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## TEXTS ADOPTED

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### P9\_TA(2022)0117

#### **Investigational medicinal products made available in the UK with respect to Northern Ireland, Cyprus, Ireland and Malta \*\*\*I**

**European Parliament legislative resolution of 7 April 2022 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 (COM(2021)0998 – C9-0476/2021 – 2021/0432(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2021)0998),
  - having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0476/2021),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 24 February 2022<sup>1</sup>,
  - after consulting the Committee of the Regions,
  - having regard to the undertaking given by the Council representative by letter of 30 March 2022 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rules 59 and 163 of its Rules of Procedure,
1. Adopts its position at first reading hereinafter set out;
  2. Takes note of the statement by the Commission annexed to this resolution;

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<sup>1</sup> Not yet published in the Official Journal.

3. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

**P9\_TC1-COD(2021)0432**

**Position of the European Parliament adopted at first reading on 7 April 2022 with a view to the adoption of Regulation (EU) 2022/... 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 and in Cyprus, Ireland and Malta**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) 2022/641.)*

### **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 Regulation (EU) 2022/641<sup>1</sup> and Directive (EU) 2022/642<sup>2</sup> 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.

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<sup>1</sup> Regulation (EU) 2022/641 of the European Parliament and of the Council of 12 April 2022 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 and in Cyprus, Ireland and Malta (OJ L 118, 20.4.2022, p. 1).

<sup>2</sup> Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 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 and in Cyprus, Ireland and Malta (OJ L 118, 20.4.2022, p. 4).

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 Regulation (EU) 2022/641 and Directive (EU) 2022/642 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 Regulation (EU) 2022/641 and Directive (EU) 2022/642 provide for temporary derogations.

In addition and beyond these immediate and necessary steps, as announced in the “Pharmaceutical Strategy for Europe”<sup>1</sup>, 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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<sup>1</sup> Commission Communication “Pharmaceutical Strategy for Europe”, COM(2020)0761 final, 25.11.2020.