



Council of the European Union  
General Secretariat

Brussels, 15 September 2025

CM 4088/25

SAN  
PHARM

### COMMUNICATION

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

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|-----------|------------------------------------------------------------------------|
| Contact:  | LIFE.Health@consilium.europa.eu                                        |
| Tel./Fax: | +32 2 281 3515                                                         |
| Subject:  | Working Party on Pharmaceuticals and Medical Devices (morning only)    |
| Date:     | 22 September 2025                                                      |
| Time:     | 10:00                                                                  |
| Venue:    | COUNCIL<br>JUSTUS LIPSIUS BUILDING<br>Rue de la Loi 175, 1048 BRUSSELS |

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#### **Format 1+2**

1. Pharmaceutical package:
  - a) Directive on the Union code relating to medicinal products for human use
  - b) Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency
    - *Update by the Presidency on the on-going negotiations*
    - 12808/25 (doc to be distributed)
    - 12804/25 (doc to be distributed)
2. Any other business