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.