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.