



Tackling medicine shortages in the EU

Communication from the Commission, Oct 2023

Longstanding challenges with *availability* of authorised, marketed medicines

Demand Side

- Unanticipated increases in demand due to changing infection patterns e.g. Post-pandemic demand increases

Supply Side

- Root causes of shortages linked to **manufacturing, quality and commercial decisions**
- Supply chain vulnerabilities, including those linked to single source suppliers and geopolitical challenges
- **Fragmentation** of single market for medicines → **Lack of coordination on unilateral measures taken by Member States**

Pharmaceutical Strategy for Europe 2020

Parliament resolutions e.g., September 2020 on the shortages of medicines – how to address emerging problem

Council Conclusions e.g., on Access to medicines and medical devices for a Stronger and Resilient EU and EUCO conclusions **October 2020**

2021: Commission Study on Shortages

2021: Structured Dialogue on Security of Supply of medicines
2022 Publication of Staff Working Document

2022: Extension of EMA mandate (Regulation (EU) 2022/123)

2023: HMA EMA Task Force on Availability of Authorised Human and Veterinary Medicines – progress on Union list

May 2023: BE initiative backed by 23 MS

June 2023: request by the European Council

September 2023: Letter by 85 MEPs

Call to the Commission to further coordinate action regarding availability of medicines

What system does the EU already have in place?

EU-level coordination

* **EMA extended mandate** (Regulation (EU) 2022/123)

* Executive Steering Group on Shortages and Safety of Medicinal Products (**MSSG**) and **SPOC WP**

* **HMA EMA Task Force** on Availability of Authorised Medicines for Human and Veterinary Use

* **Joint Action** on shortages (CHESSMEN)



Existing pharmaceutical legislation: Obligations on suppliers to ensure supplies and notify on supply interruptions (unless upon unforeseen circumstances or commercial decisions), along with deployment of **regulatory flexibilities** if needed



Reform of EU Pharmaceutical Legislation (adopted April 2023): Novel Chapter in proposed Regulation (Chapter X) with new measures and obligations to **manage shortages and ensure security of supply of critical medicines** -> **Anticipated in Communication**



Commission's **Health Emergency Preparedness and Response Authority (HERA)** for support with **foresight** and **measures** to ensure the availability of medical countermeasures



Joint procurement between Member States; of particularly benefit in smaller EU countries



RescEU stockpiles of critical medical countermeasures that can be quickly deployed when Member States cannot cope with a health emergency



+ **monitoring and dialogue** across EMA, Member States and the industry

Communication on tackling medicine shortages:

Commission steps up efforts

Key objectives

☑ **Mitigate and manage critical shortages** at EU level in a coordinated manner



- 1) Further strengthen EMA coordination and information sharing on critical shortages and mitigation measures
- 2) Anticipate elements of the Pharmaceutical proposal
- 3) Establish the Voluntary Solidarity Mechanism

☑ Strengthen security of supply of **critical medicines** for EU health systems and citizens



- 1) Anticipate elements of the Pharmaceutical proposal
 - a) Identify a Union list of critical medicines
 - b) Identify vulnerabilities in the supply chains of those medicines
 - c) Implement policy measures (regulatory, industrial or other) to strengthen the supply chains of those critical medicines

Overall aim of the EU:

Strong, risk-proof, resilient **European Health Union**

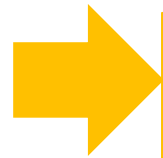


Better protection of **patients'** health + more resilient health care **systems**



Open Strategic Autonomy, EU sustainable competitiveness (Granada summit)

Goal 1: Manage **critical shortages** in the **short-term and more structurally for the long term**



Concrete measures to enhance the EU's ability to manage critical shortages in a **coordinated manner** at EU level:

Anticipate elements of the **proposed pharmaceutical legislation**, including by extension of systems and processes set out in **EMA extended mandate**

Competent authorities deploying **regulatory flexibilities where necessary** –
Launch a dedicated Joint Action (in 2024)

Established **Voluntary Solidarity Mechanism** to share medicines between Member States (under MSSG)

