the quality of those investigational medicinal products and to avoid compromising the integrity of the internal market, certain conditions should be laid down.

(5) 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.

(6) Regulation (EU) No 536/2014 should therefore be amended accordingly.

(7) 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.

(8) To ensure legal continuity for operators active in the pharmaceutical sector and to guarantee the continuous access of participants in clinical trials in Cyprus, Ireland, Malta and Northern Ireland to investigational medicinal products from the date of application of Regulation (EU) No 536/2014, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union* and should apply retroactively from 31 January 2022,

HAVE ADOPTED THIS REGULATION:

Article 1

In Article 61(1) of Regulation (EU) No 536/2014, the following subparagraph is added:

‘However, the import of investigational medicinal products from other parts of the United Kingdom into Northern Ireland and, until 31 December 2024, into Cyprus, Ireland and Malta shall not be subject to the holding of such an authorisation provided that all of the following conditions are fulfilled:

(a) the investigational medicinal products have undergone certification of batch release either in the Union or in parts of the United Kingdom other than Northern Ireland to verify compliance with the requirements set out in Article 63(1)***;***

(b) the investigational medicinal products are only made available to subjects in the Member State into which those investigational medicinal products are imported or, if imported into Northern Ireland, are only made available to subjects in Northern Ireland.’

Article 2

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

It shall apply from 31 January 2022.

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

Done at ...,

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

Commission statement on medicines supply to Cyprus, Ireland and Malta

The withdrawal of the United Kingdom from the Union has posed particular challenges for those Member States (Cyprus, Ireland and Malta) that during many years were being supplied with medicines from or through parts of the United Kingdom.

The Commission recognises the progress that has been made by Cyprus, Ireland and Malta and industrial operators to implement the necessary changes to facilitate the ongoing supply of medicines following the United Kingdom's withdrawal from the EU.

In order to ensure a long-term security of supply of medicines, the Commission stresses the need for enhanced efforts of all concerned parties in fostering the adaptation of the supply chains to the situation after the United Kingdom's withdrawal.

The Commission is fully committed to accompanying Cyprus, Ireland and Malta in their efforts towards phasing out the temporary derogations provided for in Directive [XXX][*] and Regulation [XXX][*] within three years.

To that end, the Commission will, in accordance with Union law and in full respect of the distribution of competences between the Union and Member States in the area of medicines for human use, continuously follow developments in the concerned Member States and will closely accompany the competent authorities of Cyprus, Ireland and Malta in their efforts to decrease the dependency of their domestic markets on the supply with medicinal products from or through parts of the United Kingdom other than Northern Ireland.

The Commission will invite the competent authorities of Cyprus, Ireland and Malta to provide it, on a regular basis, with information on these efforts.

[*] OJ: Please insert in the text the number of the Directive/Regulation contained in document 2021/0431(COD)/2021/0432(COD) and insert the number, name, date and OJ reference of that Directive/Regulation in the footnote.

Taking this information into account, the Commission will report in writing to the European Parliament and the Council within 18 months from the date of entry into force of Directive [XXX][*] and Regulation [XXX][*] on the progress accomplished in Cyprus, Ireland and Malta towards the complete phasing out of the derogations and the actions of the Commission to closely accompany the competent authorities of those Member States in that regard.

The Commission will remind the industrial operators concerned who still need to make changes to their supply chains that they urgently should make the necessary adaptations to ensure access to medicines in the smaller markets. In this context, the Commission will monitor the progress made by operators involved in the supply of medicines in these Member States regarding their ability to fulfil those requirements of Union law from which Directive [XXX][*] and Regulation [XXX][*] provide for temporary derogations.

In addition and beyond these immediate and necessary steps, as announced in the "Pharmaceutical Strategy for Europe"[9], the Commission will make proposals by the end of 2022 to revise the pharmaceutical legislation of the Union. These proposals will seek to provide longer-term structural solutions, in particular, to the issue of access to medicines, with special attention to enhancing security of supply and addressing risks of shortages in the smaller markets of the Union.

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[*] OJ: Please insert in the text the number of the Directive/Regulation contained in document 2021/0431(COD)/2021/0432(COD) and insert the number, name, date and OJ reference of that Directive/Regulation in the footnote.

[9] Commission Communication "Pharmaceutical Strategy for Europe", COM(2020)0761 final, 25.11.2020.