



Council of the European Union
General Secretariat

Brussels, 1 September 2026

CM 3973/26

SAN
PHARM

COMMUNICATION

NOTICE OF MEETING AND PROVISIONAL AGENDA

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Subject: Working Party on Pharmaceuticals and Medical Devices

Date: 16 and 17 September 2026

Time: 10:00, 10:00

Venue: COUNCIL

LEX BUILDING

Rue de la Loi 145, 1048 BRUSSELS

Format 2+2

1. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)
 - *Exchange of views on the first presidency compromise text on Clinical Trials*
 - *ST 12598/26 (to be issued)*

 - *Exchange of views on Chapter 7 - Regulatory Sandboxes*
 - *ST 16945/25*
2. Any Other Business