



Council of the
European Union

164362/EU XXVII. GP
Eingelangt am 29/11/23

Brussels, 29 November 2023
(OR. en)

15801/23
OJ CONS 63
SOC 816
EMPL 586
SAN 686
CONSOM 418

PROVISIONAL AGENDA

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

Europa building, Brussels

30 November 2023 (10:00)

Format: 2+2 (+2 in listening room)

1. Adoption of the agenda
2. Approval of "A" items

Non-legislative list

16031/23

Non-legislative activities

3. Open Strategic Autonomy from a health perspective¹
Exchange of views

 15064/23

4. Conclusions on Mental Health
Approval

 15053/23 + ADD 1

¹ In the presence of the Executive Director of EMA.

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
- 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*
- 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
- 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
- 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

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| e) | 1+Million Genomes (1+MG) Initiative and the implementation of the 1+MG Roadmap 2023-2027 – state of play
<i>Information from the Estonian delegation, supported by the Finnish delegation</i> | <div style="border: 1px solid black; padding: 2px; display: inline-block;">2¹</div> <div style="background-color: #f0f0f0; padding: 2px; display: inline-block;">15274/23</div> |
| f) | Common approach and organization of medical evacuations of wounded citizens from Gaza
<i>Information from the Belgian delegation, supported by the French, Irish, Italian, Luxembourg, Maltese, Netherlands and Portuguese delegations</i> | <div style="border: 1px solid black; padding: 2px; display: inline-block;">2¹</div> <div style="background-color: #f0f0f0; padding: 2px; display: inline-block;">15423/2/23 REV 2</div> |
| g) | Presidency conferences
<i>Information from the Presidency</i> | <div style="border: 1px solid black; padding: 2px; display: inline-block;">2¹</div> <div style="background-color: #f0f0f0; padding: 2px; display: inline-block;">15351/23</div> |
| h) | Negotiations for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005)
<i>Information from the Presidency and the Commission</i> | <div style="background-color: #f0f0f0; padding: 2px; display: inline-block;">15370/23</div> |
| i) | Work programme of the incoming Presidency
<i>Information from the Belgian delegation</i> | |

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| <div style="border: 1px solid black; padding: 2px; display: inline-block;">1</div> | First reading |
| <div style="border: 1px solid black; padding: 2px; display: inline-block;">2¹</div> | Public debate proposed by the Presidency (Article 8(2) of the Council's Rules of Procedure) |
| <div style="border: 1px solid black; padding: 2px; display: inline-block;">C</div> | Item based on a Commission proposal |
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