



Council of the European Union
General Secretariat

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Eingelangt am 25/01/24

Brussels, 25 January 2024

CM 1256/24

SAN
PHARM

COMMUNICATION

NOTICE OF MEETING AND PROVISIONAL AGENDA

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Subject: Att. Working Party on Pharmaceuticals and Medical Devices

Date: 30 January 2024

Time: 10:00

Venue: COUNCIL

LEX BUILDING

Rue de la Loi 145, 1048 BRUSSELS

Format 2+2

1. Revision of the pharmaceutical package:

- Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC
8759/23 + ADD 1-7

- Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006
 - 8758/23 + ADD 1-2
 - *Examination of the proposals*
- 2. Proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices
 - *Presentation by the Commission*
 - *Examination of the proposal*
 - 5712/24
- 3. Any Other Business
 - Information point by DG HERA

N.B. Delegations are informed that there is no interpretation available for this session.