Council of the European Union
General Secretariat

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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 the guidance on the application of State aid rules in the context of the Critical Medicines Act at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 15 July 2025.

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Shortages of medicines in the EU: Commission's proposal for a Critical Medicines Act

Presentation to Council Working Party on 15 July 2025

DG Competition
Med House Task Force

Competition

Critical medicines and shortages

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Critical Medicines

- No alternative available + insufficient supply would harm patients
- Over 200 CM on the Union list: Antibiotics, oncology treatments, and anesthetics, mostly **generics**

Shortages

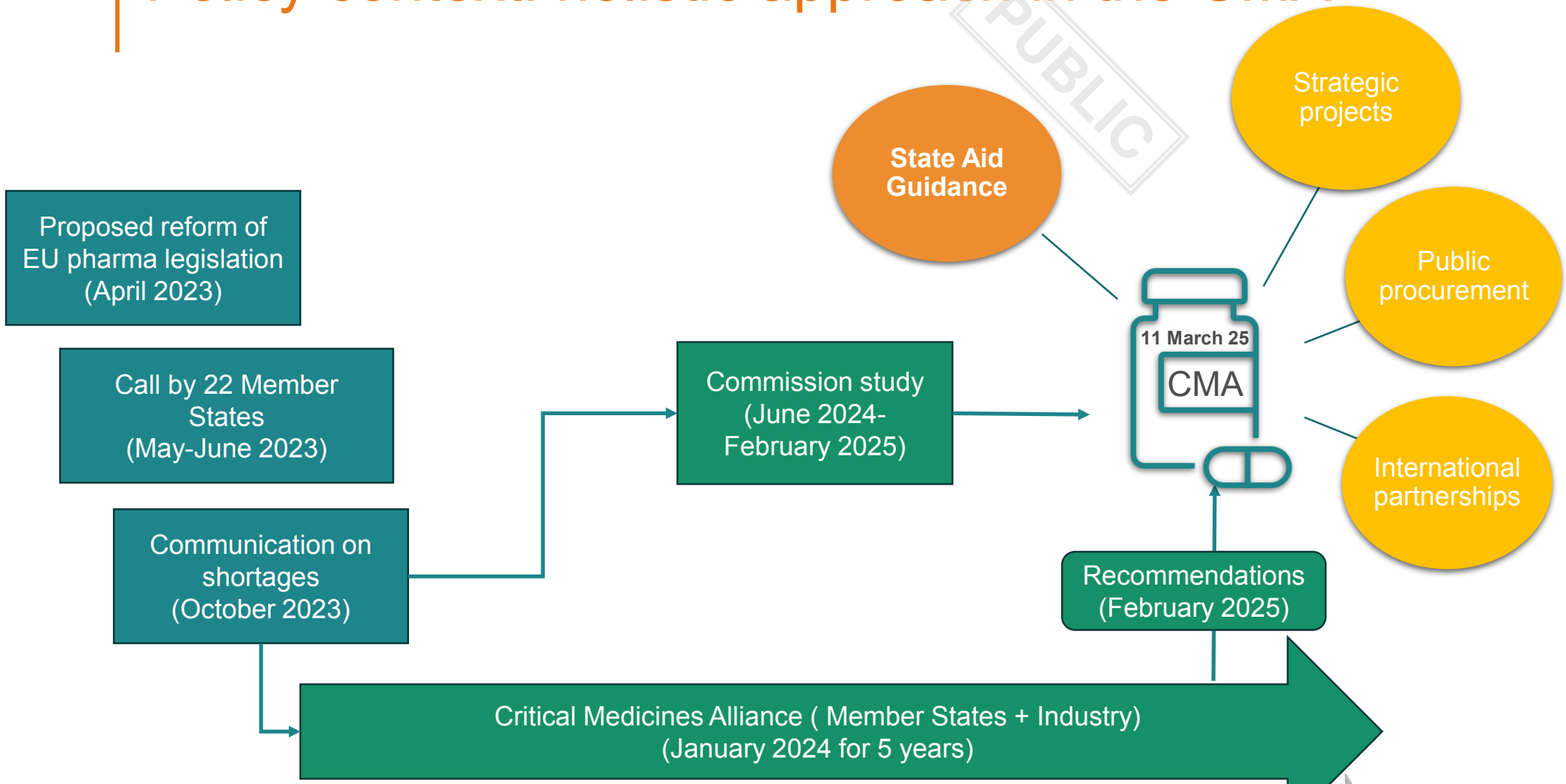
- Peak of shortages of critical medicines during COVID-19 pandemic, antibiotics shortages during winter season 2022-2023
- Long lasting and growing issue

