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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 attached the Presidency flash for the meeting of Working Party on Pharmaceuticals and Medical Devices on 22 September 2025. The draft agenda is set out in CM 4088/25.

Invitation to Working Party meetings on 22 September 2025

The Danish Presidency is pleased to invite you to the next meeting of the Working Party on Pharmaceuticals and Medical Devices. The meeting will take place on 22nd September 2025.

The meeting will be a *half-day morning event*.

Please find below a note outlining the aim of the meeting and the agenda.

Danish Presidency
Council of the European Union

Monday 22nd September 2025

Meeting of the Working Party on Pharmaceuticals and Medical Devices on the Pharma package

1. Aim of the meeting

On the 17th July and the 3rd, 4th and 9th September 2025, the interinstitutional technical meetings (ITMs) were held between the Council, the European Parliament and the Commission. In these meetings we have discussed the reading packages on Pharmacovigilance and Procedures for national MA. We are currently discussing the reading packages on EMA-governance and General and authorisations.

The aim of this Working Party meeting is to provide an overview of the progress achieved so far and to initiate discussions on difficult points and political issues that have been identified in the discussions regarding Reading package 1 – General authorisations/subject matter and scope.

2. Discussion on topics

- **National autonomy related to legislation on contraceptives or abortifacients.**

The European Parliament has proposed to delete Article 1 (10), point a. Article 1 (10), point a is a continuation of article 4 (4) from the current directive. The European Parliament sees this as a political issue.

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

- **Pharmacy Exemption (Article 1(5) and 1(6) in the Directive)**

The European Parliament is adamant that only *hospital-serving pharmacies* may be permitted to prepare medicinal products based on magistral formula in advance on the basis of the estimated medical prescriptions. The European Parliament is concerned that preparation in private pharmacies could lead to a parallel shadow industry causing quality problems and thus jeopardize patient safety. Moreover, the Parliament opts for a shorter time period of 7 days plus another two weeks (up to 3 weeks in total) taking into account the properties of the medicinal product.

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

- **Hospital exemption ATMP (cross-border) (Article 2 (8a) in the Directive)**

The European Parliament has proposed to allow member states to authorise the cross-border exchange of advanced therapy medicinal products under hospital exemption in justified cases of medical need and in the absence of other solutions for the individual patient.

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

- **Shortage and defence exemption (Article 3 (1a and 1b) in the Directive)**

The Council mandate contains two provisions that would allow a member state to temporarily exclude from the scope of the Directive medicinal products prepared to mitigate or resolve a shortage or to address the specific needs of the patients in that member state (1a) as well as medicinal products manufactured and supplied exclusively to armed forces (1b). The provisions have not yet been discussed in ITMs but the PRES anticipates opposition from the European Parliament.

Member States are invited to share their perspective and guidance on these provisions.

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