Derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta

2021/0432(COD) - 07/04/2022 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 555 votes to 0, with 3 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to 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.

This Regulation is closely linked to the Directive aimed at ensuring the long-term continuity of supply of medicinal products to Northern Ireland from the United Kingdom and at addressing the remaining supply problems in Cyprus, Ireland and Malta. It aims to ensure the supply of investigational medicinal products to these same markets.

The amendment to Regulation (EU) No 536/2014 aims to provide for derogations for medicinal products distributed in Northern Ireland, Cyprus, Ireland and Malta which are used as **investigational medicinal products** in clinical trials in these countries.

Specifically, the amending regulation provides that the importation of investigational medicinal products from other parts of the United Kingdom into Northern Ireland and, until 31 December 2024, into Cyprus, Ireland and Malta is not subject to the holding of a manufacturing and import authorisation, provided that the following conditions are met:

- the investigational medicinal products have undergone certification of batch release either in the Union or in parts of the United Kingdom other than Northern Ireland to verify compliance with the requirements set out in Regulation (EU) No 536/2014;

- the investigational medicinal products are only made available to clinical trial participants in the Member State into which the investigational medicinal products are imported or, if imported into Northern Ireland, are only made available to clinical trial participants in Northern Ireland.

The Regulation will enter into force on the day of its publication in the Official Journal of the European Union. It should apply from 31 January 2022.