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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 9 July 2025. The draft agenda is set out in CM 3384/25.



Invitation to Working Party meeting on 9 July 2025

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

The Danish Presidency is pleased to invite you to the meeting of the Working Party on Pharmaceuticals and Medical Devices. The meeting will take place on 9 July 2025. The meeting will be a full day meeting.

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

Wednesday 9 July 2025

Working Party on Pharmaceuticals and Medical Devices: The Pharma package.

We will begin the meeting with a briefing from the Danish Presidency regarding the technical negotiations with the European Parliament. Following this presentation, the Danish Presidency will provide an overview of some of the *key topics* expected to feature prominently in the upcoming negotiations. Member States are invited to share their views on the European Parliament's position regarding the identified topics.

1. Information from the Presidency on the trilogue phase negotiations

The Danish Presidency will provide a debrief on the first *Preparatory Informal Meeting* at a technical level with the Parliament regarding the working method for the technical negotiations with the European Parliament.

2. Discussion on topics in the European Parliament's position

As we were informed during the debrief by the Polish Presidency, the first trilogue took place on the evening of 17 June, during which both the Council and the European Parliament presented their respective positions. Based on the Parliament's presentation, the main elements of its mandate for the regulation are: to promote research and development in the field of AMR, to promote research and development in the field of rare diseases, the prevention of medicine shortages, patient involvement, and ensuring security of supply of medicines; for the directive: the protection periods and access incentives, environmental risk assessments, AMR, the Bolar provision and electronic package leaflets.

On this basis, the Danish Presidency will highlight the key topics expected to be central in the trilogue negotiations. Member States are invited to indicate possible flexibilities regarding the European Parliament's positions and provide guidance on possible landing zones for the following topics:

- Prevention of medicine shortages and security of supply
- Protection periods and incentives for access
- Orphan medicinal products
- Voting rights in CHMP for health care professionals and patient representatives
- Environmental risk assessments
- AMR (Prescription of antimicrobial medicinal products, awareness card and access plan as proposed by the EP)
- Electronic package leaflets

FUN FACT OF THE WEEK

Did you know that Bluetooth is named after the first king to rule over a united Denmark, King Harald Blåtand (ruled ca. 958-985). His last name literally translates to blue tooth, and the Bluetooth logo is actually a combination of the runes for his initials!