

Brussels, 24 June 2022 (OR. en)

> 10278/22 PV CONS 41 SOC 388 EMPL 264 SAN 388 CONSOM 154

> > 1 **EN**

DRAFT MINUTES

COUNCIL OF THE EUROPEAN UNION (Employment, Social Policy, <u>Health</u> and Consumer Affairs)

14 June 2022

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1. Adoption of the agenda

The Council adopted the agenda set out in 9911/22.

Legislative deliberations

(Public deliberation in accordance with Article 16(8) of the Treaty on European Union)

2. Proposal for a Regulation on the European Health Data Space

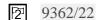
9461/1/22 REV 1 8751/22 + ADD 1

Exchange of views

<u>The Council</u> had an exchange of views on the proposal for a Regulation on the European Health Data Space.

Non-legislative activities

3. Review of the EU Global Health Strategy Exchange of views



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The Council had an exchange of views on the review of the EU Global Health Strategy.

Any other business

4. (a) Implementation of the regulations on medical devices

Information from the Commission on the state of play

9910/22

<u>The Council</u> took note of the information provided by the Commission on the state of play on the Medical Devices Regulation (MDR) and In-Vitro Devices Regulation (IVDR), as well as of comments by several delegations.

(b) Implementation of the Regulation on Health Technology Assessment (HTA) Information from the Commission on the state of play



<u>The Council</u> took note of the state of play on the implementation of the HTA Regulation, provided by the Commission.

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(c) Market entry in Europe for drugs: evidence gaps and potential solutions

9785/22

Information from the Austrian, Belgian, Irish, Luxembourg and Netherlands delegations

<u>The Council</u> took note of the information provided by AT, on behalf of BE, IE, LU and NL, on evidence gaps and potential solutions regarding market entry in Europe for drugs, as well as of the comments by the Commission.

(d) Current legislative proposals (Public deliberation in accordance with Article 16(8) of the Treaty on European Union)

Regulation on serious cross-border threats to health and repealing Decision No $1082/2013/\mathrm{EU}$

OC 12973/20 + ADD 1

Information from the Presidency

<u>The Council</u> took note of the information from the Presidency on this file and its intention, if possible, to reach agreement on it by the end of its Presidency.

(e) Increase in severe acute hepatitis cases of unknown aetiology in children and the monkeypox outbreak¹

Information from the Commission on the state of play

9857/22

(f) Medical evacuations and health support for Ukraine² Information from the Commission



<u>The Council</u> took note of the information provided by the Commission on the medical evacuations and health support for Ukraine, as well as of the comments by delegations.

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¹ In the presence of the EMA Executive Director and ECDC Director

² In the presence of the EMA Executive Director and ECDC Director

(g) Joint letter to the EC concerning revision of the provisions of the purchase agreements for vaccines, with regard to the surplus of vaccines

9865/22

Information from the Polish delegation, on behalf of the Bulgarian, Croatian, Estonian, Hungarian, Latvian, Lithuanian, Polish, Romanian, Slovak and Slovenian delegations

The Council took note of the information provided by PL, on behalf of BG, EE, HR, LT, LV, HU, PL, SI and SK, on a joint letter to the Commission concerning the revision of the provisions of the purchase agreements for vaccines, with regard to the surplus of vaccines, as well as of the comments by several delegations and the Commission.

(h) Work programme of the incoming Presidency *Information from the Czech delegation*

- First reading
- Public debate proposed by the Presidency (Article 8(2) of the Council's Rules of Procedure)
- Item based on a Commission proposal