



Council of the European Union
General Secretariat

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CM 3836/26

SAN
PHARM

COMMUNICATION

NOTICE OF MEETING AND PROVISIONAL AGENDA

Contact:	LIFE.Health@consilium.europa.eu
Tel./Fax:	+32 2 281 3577
Subject:	Working Party on Pharmaceuticals and Medical Devices
Date:	10 and 11 September 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
 - *Exchange of views on the first Presidency compromise text*
 - = *Qualification, classification and market surveillance*
 - = 12272/26 (document to be distributed)
 - = *Cluster 6 - Interplay with AI Act, dedicated IVD-specific discussion and transitional provisions for orphan devices*
 - = 12273/26 (document to be distributed)
 - *Exchange of views on the second Presidency compromise text*
 - = *Part 1 - Clusters 1, 3 and 4*
 - = 12287/26 (document to be distributed)
 2. Any other business
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