Council of the European Union
General Secretariat

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CM 4917/26

SAN
PHARM

COMMUNICATION

NOTICE OF MEETING AND PROVISIONAL AGENDA

Contact:	LIFE.Health@consilium.europa.eu
Tel./Fax:	+32 2 281 3515
Subject:	Working Party on Pharmaceuticals and Medical Devices
Date:	17 and 18 November 2026
Time:	10:00, 10:00
Venue:	COUNCIL JUSTUS LIPSIUS BUILDING Rue de la Loi 175, 1048 BRUSSELS

Format 1+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 fourth Presidency compromise text on Chapter 9 Article 58 (Clinical Trials).*
   - *ST 15678/26 (to be issued)*

   - *Exchange of views on the second Presidency compromise text on Chapter 9 Article 57 (ATMPs).*
   - *ST 15676/26 (to be issued)*

   - *Exchange of views on the third Presidency compromise text on Chapters 2, 5 and 6.*
   - *ST 15677/26 (to be issued)*

2. Any Other Business