Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2021/0431(COD)
Derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta Amending Directive 2001/20 1997/0197(COD) Amending Directive 2001/83 1999/0134(COD) Subject 4.20.01 Medicine, diseases 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

European Parliament	Committee responsible	Rapporteur	Appointed
	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			

Key events

17/12/2021	Legislative proposal published	COM(2021)0997	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	T9-0116/2022	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	2021/0431(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amending Directive 2001/20 1997/0197(COD) Amending Directive 2001/83 1999/0134(COD)
Legal basis	Rules of Procedure EP 163; Treaty on the Functioning of the EU TFEU 114
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/08050

Documentation gateway

Legislative proposal		COM(2021)0997	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		T9-0116/2022	07/04/2022	EP	Summary
Draft final act		00006/2022/LEX	12/04/2022	CSL	
Commission response to text adopted in plenary		SP(2022)281	01/06/2022	EC	

Final act

Directive 2022/642
OJ L 118 20.04.2022, p. 0004

Final legislative act with provisions for delegated acts

Derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta

PURPOSE: to ensure the continuity of supply of certain medicinal products for human use to Northern Ireland, as well as to Cyprus, Ireland and Malta.

PROPOSED ACT: Directive 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: pursuant to the Ireland/Northern Ireland Protocol, which is an integral part of the UK Withdrawal Agreement, medicines placed on the market in Northern Ireland must be covered by a valid marketing authorisation issued by the Commission (EU-wide authorisations) or the United Kingdom (UK) in respect of Northern Ireland. These national authorisations should be in compliance with the obligations of the EU acquis for medicinal products.

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) for maintaining batch testing and manufacturing / logistics in parts of the United Kingdom other than Northern Ireland to ensure undisrupted supply of medicines to Northern Ireland, Cyprus, Ireland and Malta.

Despite the transition period, it still proves very difficult for certain operators currently based in parts of the United Kingdom 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 pharmacovigilance) to Northern Ireland or the EU in respect of nationally authorised products, as required by the Protocol.

Directives 2001/20/EC and 2001/83/EC of the European Parliament and of the Council lay down rules concerning medicinal products for human use and investigational medicinal products intended to be placed on the market in the Member States. In order to avoid shortages of medicinal products and to ensure a high level of public health protection, these Directives need to be amended to provide for derogations for medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from parts of the UK other than Northern Ireland.

CONTENT: the proposal provides for derogations from Directives 2001/20/EC and 2001/83/EC in order to ensure the long-term continuity of supply of generic and innovative medicines to Northern Ireland from the UK and to address the remaining supply problems in Cyprus, Ireland and Malta.

The proposal exceptionally allows the following:

- the marketing authorisation holder and the manufacturing authorisation holder may be established in parts of the United Kingdom other than Northern Ireland;

- batch checks may be carried out in parts of the United Kingdom other than Northern Ireland;

- the qualified person for batch controls and pharmacovigilance may be located in parts of the UK other than Northern Ireland;

- an EU wholesaler located in Northern Ireland, Cyprus, Ireland or Malta will be able to purchase and obtain medicinal products from a third country (parts of the UK other than Northern Ireland) without holding a manufacturing authorisation and without the need to repeat batch checks;

This proposal allows exceptionally that:

- a marketing authorisation holder may be established in parts of the United Kingdom other than Northern Ireland;

- the manufacturing authorisation holder may be located in parts of the United Kingdom other than Northern Ireland;

- the batch testing may be carried out in parts of the United Kingdom other than Northern Ireland;

- the qualified person for batch testing and pharmacovigilance may be located in parts of the United Kingdom other than Northern Ireland;

- an EU wholesaler located in Northern Ireland, Cyprus, Ireland, or Malta may purchase and obtain medicines from a third country (parts of the United Kingdom other than Northern Ireland) without holding a manufacturing import authorisation and without re-testing the products;

- the competent authorities of the United Kingdom in respect of Northern Ireland may temporarily authorise the supply to patients in Northern Ireland of a medicinal product provided that (i) the medicinal product concerned has obtained a marketing authorisation issued by the competent authority of the United Kingdom for parts of the United Kingdom other than Northern Ireland; and (ii) the medicinal product concerned is made available to patients or end-users only within the territory of Northern Ireland and is not made available in any Member State;

- the UK should comply with EU legislation on the quality, safety and efficacy of medicinal products for human use when issuing marketing authorisations for Northern Ireland.

Malta, Cyprus and Ireland will have certain derogations for a period of three years (until 31 December 2024). In these three countries, during this period, importers of medicinal products from the UK will not be required to hold manufacturing authorisations, nor will such medicinal products be required to undergo batch testing if such testing has already been carried out in the UK.

This proposal should be read in conjunction with the proposal to amend 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.

Derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta

The European Parliament adopted by 547 votes to 0 with 4 abstentions a legislative resolution on the proposal for a directive of the European Parliament and of the Council 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, 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.

The proposal aims to ensure the long-term security of supply of medicines to Northern Ireland from Great Britain and to address the remaining supply problems in Cyprus, Ireland and Malta. Cyprus, Ireland, Malta and Northern Ireland are markets historically dependent on the supply of medicinal products from or through parts of the UK other than Northern Ireland, and the supply chains of these markets have not yet been fully adapted to comply with EU law.

The proposed amending directive aims to safeguard the uninterrupted supply of medicinal products for human use in Northern Ireland after the withdrawal of the United Kingdom under the Protocol on Ireland and Northern Ireland. It will also allow, on an exceptional basis and for a transitional period of three years, the placing on the market in Ireland, Malta and Cyprus of medicinal products originating from the United Kingdom under derogations from the requirement that authorisation holders be established in the European Union.

The changes to the medicines legislation authorise, by way of exception, that:

- the marketing authorisation holder may be established in parts of the United Kingdom other than Northern Ireland;

- the holder of the manufacturing authorisation may be established in parts of the United Kingdom other than Northern Ireland;

- batch testing may be carried out in parts of the United Kingdom other than Northern Ireland;

- the qualified person for batch testing and pharmacovigilance may be established in parts of the United Kingdom other than Northern Ireland;

- an EU wholesaler located in Northern Ireland, Cyprus, Ireland or Malta may, until 31 December 2024, purchase and obtain medicinal products from a third country (parts of the UK other than Northern Ireland) without holding a manufacturing and import authorisation and without carrying out new product testing.

The text will enter into force on the day of its publication in the Official Journal of the EU. The measures will apply retroactively from 1 January 2022.

The Commission has stated that it will continuously monitor developments in the Member States concerned and will closely accompany the competent authorities of Cyprus, Ireland and Malta in their efforts to reduce the dependence of their national markets on the supply of 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 regular information on these efforts. On the basis of this information, the Commission will report to the European Parliament and the Council within 18 months of the date of entry into force of the amending Directive on the progress made in Cyprus, Ireland and Malta towards the complete abolition of the derogations and on the measures taken by the Commission to closely accompany the competent authorities of these Member States in this respect.

The Commission will present proposals by the end of 2022 to revise the EU pharmaceutical legislation. These proposals will seek to provide longer-term structural solutions, in particular on the issue of access to medicines, and more specifically on enhancing security of supply and addressing the risks of shortages in smaller markets in the EU.