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**LIMITE**

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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<br>Working Party on Pharmaceuticals and Medical Devices (Critical Medicines Act) |
| Subject: | Meeting of the 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 25 and 26 September 2025. The draft agenda is set out in CM 4106/2025 REV1.

# Invitation to Working Party meetings on 25 and 26 September 2025

The Danish Presidency is pleased to invite you to the next meetings of the Working Party on Pharmaceuticals and Medical Devices under the Danish Presidency. The meetings will take place on the 25th and 26th of September 2025.

The meeting on the 25th of September 2025 will be a full-day event, as we will meet in the morning session for a meeting on the Pharma Package and in the afternoon session for a meeting on the Critical Medicines Act.

The meeting on the 26th of September 2025 will be a full-day event on the Critical Medicines Act.

Please find below a note outlining the objectives of the meetings and the agenda.

**Danish Presidency**
Council of the European Union

**Thursday 25 September 2025**

**Morning session: Working party on Pharmaceuticals and Medical Devices: Pharma Package**

The morning session on the 25th of September 2025 aims to initiate discussions on difficult points and political issues that are expected to be discussed during the political trilogue on the 7th of October. The Presidency will elaborate on the most challenging points identified at meetings at the technical level.

*Discussion on topics*

EMA governance: Voting rights in the CHMP (Article 148 in the Regulation)

The European Parliament has strongly advocated for voting rights of representatives of patients' organisations and representatives of healthcare professionals in the CHMP. The Parliament supports the Commission proposal regarding voting rights.

*The Presidency has taken note of the discussions from Member States shared in the Working Party on 9 July. However, Member States are invited to share their perspectives and indicate, whether there are possible flexibilities towards the EP position.*

EMA governance: Number representatives from patient and healthcare professionals' organisations (Article 149)

The Council has decreased the number of representatives from two to one per organisation as is the situation today. The Presidency expects the European Parliament to challenge this approach in support of the Commission.

EMA governance: Scientific working parties and scientific advisory groups (Article 150 in the Regulation)

*The European Parliament's position on the Scientific working parties and scientific advisory groups includes a provision on the establishment of ad hoc*

*working groups on ERA, ATMP, orphan medicinal products and paediatric medicinal products. In the Parliament position the representatives of patients, caregivers, clinicians and academia "shall" be included as members of the working parties as appropriate.*

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

### National procedures Patient group representation in the coordination group (Article 37(2) in the Directive)

The European Parliament has strongly advocated for the inclusion of one representative from patients' organisations in the coordination group (Article 37 (2) in the directive). Their argument is that a patient representative may bring valuable input to the process.

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

### General and authorisations and national procedures: Length of procedures for marketing authorisations

The European Parliament stands firm on the Commissions proposed provisions on the length of the procedures in article 6 (6) in the regulation and article 30 in the directive. The rationale for the European Parliament is to improve EU competitiveness.

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

### General and authorisations: Scope for environmental risk assessments (Article 4 (33) and 22 in the Directive)

The European Parliament proposes to broaden the scope of the environmental risk assessments to include manufacturing for all medicines and thus not just antimicrobials. They see this as a key political issue.

*Member States are invited to share their perspectives on the EP position.*

**Afternoon session:**

**Working party on Pharmaceuticals and Medical Devices: Critical Medicines Act**

In the afternoon of the 25th of September 2025, the Working Party on Pharmaceuticals and Medical Devices will be dedicated to the Critical Medicines Act. The Working Party on Public Procurement is also invited to attend this meeting.

We will begin with a presentation of the Presidency's compromise proposal, which will commence with the provisions concerning procurement and contingency stocks, i.e. Chapter IV (articles 18-24) as outlined in document 12773/25.

The Presidency invites delegations to exchange comments, views, and proposed amendments to the articles, welcoming both general observations and a detailed article-by-article discussion.

**Friday 26 September 2025**
**Working party on Pharmaceuticals and Medical Devices: Critical Medicines Act**

On the 26th of September 2025 the Working Party on Pharmaceuticals and Medical Devices will hold a full-day meeting dedicated to the Critical Medicines Act.

We will continue the presentation and discussion of the Presidency's compromise proposal as outlined in document 12773/25. The examination will continue with the provisions concerning strategic projects, i.e. Chapter III (articles 5-17). If time allows, we will continue with the provisions on the Critical Medicines Coordination Group as set out in Chapter V (articles 25-26).

The Presidency invites delegations to exchange comments, views, and proposed amendments to the articles, welcoming both general observations and a detailed article-by-article discussion.