Council of the European Union
General Secretariat

PUBLIC

Interinstitutional files:
2023/0131 (COD)
2023/0132 (COD)

Brussels, 30 April 2025

WK 5522/2025 INIT

LIMITE

SAN **VETER**
PHARM **ENV**
MI **RECH**
COMPET **CODEC**
PI

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Pharmaceutical package
Subject:	Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency

Delegations will find attached the Presidency flash for the meeting of the Working Party on Pharmaceuticals and Medical Devices on 5 - 6 May 2025. The draft agenda is set out in CM 2585/25.

PUBLIC

FLASH

MEETING OF THE

WORKING PARTY ON PHARMACEUTICALS AND MEDICAL DEVICES

5-6TH MAY 2025

INTRODUCTION

The Polish Presidency is delighted to invite you to the meeting of the Working Party on Pharmaceuticals and Medical Devices.

Please find below a note on the aim of the meeting and the agenda.

AIM OF THE MEETING

The subject of the proceedings will be the revision of Pharmaceutical Package, as laid out in full texts of:

1) the draft Directive (ST 8311/25; please keep in mind that Annex II is to be updated by the Commission as stated in recital 148 by a delegated act - via the basis of Article 213 D);

2) the draft Regulation (ST 8470/25);

We will begin the proceedings with discussing the part of the incentives cluster that was excluded from scope of the discussion in the previous meeting, namely Articles 80-82, 56a, 166.5, 216, 219 and 206.2 of the Directive, and Article 5.1a of the Regulation and point 8a of Annex II to the Regulation.