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From: General Secretariat of the Council
To: Working Party on Competitiveness and Growth (Industry)

Subject: Presentation by the European Commission, DG SANTE : Critical Medicines Act (AOB, agenda item 4.)
Working Party on Competitiveness and Growth (Industry) meeting on 10 April 2025



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Critical Medicines Act

Council Working Party on Competitiveness and Growth (Industry)

10th April 2025

DG SANTE unit D2 – Medical products: quality, safety, innovation

European Commission

Context



EUROPE'S CHOICE

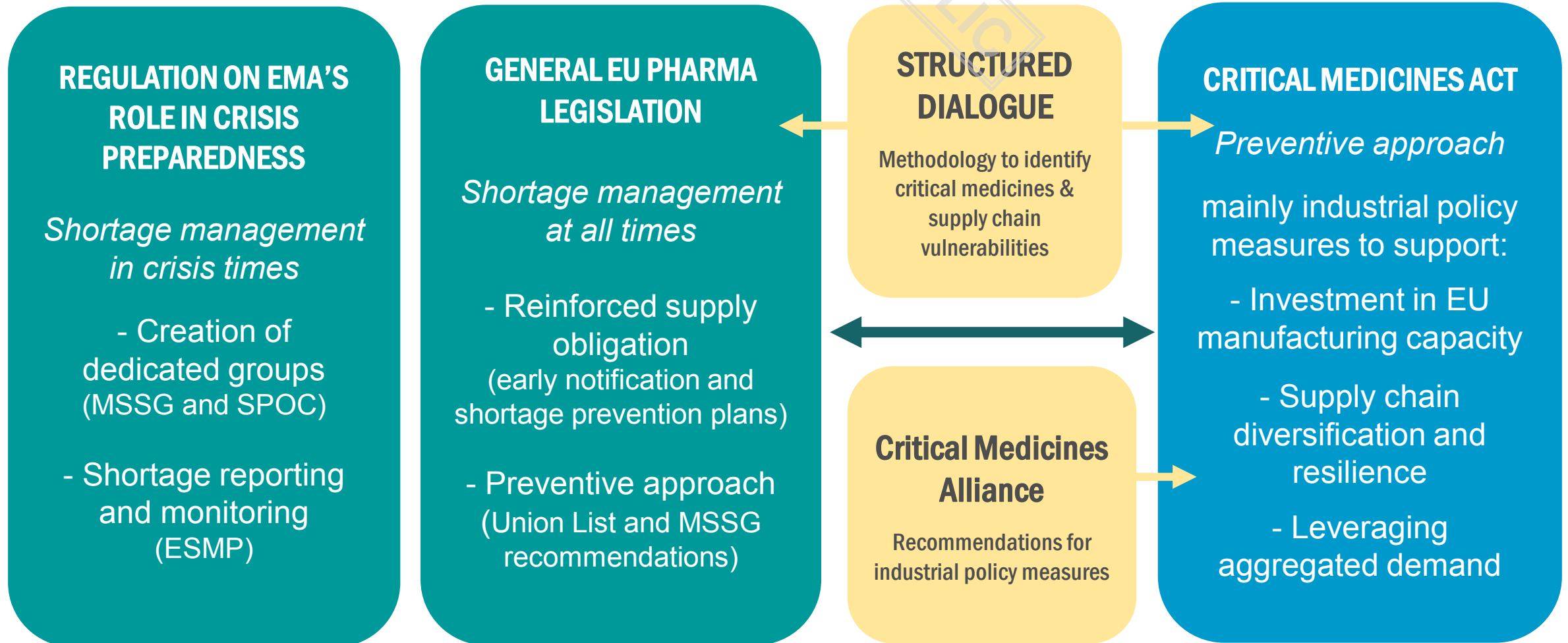
POLITICAL GUIDELINES
FOR THE NEXT EUROPEAN COMMISSION
2024–2029

President von der Leyen:

“... we will propose a Critical Medicines Act to reduce dependencies relating to critical medicines and ingredients, particularly for products where there are only a few supplying manufacturers or countries.”

- Increasing pressure and attention (COVID-19, geopolitical context)
- Complex and multifactorial root causes
- [Member States' call](#) for a Critical Medicines Act
- Recent and ongoing initiatives, e.g.:
 - [Reform of the EU pharmaceutical legislation](#)
 - [Communication on addressing medicine shortages in the EU](#)
 - [Critical Medicines Alliance](#)

Comprehensive approach to ensure availability of critical medicines



Objectives and scope

Strengthening security of supply and availability of critical medicines



Critical medicines on the Union list as envisaged in the Pharma Reform

Improved availability and accessibility of other medicines where a market failure exists



Medicines of common interest (e.g. orphans, novel antimicrobials)

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KEY ELEMENTS OF THE ACT

ENSURING



**SECURITY OF SUPPLY AND AVAILABILITY
OF CRITICAL MEDICINES**

**ACCESSIBILITY AND AVAILABILITY
OF OTHER KEY MEDICINES**

STRATEGIC PROJECTS

Facilitate investments
in manufacturing
in the EU

PUBLIC PROCUREMENT

Incentivise
supply chain
diversification and
resilience

COLLABORATIVE PROCUREMENT

Harness the
combined
demand and
buying-power of
Member States

STRATEGIC PARTNERSHIPS

Support the
diversification of
supply chains

Strategic projects

- Projects that create, increase or modernise **EU manufacturing capacity** of critical medicines, their active substances and other key inputs
- Recognition at Member States' level (lean, decentralised approach)
- Benefits:
 - **Fast-tracking of administrative procedures** (*permit granting, environmental assessment*)
 - **Regulatory and scientific support** (*incl. EMA advice & prioritised GMP inspections*)
 - **Facilitated financial support**, including through the STEP Seal
- Obligation: **Prioritise EU supply** if received financial support
- **State aid Guidance** to assist Member States
- Exchanges and coordination *via* Critical Medicines Group

Public procurement

- **Mandatory use of other requirements than price** for critical medicines (*e.g. stockholding obligations, number of diversified suppliers, monitoring of supply chains*)
- Obligation for **procurers to favour EU production** for specific critical medicines with high dependencies
- When justified, possibility to favour EU production for other medicines of common interest
- Member States to develop strategy (**national programmes**) covering procurement practices (*incl. multi-winner approaches*) and possibly pricing and reimbursement measures
- Commission guidelines on procurement practices

Collaborative procurement

- Possibility to use different tools of collaborative procurement (each subject to specific conditions and thresholds):
 - **Member States' cross-border procurement** facilitated by the Commission (*available only for other medicines of common interest*)
 - **Commission procurement** on behalf or in the name of Member States
 - **Joint procurement** by the Commission (lead) and Member States

International cooperation



- Commission to explore possibilities for:
 - Establishing **strategic partnerships** aiming at **diversification of supply chains**
 - Building on existing cooperation forms
- Critical Medicines Coordination Group to periodically discuss:
 - Potential contribution of strategic partnerships to CMA objectives
 - Prioritisation of third countries
 - Consistency and synergies between national and EU actions

Coordination

- Establishment of a **Critical Medicines Coordination Group**
- Composed of EC and Member States' representatives
- Main tasks:
 - Facilitate coordination on strategic orientation for financial support of Strategic Projects
 - Enable exchanges, cooperation and coordination on public procurement policies
 - Facilitate discussion on collaborative procurement needs
 - Advise MSSG to prioritise, review and update vulnerability evaluations
 - Discuss periodically on international cooperation

Thank you

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