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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 Public Health and 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 Public Health and the Working Party on Pharmaceuticals and Medical Devices on 3 and 4 September 2025. The draft agenda is set out in CM 3849/2025 and CM 3783/2025.

Invitation to Working Party meetings on 3 and 4 September 2025

The Danish Presidency is pleased to invite you to the next meetings of the Working Party on Public Health and the Working Party on Pharmaceuticals and Medical Devices under the Danish Presidency. The meetings will take place on the 3rd and 4th of September 2025.

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

Danish Presidency
Council of the European Union

Wednesday 3 September 2025

Meeting of the Working Party on Public Health: EEA negotiations on health preparedness

In the morning of the 3rd of September 2025, the Working Party on Public Health, in its capacity as Special Committee, will hold a short meeting dedicated to the EEA negotiations on health preparedness (reference document WK 09750/25).

The Commission will provide an update on the EEA negotiations on health preparedness. The Presidency invites delegations to provide input to the Commission to prepare for the continued negotiations with the EEA countries.

Meeting of the working Party on Pharmaceuticals and Medical Devices: Critical Medicines Act

Then, as from around 11:30 and for the rest of the day, the Working Party on Pharmaceuticals and Medical Devices will focus on the Critical Medicines Act.

First, representatives of the European Medicines Agency (EMA) and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) will provide an update on their work on vulnerability analyses in the context of the pharmaceutical package.

After those updates, the Commission will hold a presentation on existing groups and forums, their function, and why the Commission finds it relevant to establish a new group, instead of letting an existing group take on the tasks, as proposed in Chapter V of the Critical Medicines Act.

Then, the Commission will present its Staff Working Document for the Critical Medicines Act.

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Thursday 4 September 2025

Meeting of the Working Party on Pharmaceuticals and Medical Devices: Critical Medicines Act

On 4 September 2025, the Working Party on Pharmaceuticals and Medical Devices will hold a full-day meeting dedicated to the proposal for a Critical Medicines Act.

We will examine the recitals of the proposal as set out in document 6872/25. The Presidency invites delegations to exchange comments, views, and proposed amendments to the recitals, welcoming both general observations and a detailed recital-by-recital discussion.

FUN FACT OF THE WEEK

During the Informal Health Ministers Meeting in Copenhagen later this month, our Minister for Health will host a dinner at Louisiana Museum of Modern Art.

The museum's name, "Louisiana," has a romantic backstory. It was named after the three wives of its original owner, Alexander Brun, all of whom were named Louise. When Knud W. Jensen purchased the estate in 1958 to establish the museum, he retained the name.

Today, the Louisiana Museum is renowned for its impressive collection of over 4,000 modern and contemporary artworks, including pieces by artists like Pablo Picasso, Andy Warhol, and Yayoi Kusama – and Simone's favorite Alberto Giacometti.

We look forward to welcoming you all!