



Council of the  
European Union

106077/EU XXVII. GP  
Eingelangt am 24/06/22

Brussels, 24 June 2022  
(OR. en)

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

## DRAFT MINUTES

COUNCIL OF THE EUROPEAN UNION  
(Employment, Social Policy, Health and Consumer Affairs)

14 June 2022

## CONTENTS

Page

1. Adoption of the agenda..... 3

### Legislative deliberations

2. Proposal for a Regulation on the European Health Data Space ..... 3

### Non-legislative activities

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

### Any other business

4. a) Implementation of the regulations on medical devices..... 3  
b) Implementation of the Regulation on Health Technology Assessment (HTA) ..... 3  
c) Market entry in Europe for drugs: evidence gaps and potential solutions ..... 4  
d) Current legislative proposals..... 4  
Regulation on serious cross-border threats to health and repealing Decision  
No 1082/2013/EU  
e) Increase in severe acute hepatitis cases of unknown aetiology in children and the  
monkeypox outbreak ..... 4  
f) Medical evacuations and health support for Ukraine..... 4  
g) Joint letter to the EC concerning revision of the provisions of the purchase  
agreements for vaccines, with regard to the surplus of vaccines ..... 5  
h) Work programme of the incoming Presidency ..... 5

\*\*\*

## 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*

The Council 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



9362/22

*Exchange of views*

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



9910/22

*Information from the Commission on the state of play*

The Council 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)



9909/22


*Information from the Commission on the state of play*

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

- (c) **Market entry in Europe for drugs: evidence gaps and potential solutions**  9785/22  
*Information from the Austrian, Belgian, Irish, Luxembourg and Netherlands delegations*

The Council 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/EU**   12973/20 + ADD 1  
*Information from the Presidency*

The Council 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 outbreak<sup>1</sup> 9857/22  
*Information from the Commission on the state of play*

- (f) **Medical evacuations and health support for Ukraine**<sup>2</sup>  9951/22  
*Information from the Commission*

The Council 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.

---

<sup>1</sup> In the presence of the EMA Executive Director and ECDC Director

<sup>2</sup> 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