



Brussels, 6 July 2026

CM 3481/26

SAN  
PHARM

## COMMUNICATION

### **NOTICE OF MEETING AND PROVISIONAL AGENDA**

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Contact:	LIFE.Health@consilium.europa.eu
Tel./Fax:	+32 2 281 3577
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

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### **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

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