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**MEETING DOCUMENT**

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

Delegations will find attached the Presidency flash for the meeting of the Working Party on Pharmaceuticals and Medical Devices on 12 November 2024. The draft CM is set out in CM 4890/24.

# FLASH

**WORKING PARTY ON PHARMACEUTICALS AND MEDICAL DEVICES**

**NOVEMBER 12, 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 discuss the new compromise proposal on the **Security of supply** cluster following the order set out in document **15067/24.** (Reg. Rec. 136-139., Art. 16.4., 24., 115a.-117., Annex IV., 118., 2. def. (14), 119-121., 2. def. (15), 122-123., 2. def. (16)., 124-127., 2. def. (13)., 128-134., 171-172., Annex II, Dir. Art. 56.3., 162., 166-167., 203.).

Due to the complexity of the chapter and taking into account that these articles will be discussed for the first time during the Hungarian Presidency, we would like to highlight the following changes:

***Derogations from the provisions of this chapter - Article 115a*** –: the amendments aim to link the exceptions to the medicinal product rather than to the marketing authorisation holder; otherwise, the marketing authorisation holder would enjoy broader exceptions just because, among others, it deals with medicinal products deserving exceptional treatment.

***The shortage prevention plan - Article 117, 119(1) (-a), 123(4a), 126(2a), 127 (1), Annex IV*** – As you remember this part of the text divides most Member States. The original proposal would introduce SPP for all medicinal products; some Member States would prefer to restrict SPP to medicines listed on the Union list of critical medicinal products, while others would like to allow Member States to request SPP for any other medicinal products. The Presidency is trying to find a compromise, but for that, flexibility from all sides is needed. Our aim is to establish a middle ground in the scope of SPP, while avoiding fragmented national approaches that would counter the very objective of the chapter, which is to improve the security of supply.

According to Art 117, SPP would apply to medicines identified as critical by the competent authorities of the Member States, using the common EU methodology. The list shall be adopted by the Commission via implementing acts (Art 127 (1)). Please note that this category is broader than the *Union* list of critical medicines, which is a result of further filtering after critical medicines are identified by the Member States as mentioned above.

To provide further flexibility without causing fragmentation, under Article 123(4a) the MSSG will be invited to propose additional medicines (in addition those identified by Art 127 (1)) for which SPP is considered necessary. On the basis of these recommendations, the Commission can supplement the regulation with other medicinal products via a delegated act, as set out in Article 126 (2a). *Why a delegated act?* While critical medicines, identified by the common methodology, are automatically under the SPP scope (therefore requiring implementing acts for uniform application of the common methodology), the MSSG recommendations represent an *ad hoc* extension of the scope, and in this way, we are talking about supplementing the regulation, in which case delegated acts are the right choice.

For the rest of the medicinal products where no SPP is needed, Article 119 (3a) stipulates that the marketing authorisation holder must conduct regular and documented risk assessments of potential supply chain risks.

We agree that this is a rather complex approach, but we see no other way to create middle ground on the SPP scope without causing fragmented national approaches.

***List of critical shortages of medicinal products of Union concern - Article 123 (1)-(2a)*** – This list exists in the original proposal; however since the inclusion of a medicinal product in the list triggers legal obligations, the only way to adopt it is via implementing acts. Therefore, on the basis of monitoring under Art 118 (1) and following the consultations under Art 121(1) c), the MSSG is invited to recommend which medicinal products shall be included in the list of critical shortages, and the Commission will adopt an implementing act.

We have, therefore, altogether three special scopes of medicines:

***(1)*** ***"SPP obliged" products*** - identified on one side by implementing act based on Member State inputs (using the common methodology) in accordance with Article 127 (1) second subparagraph, and, on the other side, by delegated acts based on MSSG inputs (independent from common methodology) in accordance with Article 126 (2a)

*Main consequence:* the marketing authorisation holder must prepare an SPP and these products are covered by the obligation to try to transfer the marketing authorisation under Article 116 (3a)

***(2)*** ***Union list of critical medicinal products*** – adopted by implementing acts in accordance with Article 131 (3) based on Member State input using the common methodology with further filtering by MSSG.

*Main consequence:* for these "union listed" medicines, the Agency can request further information and MSSG may provide recommendations on diversification of suppliers, and inventory management and regulatory flexibilities.

***(3)*** **List of critical shortages of medicinal products of Union concern –** based on shortage monitoring by the competent authority or the Agency, adopted via implementing acts under Article 123 (2a)

*Main consequence:* reinforced monitoring by Member States and recommendations by the MSSG under Articles 124 and 125.

**Notification requirement in case of parallel export – Article 120 paragraph (1a)** – This article should not apply to exports to third countries. *Why?* Because this Article requires Member States to justify the introduction of notification as it is necessary to strengthen compliance with internal market rules. This constraint does not exist *vis-a-vis* third countries; therefore, we do not see the need to restrict the room for manoeuvre of Member States and the references to third countries are deleted. On the other hand, we have strengthened compliance with internal market rules in such a way that, under the second subparagraph, Member States will have to notify the introduction of notification requirements. This *is ex post* notification, given the fact that sometimes those measures are taken in urgency. Any measures taken afterward (such as export restrictions) fall under the TRIS notification in accordance with Directive 2015/1535. In this regard, we propose no changes; however, we propose to introduce an obligation to inform the Agency as well.

**Commission power to adopt implementing act under Article 134** – In paragraph 2 there are two elements that would justify the adoption of implementing acts:

(1) to provide for uniform application and temporary criteria for national measures aiming at improving the security of supply
(2) or to impose Union-level contingency stock requirements of active pharmaceutical ingredients or finished dosage forms, or other relevant measures required to improve security of supply on marketing authorisation holders, wholesale distributors, or other relevant entities

The first possibility is, *stricto sensu*, meant for aligning potential national measures to ensure the smooth functioning of the market. The second, however, gives more power to Commission to regulate the internal market regardless of whether national measure have already been taken. Regarding this second option, the opinion of the Council Legal Service will further guide the discussion, but we obviously like to hear your views.

Dear Colleagues, we tried to give you a map to navigate this very complex chapter, and we request your pragmatic approach to reach a workable compromise and make a progress in the dossier.

## DEADLINE FOR WRITTEN COMMENTS

19 November using the templates provided by the Secretariat.