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) - 17/12/2021 - Legislative proposal

PURPOSE: to ensure the continuity of supply of investigational medicinal products to Northern Ireland, as well as to Cyprus, Ireland and Malta.

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: Regulation (EU) No 536/2014 of the European Parliament and of the Council lays down the rules for investigational medicinal products intended to be used in clinical trials in the Union. According to the Regulation, read in conjunction with the Ireland/Northern Ireland Protocol to the UK Withdrawal Agreement, the importation of investigational medicinal products from third countries into the Union or Northern Ireland is subject to the holding of a manufacturing and import authorisation.

Cyprus, Ireland, Malta and Northern Ireland have always relied on the supply of medicines, including investigational medicines, from or through parts of the UK other than Northern Ireland.

On 25 January 2021, the Commission issued a notice on the application of the EU pharmaceutical acquis in markets historically dependent on the supply of medicines from or via Great Britain (i.e. Cyprus, Ireland, Malta and Northern Ireland) after the end of the transitional period. This notice provides for a one-year grace period (until the end of December 2021), including for import requirements for investigational medicinal products, in order to ensure an uninterrupted supply of medicines to Northern Ireland, Cyprus, Ireland and Malta.

Despite the transition period, it is still proving very difficult for some operators currently based in parts of the UK other than Northern Ireland to adapt as required by the Protocol. An interruption in the supply of investigational medicinal products would present a potential risk to the safety and well-being of participants in ongoing clinical trials and would hamper the establishment of new clinical trials in these Member States and Northern Ireland.

CONTENT: the proposal to amend Regulation (EU) No 536/2014 aims to **provide for exemptions for medicinal products distributed in Northern Ireland, Cyprus, Ireland and Malta** that are used as investigational medicinal products in clinical trials in those countries.

Specifically, the proposal 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 Article 63(1);

- 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.

This proposal should be read in conjunction with the proposal to amend Directives 2001/20/EC and 2001/83/EC in order to introduce exemptions from certain obligations relating to medicinal products for human use available in the United Kingdom in respect of Northern Ireland, as well as Cyprus, Ireland and Malta.