

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 ☐ 15064/23
Exchange of views
4. Conclusions on Mental Health ☐ 15053/23 + ADD 1
Approval

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 11396/22
substances of human origin intended for human
application
- iv) Revision of the pharmaceutical package:
- Directive on the Union code relating to 8759/23 + ADD 1
medicinal products for human use
 - Regulation laying down Union procedures for 8758/23 + ADD 1
the authorisation and supervision of medicinal
products for human use and establishing rules
governing the European Medicines Agency
- 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)  15385/2/23 REV 2
and the In Vitro Diagnostic Medical Device Regulation
(IVDR)
*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> | [2] 15274/23 |
| 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> | [2] 15423/2/23 REV 2 |
| g) | Presidency conferences
<i>Information from the Presidency</i> | [2] 15351/23 |
| 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> | 15370/23 |
| i) | Work programme of the incoming Presidency
<i>Information from the Belgian delegation</i> | |

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