



Availability of medicines: Commission Communication on addressing shortages of medicines

Unit D2

DG SANTE, European Commission

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 of 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 **2020**

2021: Commission study on Shortages
2021: Structured Dialogue on security of supply of medicines
2022: Publication of associated Staff Working Document

2022: Extension of EMA mandate (Regulation (EU) 2022/123
- Systems and processes for preparedness and crisis response

2023: Commission proposal on pharmaceutical reform – novel chapter on availability of medicines

May 2023: BE non-paper supported by 23 MS

June 2023: request from the European Council

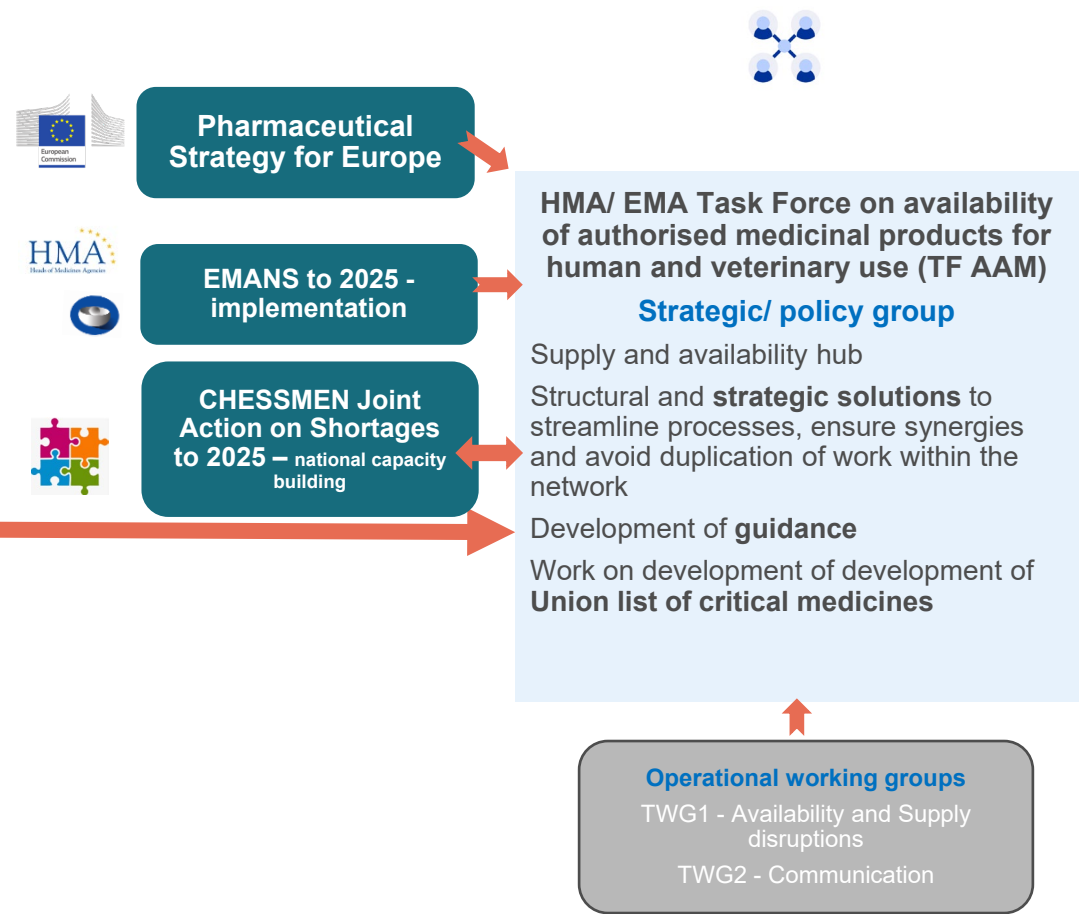
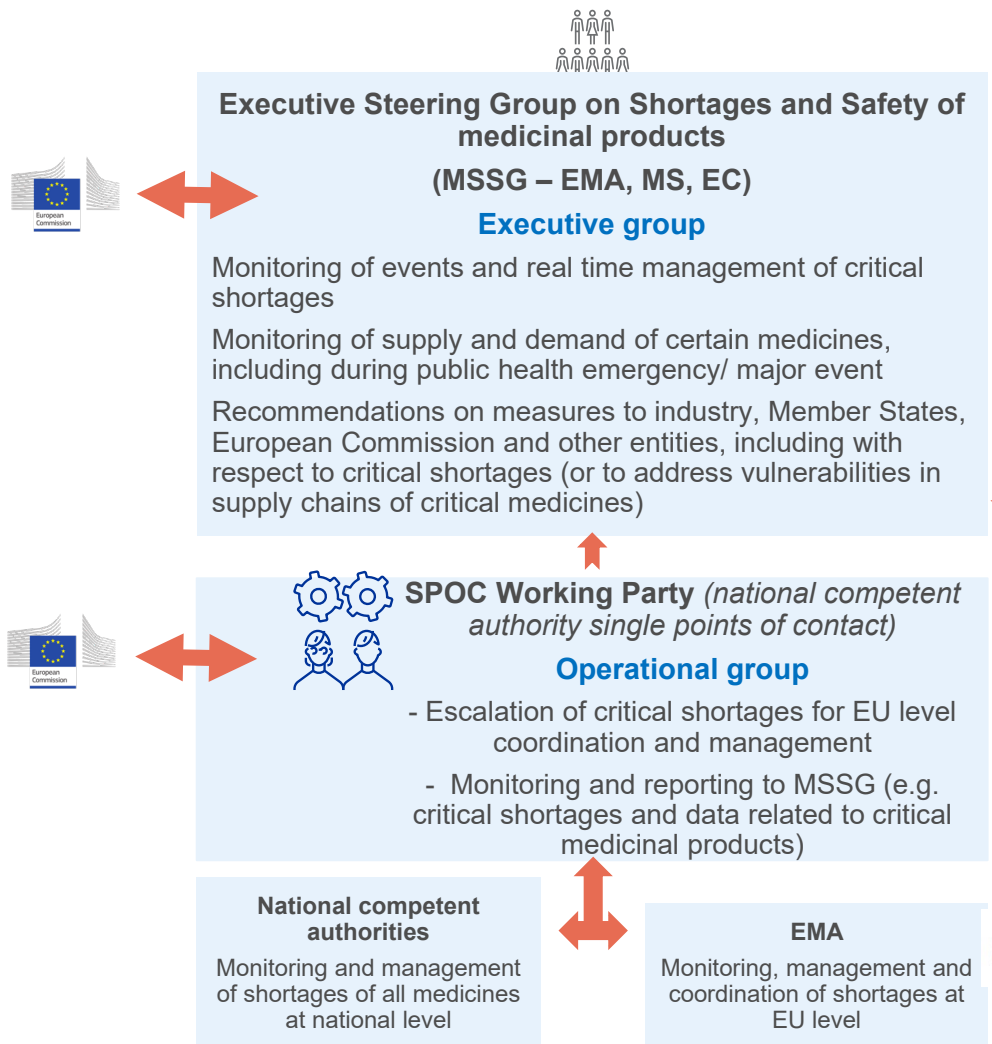
September 2023: Letter signed by 85 MEPs