Root causes are complex and multi-faceted

- Manufacturing issues, incl. heavy reliance on China and India for active pharmaceutical ingredients (APIs) used to produce generic medicines
- Commercial reasons
- Unexpected demand fluctuation
- Price and reimbursement regulations (national)
- ….

Policy context: holistic approach in the CMA

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CMA: strengthen security of supply and improve availability of critical medicines

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Strategic Projects	**Create, increase or modernise EU manufacturing capacity for critical medicines or their ingredients**
Financial incentives	**MS support → State aid guidance Union funding**
Public procurement	**Support security of supply with specific award criteria (e.g., diversified sources of input material, departure from price-only criteria)**
Collaborative procurement	**Joint procurement, procurement on behalf of MS: address availability and access disparities of critical medicines**
International partnerships	**Broaden the supply chain and reduce dependencies on single or limited numbers of suppliers**

Service of General Economic Interest (SGEI) [1/2]

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SGEIs can address security of supply market failures demonstrated by a proper vulnerability assessment

1. **Allows imposing obligations to reserve capacity, produce, supply, etc**
2. **Incentivises EU approach: joint entrustment by several MS**
3. **Does not necessarily require notification**
4. **Covers investment and operating costs**

Service of General Economic Interest (SGEI) [2/2]

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1. Assessment of vulnerabilities in the supply chain	• Market failures from national to EU levels. Actual market failures needed, no presumption possible.
2. One to 27 Member States (MS) define public service obligations	• e.g. obligation to reserve capacity to be activated in times of crisis, obligation to produce, supply obligations etc.
3. MS agree on compensation	• Member States can share compensation as they see fit. • No overcompensation of the provider
4. MS select provider	• Competitive tender, Most Economically Advantageous Tender criteria possible ➔ may lead to no aid (Altmark) • Other procurement procedures possible but aid
5. MS seek State aid validation (if need be)	• No notification for no aid (Altmark) or aid below EUR 15 million/year (SGEI Decision) otherwise notification (SGEI Framework)
6. MS sign and monitor public service contract	• Respect of the contract conditions/PSO obligations • No overcompensation

Other instruments

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Other instruments not aiming at security of supply but at other market failures may still offer possibilities to support Strategic Projects for critical medicines (even absent vulnerability assessment)

State aid instruments	Possible use
General Block Exemption Regulation (GBER)	• Support for regional economic development (Art. 14) • Support `for SME (Art. 17) • Support for decarbonisation and energy efficiency (Art. 36 and Art. 38) • Support for process optimisation (Art. 47)
Regional aid	• Support for regional economic development beyond GBER thresholds
Guidelines on State aid for climate, environmental protection and energy (CEEAG)	• Support decarbonisation and energy efficiency beyond GBER thresholds
IPCEI Communication	• Support beyond-the-state of the art innovation
R&D&I framework	• Support Research, Development and Innovation beyond GBER thresholds
Approval under the Treaty (Article 107.3c)	• Support investments in limited circumstances (cf. Sandoz)

Strategic report of the Alliance - recommendations

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New dedicated State aid rules for critical Medicines

- Existing rules seem fit for purpose based on available information.
- Assessment of specific cases should allow to clarify whether there are gaps to be covered.

Dedicated IPCEI when documented evidence suggests a substantial competitivity gain potential from beyond state-of-the-art innovation.

- Well in line with the guidance.
- IPCEI is a horizontal tool which supports beyond the state-of-the-art innovation and not mass production.
- A major change of scope for one particular sector does not seem warranted.

Critical Medicines SGEI coordinated at EU level to limit the risk of critical shortages

- Well in line with the guidance.

Extending the scope of the Clean Industrial Deal State Aid Framework (CISAF)

- Public consultation ongoing.
- CISAF focus is decarbonation and clean energy/clean tech.

Thank you





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