



Council of the European Union
General Secretariat

Brussels, 6 July 2026

CM 3481/26

SAN
PHARM

COMMUNICATION

NOTICE OF MEETING AND PROVISIONAL AGENDA

Contact: LIFE.Health@consilium.europa.eu

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Subject: Working Party on Pharmaceuticals and Medical Devices

Date: 15 and 16 July 2026

Time: 10:00, 10:00

Venue: COUNCIL

LEX BUILDING

Rue de la Loi 145, 1048 BRUSSELS

Format 2+2

1. Regulation to simplify rules on medical and in vitro diagnostic devices – cluster 3 and 4
 - *Exchange of views*

= *Block 1 - Classification of Devices, Notified Bodies and conformity Assessment (excluding elements relating to sampling and certificate validity)*
= 11243/26 (document to be distributed)

= *Block 2 - Clinical evidence, clinical evaluation, clinical investigations, non-clinical data, -clinical data, SS(C)P, PMCF, combined studies and technical documentation*
= 11244/26 (document to be distributed)

= *(poss.) Block 3 - Notified Bodies / Conformity Assessment (elements relating to sampling / certificate validity)*
= 11546/26 (document to be distributed)

= (poss.) Block 4 - PMS, PSUR, vigilance reporting, reporting of actively exploited vulnerabilities and severe cybersecurity incidents, analysis of vigilance reports, trend reporting
= 11549/26 (document to be distributed)

2. Any other business
