



Council of the European Union
General Secretariat

Brussels, 8 September 2026

CM 3836/1/26

REV 1

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: 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
 - = *Cluster 6 - Interplay with AI Act, dedicated IVD-specific discussion and transitional provisions for orphan devices*
 - = 12273/26
 - = WK 13494/26
- *Exchange of views on the second Presidency compromise text*
 - = *Part 1 - Clusters 1, 3 and 4*
 - = 12287/26

2. Any other business
