Council of the European Union
General Secretariat

PUBLIC

Brussels, 26 April 2025

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

WK 5152/2025 REV 1

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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 enclosed the revised Presidency flash for the meeting of the Working Party on Pharmaceuticals and Medical Devices on 28 April 2025. The draft agenda is set out in CM 2336/25.

Changes are highlighted in yellow.

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FLASH

MEETING OF THE

WORKING PARTY ON PHARMACEUTICALS AND MEDICAL DEVICES

28TH 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 main subject of the proceedings will be the revision of Pharmaceutical Package, however, we shall begin the session with inviting the delegations of the Member States to **express their preference for four civil society representatives of the European Medicines Agency Management Board** (CVs of the candidates have been circulated on 1/04/25). Their preferences for the four civil society representatives will then be approved/adopted by Coreper and Council as non- discussion item.

Next, we shall move to discussing the provisions contained in ***reading package 4 (security of supply).*** We shall also include in the discussion art. 162.2a of the Directive concerning parallel trade conditions as presented below.

Following that, we shall proceed with ***reading package 2 (regulatory protection, innovation, UMN)*** **– excluding the provisions concerning regulatory protection and supply obligation** (i.e. excluding 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).

The specific range of the relevant provisions is presented at the end of this document.

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Besides the issues related to regulatory protection and supply obligation in the incentives cluster and the empowerments of the Commission in the shortages cluster we consider those clusters in principle ready for closing as they were presented in the document **ST16051/24** of 13th December 2024 by the Hungarian Presidency.

We kindly ask the delegations to perform the final analysis of those provisions and provide **only critical comments or indicate the areas of red lines**.

Reading package 4 relevant provisions in accordance with ST 16051/24 (p. 245-292).

I. The Regulation:

1) relevant recitals p. 245-251;

2) Article 16 and Article 24, p. 251-254;

3) Article 115a, Articles 116 – 117, p. 255-260;

4) Annex V - The shortage prevention plan; p. 261-262;

5) Article 118, p. 262;

6) Article 2(14), p. 263;

7) Article 119-121, p. 264-268;

8) Article 2(15), p. 269;

9) Article 122-123, p. 269-272;

10) Art. 2 (16), p. 272;

11) Articles 124-127, p. 272-277;

12) Article 2(13), p. 278;

13) Articles 128-134, p. 278- 285;

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14) Articles 171-172, and Annex II *List of the obligations referred to in Article 172*, p. 285-291.

II. The Directive:

1) Article 56(3), p. 291

2) Article 162 paragraphs 3 to 5 Articles 166-167, p. 292-294;

3a) Article 203, p. 295-296;

4) Article 162(2a).

With regard to the Article 162(2a) the Presidency has considered the positions of numerous delegations given in the last meeting concerning manufacturing and upheld in the written comments, and has decided to return to the previous proposal with some adjustments suggested in the previous written comments to the manufacturing cluster. Since art. 162(2a) was not a part of the Coreper text in document ST 16051/24, the proposed wording is presented below. Changes compared to the text in ST 7585/25 are highlighted in grey.

"Article 162
Wholesale distribution of medicinal products

2a. For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') share a common origin ~~is essentialy similar~~ with the medicinal product already authorised in the destination Member State. Medicinal products are considered to be sharing a common origin~~essentially similar~~ if they fulfil all the following conditions:

(a) they have the same qualitative and quantitative composition in terms of active substances ~~and excipients~~;

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(b) they have the same pharmaceutical form;

~~**(c) they have the same clinical information; and**~~

(d) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation."

Reading package 2 relevant provisions in accordance with ST 16051/24:

I. The Directive:

1) relevant recitals (p. 147-157);
2) Article 28 (p. 161-164);
3) Annex VII - *Areas for adapted frameworks referred to in Article 28*

   "Phage-containing medicinal products, in cases where the medicinal product has a variable composition depending on the specific clinical context."'

   [not included in the ST 16051/24, cited in its entirety above];
4) Articles 83-86 (p. 182-187);
5) Article 4(52), p. 192;
6) Article 4(22), p. 206.

II. The Regulation:

1) relevant recitals: p. 157-161;
2) Article 6(8) and Article 176 (p. 165);
3) Article 48 (p. 191-192);
4) Article 29, Articles 70-72, Articles 58-60 (p. 193-195);
5) Articles 113-115, (p. 196-201);
6) Article 40 (p. 201-202), Article 170(6) (p. 203), Articles 41-43 (p. 203-206).