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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 5 March 2026. The draft agenda is set out in CM 1739/26 .

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Presidency Flash Note
Working Party on Pharmaceutical and Medical Devices

Format 1+2

05 March 2026
10:00 – 13:00

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Critical Medicines Act

The Cyprus Presidency is pleased to invite to the next meeting of WPPMD, that will take place in the morning session on the 5 March. Please find below a note outline the objectives of the meeting.

1. Adoption of the agenda

The Presidency will invite delegations to adopt the agenda set out in CM 1739/26.

2. Preparation for the 2nd political trilogue– Initial Exchange of views on Key EP Amendments

After the adoption of the General Approach on CMA, one political trilogue and five inter-institutional technical meetings (ITMs) have been held with the European Parliament and the Commission. During the morning session on the WPPMD on the 5th of March, the Presidency aims to initiate discussions on difficult and political issues that are expected to be discussed during the 2nd political trilogue.

The Presidency will elaborate on the most challenging points identified during the ITMs, as indicated in the in the four-column table (ST 6589/26) and stated below.

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.

Medicines of common interest (MCI)– expansion of the scope (row 73)

The European Parliament position broadens the definition of MCI to include all orphan medicinal products, as defined in the Pharmaceutical Package, as well as contraceptive and abortifacient products.

Member States are invited to share their perspectives and indicate, whether there are possible flexibilities towards the EP position.

Chapter III – Expansion of the scope (row 66)

The European Parliament expands the scope of Chapter III (articles 5-15) to medicines of common interest where applicable, subject to a positive recommendation of the Critical Medicines Coordination Group.

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The Presidency proposes to maintain the Council mandate at this stage. However, Member States are invited to share their perspectives and indicate, whether there are possible flexibilities towards the EP position.

Article 6: Recognition of strategic projects and timelines for assessments and designations

The European Parliament has introduced two deadlines in the procedure: one concerning the designation of the designated authorities (within three months following the entry into force of the Regulation) and another relating to the assessment of projects by the designated authority (three months).

Furthermore, under its current mandate, the Parliament maintains the designated authority as responsible for verifying whether the relevant criteria are fulfilled. Where project promoters initially approach national authorities, they may subsequently refer to the designated authority for verification of the determination. However, the Parliament is currently reflecting further on this aspect of its mandate.

The Commission has also presented a new proposal clarifying that project promoters would carry out a self-assessment of whether their project fulfils the criteria and submit it to a national authority. The national authority would then take this assessment into account when determining whether the project qualifies as a strategic project and whether the criteria are met. In cases of doubt, the possibility of verification by the designated authority would remain.

The Presidency proposes to maintain the Council mandate at this stage. Nevertheless, Member States are invited to share their views on the proposed timelines by the European Parliament and on the Commission's new proposal, and to indicate whether any possible flexibilities could be envisaged.

Environmental assessments: timelines (article 12)

European Parliament introduces 45 days for a reasoned conclusion and if duly justified, there could be an extension of 45 days (row 131). In exceptional cases they keep the time limit extension by 15 days (row 132). The Council provides for 90 days for the reasoned conclusion and 20 days extension for exemptional cases.

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Member States are invited to share their perspectives on the timelines and indicate whether there are possible flexibilities.

Article 4: Strategic objective of the Union

The European Parliament has retained Article 4 in the operative part of the text, as it considers it important for anchoring the notion of security of supply.
The Presidency maintains the Council position of not including the concept of a "strategic objective of the Union" in the operative provisions.

Member States are therefore invited to share their views and to indicate whether any possible flexibilities could be envisaged regarding the inclusion of Article 4

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 as nothing is agreed until everything is agreed.

Did you know that ..

According to tradition, people in Cyprus are considered the earliest wine producers in the world. The history of winemaking on the island can be traced back nearly 5,500 years. In 2005, a team of Italian archaeologists concluded



