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.