



Brussels, 15 November 2023

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NOTICE OF MEETING AND 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)


Adoption of the agenda

(poss.) Approval of "A" items


- a) Non-legislative list
- b) Legislative list (Public deliberation in accordance with Article 16(8) of the Treaty on European Union)

Non-legislative activities

Open Strategic Autonomy from a health perspective
Exchange of views

 15064/23

Conclusions on Mental Health
Approval

 15053/23 + ADD 1

Any other business

- a) Current legislative proposals (Public deliberation in accordance with Article 16(8) of the Treaty on European Union) OC
- 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) 1+Million Genomes (1+MG) Initiative and the implementation of the 1+MG Roadmap 2023-2027 – state of play 21 15274/23
Information from the Estonian delegation, supported by the Finnish delegation
- c) Implementation of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) 21 15385/23
Information from the French delegation, supported by the Belgian, German, Irish and Italian delegations
- d) Presidency conferences 21
Information from the Presidency

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

Information from the Presidency and the Commission

f) 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

NB: Please send a list of your delegates to this meeting as soon as possible to the email address access.general@consilium.europa.eu