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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 09 December 2024. The draft CM is set out in CM 5245/24.

FLASH

WORKING PARTY ON PHARMACEUTICALS AND MEDICAL DEVICES

DECEMBER 9, 2024

INTRODUCTION

The Hungarian Presidency invites you to the last Working Party on Pharmaceuticals and Medical Devices in 2024.

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

AIM OF THE MEETING

We will discuss the new revised text on the **on the Shortages cluster** set out in document **15067/24** and the **Incentives cluster** set out in document **15044/24.**

The discussion will be held in the following order:

Shortages cluster

1) R116.3., R117, R120, R126, R134 (shortages articles)
2) Rest of the articles

Incentives cluster

3) NEW: Reg 5 and Annex II (obligation to supply in all MS and Union sanctions)
4) Dir. 56a.,166., 216., 219., Dir. 206. (equal access)
5) Dir. 80-83 (regulatory data and market protection, unmet medical need)
6) Dir. 85., Recitals 63-65 (Bolar exemption)
7) D4.1 (52)‘entity not engaged in an economic activity’
8) Reg. 40-42., 170(6) (transferable data exclusivity voucher)
9) Rest of the articles.

Since no written comment is expected following the working party meeting, we ask you to focus on critical elements during the discussion.

In this flash, we highlight the most important changes we made to the latest version of the text:

In the shortages cluster, In Article 116 (3) we included the case when MAHs intend to withdraw a marketing authorisation or permanently cease to market a critical medicine in some of the Member States where the marketing authorisation is valid. In such case, the MAH can either offer the transfer of MA or can offer the issuance of an access letter for marketing authorisation based on consent under Article D 14. The latter is particularly relevant in case of permanent cessation of the marketing of a centrally authorise medicinal product. We clarified in recital 138, that contractual arrangements on wholesale distribution of medicinal products authorised upon a letter of access may for example preclude the distribution of such medicinal products where the reference medicinal product remains marketed.

In Article 126 (2a) we kept the delegated act to identify medicinal products under SPP, because it requires less framing compared to an implementing act. However some framing was still necessary, therefore we included some conditions.

In Article 134 (2) for legal clarity we further framed the conditions for **Commission empowerment to adopt implementing acts** to improve the supply of critical medicines by ensuring the smooth functioning of the internal market.

Regarding the incentives cluster, the starting point for the Presidency has been that Member States assess the provisions for modulation and market access together as elements in a single package. Accordingly, in its 6th PRES revised text, HUPRES proposes a meaningful and predictable modulation system and strong obligations to support market launch and supply in each Member State.

Therefore as a response to call from several Member States at the EPSCO meeting, we introduced in the Regulation an obligation and a penalty condition (R5 and Annex II) for MAHs to **make the medicinal product available in all Member States to meet their medical needs**. This obligation applies to centrally authorised medicinal products that are potentially in a monopolistic situation due to regulatory data protection, patent, supplementary protection certificate or market exclusivity. In case at least two Member States inform the Commission that MAH does not comply with the obligation the Commission may impose **Union penalties**.

This new obligation can be used complementarily to Article D56a with all the consequences (in case of non-compliance with D56a, non-application of 2 years of market protection, naming and shaming and national penalty).

Articles D56a and Article D219 were updated in relation to circumstances outside the control of the marketing authorisation holder (D56a.1.and 5), P&R applications (D56a.2), coordination in the Pharma Committee (D56.8) and the transposition of

marketing authorisations in accordance with both the Regulation 726/2004 or the Directive 2001/83 (D219.1). For legal reasons we needed to better delineate between Article D56 (continuous supply) and D56a ("initial" supply within the period set in D56a.5.). D56 is about the continuous supply after market launch, while D56a focusses on the market launch and first 4 years to make sure that supply starts in every Member State that requested the medicine to cover the needs of its patients.

We clarified that the 12 months of RDP can be granted to UMN products independently of whether they have authorised alternative or not (D83.1(a) and 1(b)). However, in case of UMN products with an authorised alternative (D83.1(b)) the 12 months RDP prolongation will be granted only if a comparative clinical trial was conducted to prove improved efficacy or safety.

We also differentiated between the use of the **UMN concept (D83) for the incentives (D81)** and for granting a **conditional marketing authorisation (R19).** An initial conditional marketing authorisation (CMA) can be granted, with less comprehensive data, if one of the UMN conditions (D83.1(a) or 1(b)) is met. On the other hand, with the amendment of Article D81 third subparagraph, we make it clear that in case of a CMA for UMN medicines with authorised alternatives (D83.1(b)) the 12 months RDP prolongation can be granted only if comparative clinical trial was also conducted to prove improved efficacy or safety. Why is this important? To understand this we need to take into account, that under Article R19 a CMA can be granted with lower evidence requirements. In reality, it is possible to convert CMA into standard authorisation without comparative clinical trials even if the likelihood of the existence of the UNM was based on improved efficacy or safety (see 83 (1) b)). Without proposed change to Art 81 (1) third subpara, the 12 month RDP extension would be granted also in such cases. With the changes however we create level playing field between medicines having a standard or a standard-after-CMA authorisation. The paragraph remains unchanged regarding UMN medicines which do not have an authorised alternative (D83.1a), in their case comparative trials are not expected.

Regarding **Bolar exemption (D85),** we further clarified to be more comprehensive, and to avoid potential breaches of IP rights in the framework of tenders.

DEADLINE FOR WRITTEN COMMENTS

No written comments are expected following this meeting.