Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2021/0432(COD)
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 Amending Regulation 2014/536 2012/0192(COD) Subject 4.20.02 Medical research 4.20.02.06 Clinical practice and experiments 4.20.04 Pharmaceutical products and industry Geographical area Ireland Malta United Kingdom Cyprus	Procedure completed

Key players

	Committee responsible	Rapporteur	Appointed
European Parliament	ENVI Environment, Public Health and Food Safety	renew europe. CANFIN Pascal Shadow rapporteur epp CLUNE Deirdre S&D ENGERER Cyrus EICKHOUT Bas VILLANUEVA RUIZ Idoia	02/02/2022
Council of the European Union			
European Commission	Commission DG	Commissioner	
	Health and Food Safety	KYRIAKIDES Stella	
European Economic and Social Committee			
European Committee of the Regions			

Key events

17/12/2021	Legislative proposal published	COM(2021)0998	Summary
20/01/2022	Committee referral announced in Parliament, 1st reading		
28/03/2022	Decision by committee, without report		
07/04/2022	Results of vote in Parliament		
07/04/2022	Decision by Parliament, 1st reading	T9-0117/2022	Summary
12/04/2022	Act adopted by Council after Parliament's 1st reading		
12/04/2022	Final act signed		
20/04/2022	Final act published in Official Journal		

Technical information

Procedure reference	2021/0432(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2014/536 2012/0192(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 168-p4; Rules of Procedure EP 163
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/08019

Documentation gateway

Legislative proposal		COM(2021)0998	17/12/2021	EC	Summary
Economic and Social Committee: opinion, report		CES0378/2022	23/02/2022	ESC	
Text adopted by Parliament, 1st reading/single reading		T9-0117/2022	07/04/2022	EP	Summary
Draft final act		00007/2022/LEX	12/04/2022	CSL	
Commission response to text adopted in plenary		SP(2022)281	01/06/2022	EC	

Final act

Regulation 2022/641
OJ L 118 20.04.2022, p. 0001

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

PURPOSE: to ensure the continuity of supply of investigational medicinal products to Northern Ireland, as well as to Cyprus, Ireland and Malta.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Regulation (EU) No 536/2014 of the European Parliament and of the Council lays down the rules for investigational medicinal products intended to be used in clinical trials in the Union. According to the Regulation, read in conjunction with the Ireland/Northern Ireland Protocol to the UK Withdrawal Agreement, the importation 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 always relied on the supply of medicines, including investigational medicines, from or through parts of the UK other than Northern Ireland.

On 25 January 2021, the Commission issued a notice on the application of the EU pharmaceutical acquis in markets historically dependent on the supply of medicines from or via Great Britain (i.e. Cyprus, Ireland, Malta and Northern Ireland) after the end of the transitional period. This notice provides for a one-year grace period (until the end of December 2021), including for import requirements for investigational medicinal products, in order to ensure an uninterrupted supply of medicines to Northern Ireland, Cyprus, Ireland and Malta.

Despite the transition period, it is still proving very difficult for some operators currently based in parts of the UK other than Northern Ireland to adapt as required by the Protocol. An interruption in the supply of investigational medicinal products would present a potential risk to the safety and well-being of participants in ongoing clinical trials and would hamper the establishment of new clinical trials in these Member States and Northern Ireland.

CONTENT: the proposal to amend Regulation (EU) No 536/2014 aims to provide for exemptions for medicinal products distributed in Northern Ireland, Cyprus, Ireland and Malta that are used as investigational medicinal products in clinical trials in those countries.

Specifically, the proposal provides that the importation of investigational medicinal products from other parts of the United Kingdom into Northern Ireland and, until 31 December 2024, into Cyprus, Ireland and Malta is not subject to the holding of a manufacturing and import authorisation, provided that the following conditions are met:

- 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);

- the investigational medicinal products are only made available to clinical trial participants in the Member State into which the investigational medicinal products are imported or, if imported into Northern Ireland, are only made available to clinical trial participants in Northern Ireland.

This proposal should be read in conjunction with the proposal to amend Directives 2001/20/EC and 2001/83/EC in order to introduce exemptions from certain obligations relating to medicinal products for human use available in the United Kingdom in respect of Northern Ireland, as well as Cyprus, Ireland and Malta.

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

The European Parliament adopted by 555 votes to 0, with 3 abstentions, a legislative resolution 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.

Parliament adopted its position at first reading under the ordinary legislative procedure by taking over the Commission proposal.

This Regulation is closely linked to the Directive aimed at ensuring the long-term continuity of supply of medicinal products to Northern Ireland from the United Kingdom and at addressing the remaining supply problems in Cyprus, Ireland and Malta. It aims to ensure the supply of investigational medicinal products to these same markets.

The amendment to Regulation (EU) No 536/2014 aims to provide for derogations for medicinal products distributed in Northern Ireland, Cyprus, Ireland and Malta which are used as investigational medicinal products in clinical trials in these countries.

Specifically, the amending regulation provides that the importation of investigational medicinal products from other parts of the United Kingdom into Northern Ireland and, until 31 December 2024, into Cyprus, Ireland and Malta is not subject to the holding of a manufacturing and import authorisation, provided that the following conditions are met:

- 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 Regulation (EU) No 536/2014;

- the investigational medicinal products are only made available to clinical trial participants in the Member State into which the investigational medicinal products are imported or, if imported into Northern Ireland, are only made available to clinical trial participants in Northern Ireland.

The Regulation will enter into force on the day of its publication in the Official Journal of the European Union. It should apply from 31 January 2022.