Council of the European Union

Brussels, 7 April 2022
(OR. fr)

7830/22
ADD 1

Interinstitutional File:
2021/0432(COD)

CODEC 426
UK 61
PHARM 60
SAN 203
MI 251
COMPET 206

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft 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 in respect of Northern Ireland as well as in Cyprus, Ireland and Malta (**first reading**) - Adoption of the legislative act = Statement

Commission statement on medicines supply to Cyprus, Ireland and Malta

The withdrawal of the United Kingdom from the Union has posed particular challenges for those Member States (Cyprus, Ireland and Malta) that during many years were being supplied with medicines from or through parts of the United Kingdom.

The Commission recognises the progress that has been made by Cyprus, Ireland and Malta and industrial operators to implement the necessary changes to facilitate the ongoing supply of medicines following the United Kingdom's withdrawal from the EU.

In order to ensure a long-term security of supply of medicines, the Commission stresses the need for enhanced efforts of all concerned parties in fostering the adaptation of the supply chains to the situation after the United Kingdom's withdrawal.

The Commission is fully committed to accompanying Cyprus, Ireland and Malta in their efforts towards phasing out the temporary derogations provided for in Directive [XXX] and Regulation [XXX] within three years.

To that end, the Commission will, in accordance with Union law and in full respect of the distribution of competences between the Union and Member States in the area of medicines for human use, continuously follow developments in the concerned Member States and will closely accompany the competent authorities of Cyprus, Ireland and Malta in their efforts to decrease the dependency of their domestic markets on the supply with 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 it, on a regular basis, with information on these efforts.

Taking this information into account, the Commission will report in writing to the European Parliament and the Council within 18 months from the date of entry into force of Directive [XXX] and Regulation [XXX] on the progress accomplished in Cyprus, Ireland and Malta towards the complete phasing out of the derogations and the actions of the Commission to closely accompany the competent authorities of those Member States in that regard.

The Commission will remind the industrial operators concerned who still need to make changes to their supply chains that they urgently should make the necessary adaptations to ensure access to medicines in the smaller markets. In this context, the Commission will monitor the progress made by operators involved in the supply of medicines in these Member States regarding their ability to fulfil those requirements of Union law from which Directive [XXX] and Regulation [XXX] provide for temporary derogations.

In addition and beyond these immediate and necessary steps, as announced in the 'Pharmaceutical Strategy for Europe'[1], the Commission will make proposals by the end of 2022 to revise the pharmaceutical legislation of the Union. These proposals will seek to provide longer-term structural solutions, in particular, to the issue of access to medicines, with special attention to enhancing security of supply and addressing risks of shortages in the smaller markets of the Union.

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[1] Commission Communication 'Pharmaceutical Strategy for Europe', COM(2020) 761 final, 25.11.2020.