Council of the
European Union

Brussels, 28 April 2022
(OR. en)

8166/22
PV CONS 26

DRAFT MINUTES

COUNCIL OF THE EUROPEAN UNION
(General Affairs)

12 April 2022

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Non-legislative activities

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1. Adoption of the agenda

The Council adopted the agenda set out in 7958/22.

2. Approval of 'A' items 7959/22
(a) Non-legislative list

The Council adopted the "A" items listed in 7959/22 including COR and REV documents presented for adoption.

For the following items, the documents should read as follows:

Institutional affairs

Appointments

2.	Two members and five alternate members (PT) of the Committee of the Regions *Adoption* approved by Coreper, Part 2, on 6 April 2022	7618/22 **+ COR 1 (sv)** 7617/22 **+ COR 1 (sv)** CDR

Transport

13.	Council Decision on the signing, on behalf of the Union and its Member States, of the Accession Protocol of the Republic of Bulgaria, the Republic of Croatia and Romania to the Cooperation Agreement on a Civil Global Satellite Navigation System (GNSS) with the Republic of Korea (Irish-language version) *Adoption* approved by Coreper, Part 1, on 6 April 2022	C 7697/22 6756/19 **+ COR 2 (lv)** 6738/19 TRANS

(b) **Legislative list** (public deliberation in accordance with Article 16(8) of the Treaty on European Union) 7960/22

General Affairs

1. **Amended Regulation on increased pre-financing from REACT-EU resources** 7832/22
PE-CONS 14/22
COH
Adoption of the legislative act
Decision to derogate from the eight-week period provided for in Article 4 of Protocol 1 on the role of national parliaments in the EU
approved by Coreper, Part 1, on 8 April 2022

The Council approved the European Parliament's position at first reading and the proposed act was adopted, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Articles 175(3) and 177 TFEU).

The Council agreed to derogate from the eight- week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments.

2. **Directives 2001/20/EC and 2001/83/EC 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** 7829/22 + ADD 1
PE-CONS 6/22
UK
Adoption of the legislative act
approved by Coreper, Part 1, on 8 April 2022

The Council approved the European Parliament's position at first reading and the proposed act was adopted, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 114 TFEU).

A statement to this item is set out in the Annex.

3. Regulation (EU) No 536/2014 concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta
Adoption of the legislative act
approved by Coreper, Part 1, on 8 April 2022

7830/22 + ADD 1
PE-CONS 7/22
UK

The Council approved the European Parliament's position at first reading and the proposed act was adopted, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 114 and Article 168(4)(c)TFEU).

A statement to this item is set out in the Annex.

Economic and Financial Affairs

4. Digital finance – DLT Pilot Regime Regulation
Adoption of the legislative act
approved by Coreper, Part 2, on 6 April 2022

7351/22
PE-CONS 88/21
EF

The Council approved the European Parliament's position at first reading and the proposed act was adopted, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 114 TFEU).

Justice and Home Affairs

5. Regulation on e-CODEX system and amending Regulation (EU) 2018/1726
Adoption of the legislative act
approved by Coreper, Part 2, on 6 April 2022

7264/22
PE-CONS 87/21
EJUSTICE

The Council approved the European Parliament's position at first reading and the proposed act was adopted, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. In accordance with the relevant Protocols annexed to the Treaties, the Danish and Irish delegations did not participate in the vote (Legal basis: Articles 81(2) and 82(1) TFEU).

Non-legislative activities

3.	Annual rule of law dialogue: country-specific discussion *Exchange of views*	6705/22
4.	Conference on the Future of Europe *Information from the Presidency* *Exchange of views*	8049/22
5.	Any other business	

Statements to the legislative "A" items set out in doc. 7960/22

Ad "A" item 2: **Directives 2001/20/EC and 2001/83/EC 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**
Adoption of the legislative act

Ad "A" item 3: **Regulation (EU) No 536/2014 concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta**
Adoption of the legislative act

STATEMENT BY THE COMMISSION

"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.