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

2021/0431(COD) - 07/04/2022 - Text adopted by Parliament, 1st reading/single reading

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.