



Council of the European Union
General Secretariat

Brussels, 5 December 2023

CM 5645/23

**SAN
PHARM**

COMMUNICATION

NOTICE OF MEETING AND PROVISIONAL AGENDA

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Subject: Working Party on Pharmaceuticals and Medical Devices

Date: 11 December 2023

Time: 14:30

Venue: COUNCIL

JUSTUS LIPSIUS BUILDING

Rue de la Loi 175, 1048 BRUSSELS

Format 1+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
 - *Continued presentation by the Commission of the impact assessment*
 - *Exchange of views*

2. Opinion of the European and Social Committee (EESC) on the revision of the pharmaceutical package
 - 14863/23
 - *Presentation by the EESC¹*
 3. Any Other Business
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¹ In the presence of an EESC representative