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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 - Presentation by the Commission

Delegations will find attached the presentation given by the Commission on Existing groups and CMG at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 3 September 2025.

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Critical Medicines Act
-
Existing groups and CMG

Working Party on Pharmaceuticals and Medical Devices,

3rd September 2025

Director SANTE D
European Commission

Existing groups and forums

	Group	Legal basis	Membership	Mandate/ main tasks
Pharma regulatory	**Medicine Shortages Steering Group (MSSG)**	Article 3 of Regulation 2022/123 (EMA extended mandate)	High-level representatives from **national medicines agencies**, EMA and EC	- Focus on critical **shortage management** (EMA extended mandate and proposed pharma regulation) - Its working party at expert level (**Single Points of Contact – SPOC WP**) oversees the day-to-day reporting and monitoring of critical shortages and events
	Pharmaceutical Committee	Council decision 75/320/EEC	Member States (**ministries of health**) and EC	- Advisory body on policy and implementation issues related to **pharma acquis**
Critical medicines	**Critical Medicine Alliance**	No legal basis in EU law	**Large range of stakeholders** from EU MS, key industries, civil society and scientific community	- Consultative mechanism that aims to identify key areas and priorities for action to strengthen supply of **critical medicines**
MCMs	**HERA Board**	Article 6 of Commission decision of 16.9.2021 establishing HERA	**One high-level representative from each MS**, EU institutions and agencies (ECDC and EMA) as observers	- Assists and advices EC on strategic orientations in relation to **crisis preparedness and response** to cross-border threats in the area of **medical countermeasures**
	Joint Procurement Agreement Steering Committee (JPASC)	Article 5 of Commission Decision of 10.4.2014 on approval of JPA to procure MCM	One technical level representative of each **contracting party** and EC	- Responsible for steering matters relating to the **Joint procurement procedures of medical countermeasures**
Pricing	**National Competent Authorities on Pricing and Reimbursement (NCAPR)**	No legal basis in EU law (Special expert group)	MS representatives (**pricing and reimbursement authorities**) and EC	- Exchange of information and collaboration on **pricing and reimbursement of medicines**

Why a CMG?

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- To ensure the sharing of information, effective coordination and build synergies
- Multidisciplinary approach and expertise required for CMA implementation covering:
  - industrial policy,
  - public procurement,
  - joint procurement, and
  - international cooperation

Thank you





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