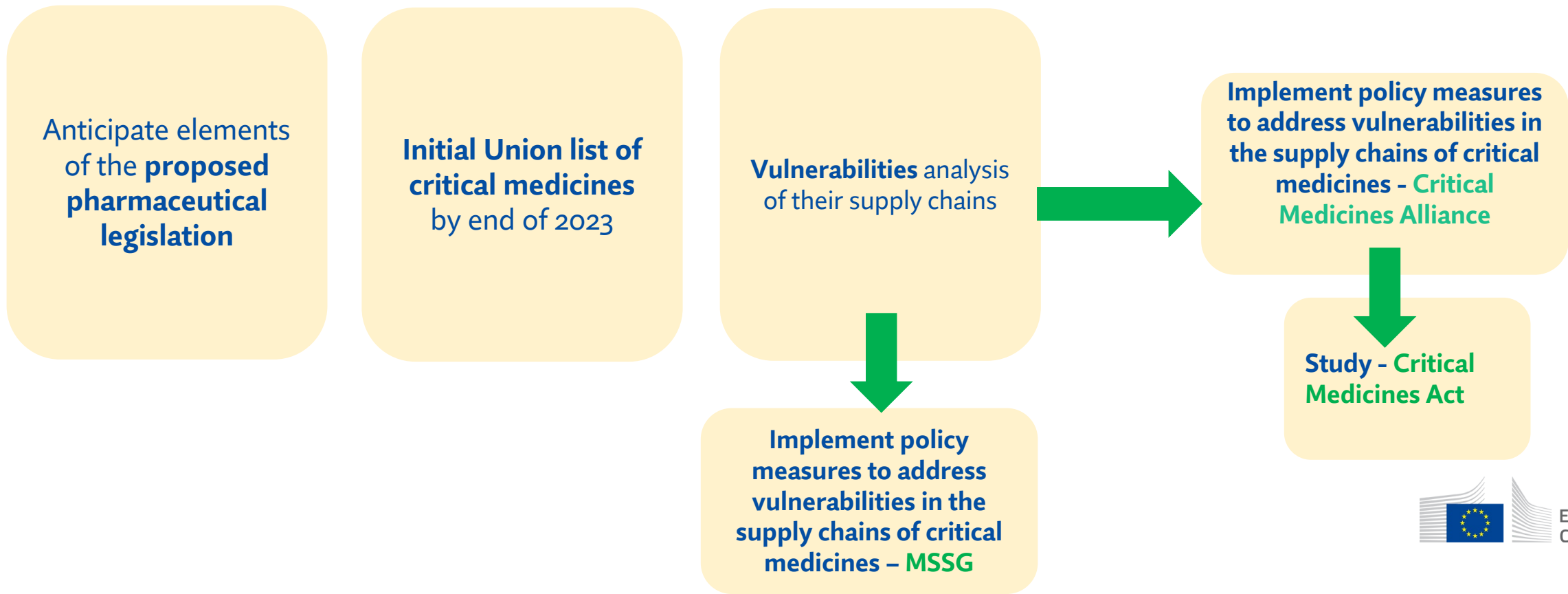
Joint Procurement -
- Launch a dedicated Joint Action (in 2024)
- **Joint Procurement** of specific medicines in preparation for winter 2024/25

Guidance on public procurement (NCAPR), early 2024

EMA, Member States and the Commission will continue to **collaborate**, in contact with the industry and civil society as appropriate.

Goal 2: Improve security of supply of **critical medicines** for the **mid to long term**

➔ Concrete measures to ensure the security of supply of critical medicines (including follow up to Pharma Strategy and Structured Dialogue):



Goal 3: Support availability on the **global level**, acting as 'Team Europe'

Establish a network of **international partners and companies**

To **enhance exchange of information** on supply issues

Develop Initiatives in **low- and middle-income countries**

To support **production capacity** and reinforce cooperation on prevention and preparedness

Conclusion of **strategic partnerships with third countries** for production of critical medicines

To better reflect on both **local demand and needs** at the EU and global level

Thank you



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