



Council of the
European Union

Brussels, 13 December 2023
(OR. en)

16277/23
PV CONS 62
SOC 843
EMPL 606
SAN 718
CONSOM 456

DRAFT MINUTES

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

30 November 2023

1. Adoption of the agenda

The Council adopted the agenda set out in document 15801/23.

2. Approval of "A" items

Non-legislative list

16031/23

The Council adopted all "A" items listed in the document above, including all linguistic COR and REV documents presented for adoption.

Non-legislative activities

3. Open Strategic Autonomy from a health perspective¹

 15064/23

Exchange of views

The Council held an exchange of views on the topic of Open Strategic Autonomy from a health perspective.

4. Conclusions on Mental Health

 15053/23 + ADD 1

Approval

The Council approved conclusions on mental health as set out in the document above.

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

Any other business

5. a) Current legislative proposals

 

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

i) Regulation on fees and charges payable to EMA

16070/22 + COR 1
ADD 1-7

ii) Regulation on the European Health Data Space

8751/22 + ADD 1

iii) Regulation on standards of quality and safety for substances of human origin intended for human application

11396/22

¹ In the presence of the Executive Director of EMA.

iv) Revision of the pharmaceutical package:

- **Directive on the Union code relating to medicinal products for human use** 8759/23 + ADD 1
- **Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency** 8758/23 + ADD 1

Information from the Presidency

The Council took note of the information provided by the Presidency on the current legislative proposals, as well as of the comments from the Commission and the Austrian, Danish, French, German, Irish, Italian and Slovenian delegations.

b) Health and Climate change

 15377/2/23 REV 2

Information from the Maltese delegation, on behalf of the Austrian, Belgian, Croatian, Cyprus, Czech, Danish, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Luxembourg, Maltese, Netherlands, Portuguese, Romanian, Slovak and Slovenian delegations

The Council took note of the information provided by the Maltese delegation on health and climate change, as well as of the comments from the Commission and the Cyprus, Hungarian, Latvian, Portuguese, Netherlands and Slovenian delegations.

c) Collaboration and exchange on Long COVID

 15513/1/23 REV 1

Information from the German and Netherlands delegations, supported by the Austrian, Cyprus, Czech, Finnish, French, Luxembourg, Maltese and Portuguese delegations

The Council took note of the information provided by the German and Netherlands delegations on long COVID, as well as of the comments from the Commission and the Slovenian delegation.

d) Implementation of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR)

 15385/2/23 REV 2

Information from the French delegation, supported by the Austrian, Belgian, Czech, Finnish, German, Irish, Italian, Luxembourg and Netherlands delegations

The Council took note of the information provided by the French delegation on the implementation of the MDR and IVDR as well as of the comments by the Commission and the Belgian, German, Hungarian, Irish, Italian, Maltese, Polish, Portuguese and Slovenian delegations.

e) 1+Million Genomes (1+MG) Initiative and the implementation of the 1+MG Roadmap 2023-2027 – state of play

 15274/23

Information from the Estonian delegation, supported by the Finnish delegation

The Council took note of the information provided by the Estonian delegation on the 1+Million Genomes Initiative and the implementation of the 1+MG Roadmap 2023-2027 as well as of the comments from the Commission and the Estonian and Slovenian delegations.

f) Common approach and organization of medical evacuations of wounded citizens from Gaza

 15423/2/23 REV 2

Information from the Belgian delegation, supported by the French, Irish, Italian, Luxembourg, Maltese, Netherlands and Portuguese delegations

The Council took note of the information provided by the Belgian delegation on the humanitarian situation in Gaza and the comments from the Commission and the Cyprus, German, Greek, Irish, Netherlands, Polish, Portuguese and Slovenian delegations.

g) Presidency conferences

 15351/23

Information from the Presidency

The Presidency informed the Council of the conferences organised during the second semester of 2023.

- h) Negotiations for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005)

15370/23

Information from the Presidency and the Commission

- i) Work programme of the incoming Presidency

Information from the Belgian 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

Statement to the legislative "B" item set out in doc. 15801/23

Ad "B" item 4: **Conclusions on Mental Health**
 Approval

STATEMENT BY HUNGARY

“Hungary recognises and promotes equality between men and women in accordance with the Fundamental Law of Hungary and the primary law, principles and values of the European Union, as well as commitments and principles stemming from international law. Equality between women and men is enshrined in the Treaties of the European Union as a fundamental value. In line with these and its national legislation, Hungary interprets the term ‘gender’ as a reference to sex and the concept of ‘gender equality’ as reference to ‘providing equal rights and opportunities to women and men’ in the draft Council conclusions on mental health.

Hungary declares that the Commission’s communication on ‘Union of Equality: LGBTIQ Equality Strategy 2020-2025’, mentioned in footnote of the draft Council conclusions on mental health, should be interpreted with due regard to national competences and the specific circumstances in each Member State.”
