Council of the European Union
General Secretariat

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Interinstitutional files:
2025/0102 (COD)

Brussels, 26 January 2026

WK 1123/2026 INIT

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Critical Medicines Act)
Subject:	Meeting of the 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 30 January 2026. The draft agenda is set out in CM 1307/26 .

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Presidency Flash Note
Working Party on Pharmaceutical and Medical Devices
Format 2+2

30 January 2026 14:30

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1. Adoption of the agenda

The Presidency will invite delegations to adopt the agenda set out in CM 1307/26.

2. Critical Medicines Act – Initial Exchange on Key EP Amendments

Following the adoption of the European Parliament's position on the Critical Medicines Act (P10_TA(2026)0001), the Presidency invites delegations to an initial exchange of views on selected amendments that introduce new or reinforced Union-level mechanisms. The objective is to identify possible flexibilities in the Parliament's position and to gather guidance on potential landing zones for the next phase of negotiations. Therefore, the Presidency looks forward to delegations' guidance on how best to bridge positions in a way that ensures security of supply, respects the internal market, and remains operational for Member States

I. Main Thematic Block – Union Coordination on Stockpiling and Shortages

Delegations are invited to share their views on the amendments related to Article 20 and the new articles proposed by the Parliament, which together form a coherent policy concept:

- Article 20 (new paragraphs) – AMs 152–155
- Union coordination mechanism (Articles 20a, 20b, 20c, 20e, 20f /AMs 157–159, 162–163)
- Stockpile information and reporting mechanism (Article 20d – AM 160)
- Union stockpile (Article 20h – AM 164)

II. Additional Amendments for Initial Reactions

Subject to time, the Presidency would also welcome delegations' views on the following amendments, which raise broader governance or market-related considerations:

- Expansion of the role of the CMCG - Article 26a (AM 217)
- Assessment of possible duplication of strategic projects (AM 102)
- Possible introduction of export authorisation mechanisms -Articles 15 and 16 (AM 127 and AM 133)

These points are presented for orientation purposes and without prejudice. Delegations are invited to indicate whether they see scope for flexibility, safeguards, or alternative

approaches. The Presidency underlines that the list above is not exhaustive and does not prejudge future Presidency proposals.

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