EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

Brussels, 12 April 2022
(OR. en)

2021/0432 (COD)
LEX 2158

PE-CONS 7/1/22
REV 1

UK 15
PHARM 22
SAN 86
MI 106
COMPET 87
CODEC 143

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 IN RESPECT OF NORTHERN IRELAND AND IN CYPRUS, IRELAND AND MALTA

REGULATION (EU) 2022/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 April 2022

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[1],

After consulting the Committee of the Regions,

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

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1 Opinion of 24 February 2022 (not yet published in the Official Journal).

2 Position of the European Parliament of 7 April 2022 (not yet published in the Official Journal) and decision of the Council of 12 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[1] (the 'Withdrawal Agreement') was concluded on behalf of the Union by Council Decision (EU) 2020/135[2] and entered into force on 1 February 2020. The transition period referred to in Article 126 of the Withdrawal Agreement, during which Union law continued to apply to and in the United Kingdom in accordance with Article 127 of the Withdrawal Agreement, ended on 31 December 2020.
On 25 January 2021, the Commission issued a Notice[3] on the application of the Union's pharmaceutical *acquis* in markets historically dependent on 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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1 OJ L 29, 31.1.2020, p. 7.

2 Council Decision (EU) 2020/135 of 30 January 2020 on the conclusion of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 1).

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

(2) In accordance with the Protocol on Ireland/Northern Ireland (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[1] 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.

[1] 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 Brussels,

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