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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 8 April 2025. The draft agenda is set out in CM 2231/25.

FLASH

MEETING OF THE

WORKING PARTY ON PHARMACEUTICALS AND MEDICAL DEVICES

8TH APRIL 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 and the presentation of the Critical Medicines Act. We will begin with the Pharmaceutical Package and the presentation of the Presidency's final compromise text of ***reading package 7: manufacturing and import***, as set out in document st 7585/25.

The main changes introduced by the Presidency concern:

1) introducing the definition of manufacturing to Article 4, along with moving the definitions of decentralised manufacturing and manufacturing of active substances to Article 4;
2) modifying the terminology in Article 26a to accommodate MSs remarks. It has also been enhanced with regard to cooperation of the relevant authorities, and the inclusion of the manufacturing and import authorisation (MIA) for the central site in the marketing authorisation (MA) application (although obvious anyway). An implementing act has been introduced instead of EMA's guidelines to safeguard the functioning of the procedure;
3) redrafting Article 148 paragraph 2 to indicate that the registration can be refused.

4) amending Article 151 to limit, in a flexible way, the number of decentralised sites per one qualified person (QP);

5) redrafting Article 162.2a to be both more flexible and provide better guarantees in terms of safety profile of medicinal products subject to parallel trade;

6) in Article 188 paragraph 3, responding to the concerns of Member States on the available resources, we introduced the change specifying that the competent authority of the Member State should take necessary action based on the risk assessment.

7) modifying the provisions on joint inspections, to make the role of the Agency only subsidiary and based on MSs requests. We clarified that the involvement of the Agency should be considered as an action of last resort;

8) in Article 193 we explicitly specified that the Member States shall ensure that the examination of the samples referred to in paragraph 1 is completed within 30 days of the receipt both of the samples and documentation of the controls carried out by the marketing authorisation holder in accordance with Article 191. Still this period of time shall be extended to 60 days if necessary to complete the examination. We introduced similar wording concerning the samples for medicinal products derived from human blood or human plasma in paragraph 2.

We believe those changes should alleviate Member States' concerns expressed so far.

Please note that in the working party we will focus on the introduced changes only. We also put your attention to the published overview of regulatory approval process prepared by Commission (WK 4351 2025).



Reading package 7 relevant provisions:

I. Relevant provisions of the **directive** on:

1) **manufacturing and import**: art. 142-161 and Annex III: C*onditions for qualification of a qualified person*;

2) **wholesale and distribution**: art. 162-174;

3) **supervision and controls** art. 188-194;

II. relevant provisions of the **regulation** on inspections: art. 52-54 and Annex III: Procedure and criteria governing inspections carried out by the Agency.

In the afternoon, we will move to the Commission presentation on the Critical Medicines Act (**ST 6872/25)**.