



Council of the European Union
General Secretariat

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CM 3973/1/26
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:	16 and 17 September 2026
Time:	10:00, 09:30
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