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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 21 October 2024. The draft agenda is set out in CM 4552/24.

FLASH

WORKING PARTY ON PHARMACEUTICALS AND MEDICAL DEVICES

OCTOBER 21, 2024

INTRODUCTION

The Hungarian Presidency invites you to 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

We will examine a new compromise text (**ST13935/24**) related to the **Incentives cluster** in the order as set out in the list at the bottom of this document.

In addition, as time allows, you will be given the opportunity to raise further concerns, if necessary, regarding those articles in the cluster where there have been no changes from the previous compromise text.

The examination is planned to focus on the most important changes to the previous Presidency compromise and is related to the following topics indicated in the order of discussion:

- regulatory data protection (D80-81): where the Presidency proposes to:
 - (D80) **remove the provisions for including RDP information from national authorisations in the central registry**, as this seems to impose a disproportionate complexity given the low volume of such authorisations. In order to have a full picture of this matter, Member States are invited to provide information on the number of medicines with regulatory data protection they have authorised annually over the past 5 years (this information can be flagged in the template at Art 80).
 - (D81) (1) **specify the EU research incentive** as the conduct of multi-national (in at least 2 Member States) registration trials evaluating efficacy and used for the marketing authorisation application ('pivotal' registration trials) and (2) add a **new incentive for early marketing authorisation application in the EU**.

- medicinal products addressing an unmet medical need (D83): where a **new, efficacy and safety driven** approach was included to **define UMN**.
- market launch and continuous supply in a Member State (D56a and D219): where changes were introduced to (1) allow the **assessment of applications for generic or biosimilar** medicinal product already **after year 6 of the data protection period** of the reference medicinal product concerned in Art 56a, (2) to allow **early implementation of Art 56a** after the Directive enters into force.
- Bolar exemptions (D85): where we will have a discussion regarding the **scope of Bolar exemptions**.
- transferable exclusivity voucher (R40 and R41 (“blockbuster clause”)): where the Presidency proposed
 - o R40: (1) a new, additional requirement for **early regulatory submission at EMA**, (2) the possibility of an **early inclusion** of the priority antimicrobial on the **Union list of critical medicines**,
 - o R41: a more detailed mechanism to the **application of the blockbuster clause** (use following a transfer is restricted to take place in year 6 of the RDP, following an assessment (validated by an independent audit) by the marketing authorisation holder of the sales data of the secondary medicine in the preceding years.)
- adapted frameworks (D28): where the text was updated regarding **Commission empowerment**.

Thank you for sharing your views and positions in advance regarding these or other provisions in this latest Presidency compromise proposal.

DEADLINE FOR WRITTEN COMMENTS

25 October using the template provided by the Secretariat.