Basic information

2023/0064(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland **Subject** 4.20.04 Pharmaceutical products and industry	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	CANFIN Pascal (Renew)	23/03/2023
	Shadow rapporteur CLUNE Deirdre (EPP) COVASSI Beatrice (S&D) EICKHOUT Bas (Greens /EFA) VONDRA Alexandr (ECR) SARDONE Silvia (ID) VILLANUEVA RUIZ Idoia (The Left)	

Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
JURI Legal Affairs	VOSS Axel (EPP)	01/04/2023

Council of the European Union

European Commission

Commission DG	Commissioner
Health and Food Safety	KYRIAKIDES Stella

European Economic and Social Committee

Key events

Date	Event	Reference	Summary

27/02/2023	Legislative proposal published	COM(2023)0122	Summary
13/03/2023	Committee referral announced in Parliament, 1st reading		
27/04/2023	Vote in committee, 1st reading		
28/04/2023	Committee report tabled for plenary, 1st reading	A9-0167/2023	
09/05/2023	Decision by Parliament, 1st reading	T9-0122/2023	Summary
09/05/2023	Results of vote in Parliament		
01/06/2023	Act adopted by Council after Parliament's 1st reading		
14/06/2023	Final act signed		
20/06/2023	Final act published in Official Journal		

Technical information

Procedure reference	2023/0064(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Rules of Procedure EP 41 Treaty on the Functioning of the European Union TFEU 114
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/11389

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE745.428	29/03/2023	
Amendments tabled in committee		PE745.507	12/04/2023	
Specific opinion	JURI	PE746.888	25/04/2023	
Committee report tabled for plenary, 1st reading/single reading		A9-0167/2023	28/04/2023	
Text adopted by Parliament, 1st reading/single reading		T9-0122/2023	09/05/2023	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00020/2023/LEX	14/06/2023	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2023)0122	27/02/2023	Summary
Commission response to text adopted in plenary	SP(2023)273	17/07/2023	
Follow-up document	COM(2024)0565	29/11/2024	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1620/2023	27/04/2023	

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Regulation 2023/1182 OJ L 157 20.06.2023, p. 0001	Summary

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

2023/0064(COD) - 09/05/2023 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 617 votes to 3, with 2 abstentions, a legislative resolution on the 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.

The European Parliament adopted its position at first reading under the ordinary legislative procedure.

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

Specifically, the proposed regulation provides 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.

The proposal 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 UK will provide the Commission with written guarantees that the placing on the market of medicinal products does not lead to an increase in risk to public health in the internal market and that such medicinal products will not be moved to a Member State.

In the event that those written guarantees are provided earlier than 1 January 2025 or later than that date, this Regulation will apply from the first day of the month following the month during which the United Kingdom provides those written guarantees. Within one month of reception of those written guarantees, the Commission will provide a report to the European Parliament and to the Council with its assessment of those written guarantees.

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

2023/0064(COD) - 27/02/2023 - Legislative proposal

PURPOSE : to provide specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland.

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: the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union entered into force on 1 February 2020. The Protocol on Ireland/Northern Ireland 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, but it is not limited to, Directive 2001/83/EC of the European Parliament and of the Council lays down the rules for medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council lays down Union procedures for the authorisation of medicinal products for human use. Therefore, medicinal products placed on the market in Northern Ireland are required to comply with those provisions of Union law.

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.

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.

This proposal reflects these joint solutions.

CONTENT: the proposal provides 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.

The proposal 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.

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

2023/0064(COD) - 20/06/2023 - Final act

PURPOSE: to provide specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland.

LEGISLATIVE ACT: Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC.

CONTENT: with this Regulation, the Union is continuing to put in place the Windsor framework, which was the subject of a political agreement between the Commission and the United Kingdom Government on 27 February 2023, to address, in a definitive manner, the challenges concerning Northern Ireland following the UK's withdrawal from the EU.

The Regulation aims to implement the **joint solutions** agreed with the UK on medicinal products. It establishes specific rules relating to **medicinal products for human use** intended to be placed on the market in Northern Ireland.

The new rules ensure that all medicines, including novel medicines, will be available in Northern Ireland at the same time as in the rest of the UK. They will be put on the market in accordance with UK rules and authorisation procedures.

These new provisions are accompanied by new **safeguards** to prevent all medicines placed on the market in Northern Ireland from entering the EU single market. They include a specific **'UK only' label** on the packaging of medicines destined for the UK, ongoing monitoring by the UK competent authorities and the possibility for the Commission to unilaterally suspend the application of the new rules if the UK does not fulfil its obligations.

The UK will provide the Commission with written guarantees that the placing on the market of medicinal products does not increase the risk to public health in the internal market and that such medicinal products will not be moved to a Member State.

ENTRY INTO FORCE: 21.6.2023. The regulation is applicable from 1.1.2025, provided that the United Kingdom has provided the required written guarantees.