Oct 2023: Commission communication on addressing medicine shortages in the EU

EMA extended mandate Regulation (EU) 2022/123

Crisis preparedness and response (public health emergencies and major events)

Structural measures



Reform of the EU pharmaceutical legislation

Current challenges

Growing concern for **all EU countries**

- **Critical shortages** of medicines;
- Security of supply of **critical medicines**

Ad hoc processes for dealing with **critical shortages**

Proposed solutions

Improved **coordination, monitoring and management** of shortages, in particular critical shortages (MS and EMA); **Earlier** and **harmonised notification** of shortages and withdrawals (industry)

Shortage Prevention Plans

Union list of critical medicines

Stronger coordinating role for **EMA &** more powers for **MS** and **Commission**

2023: Communication on addressing medicine shortages

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) to strengthen the supply chains of those critical medicines
- 2) Identify and apply other policy measures (industrial policy/ other) to strengthen the supply chains of those critical medicines

Overall aim of the EU:

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

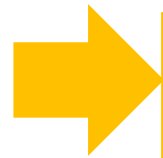


Better protection of **patients' health** + more resilient health care **systems**



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)

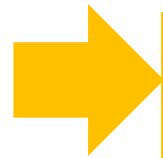
Established **Voluntary Solidarity Mechanism** to share medicines between Member States (under MSSG) and MSSG toolkit on recommendations on tackling shortages of medicinal products

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

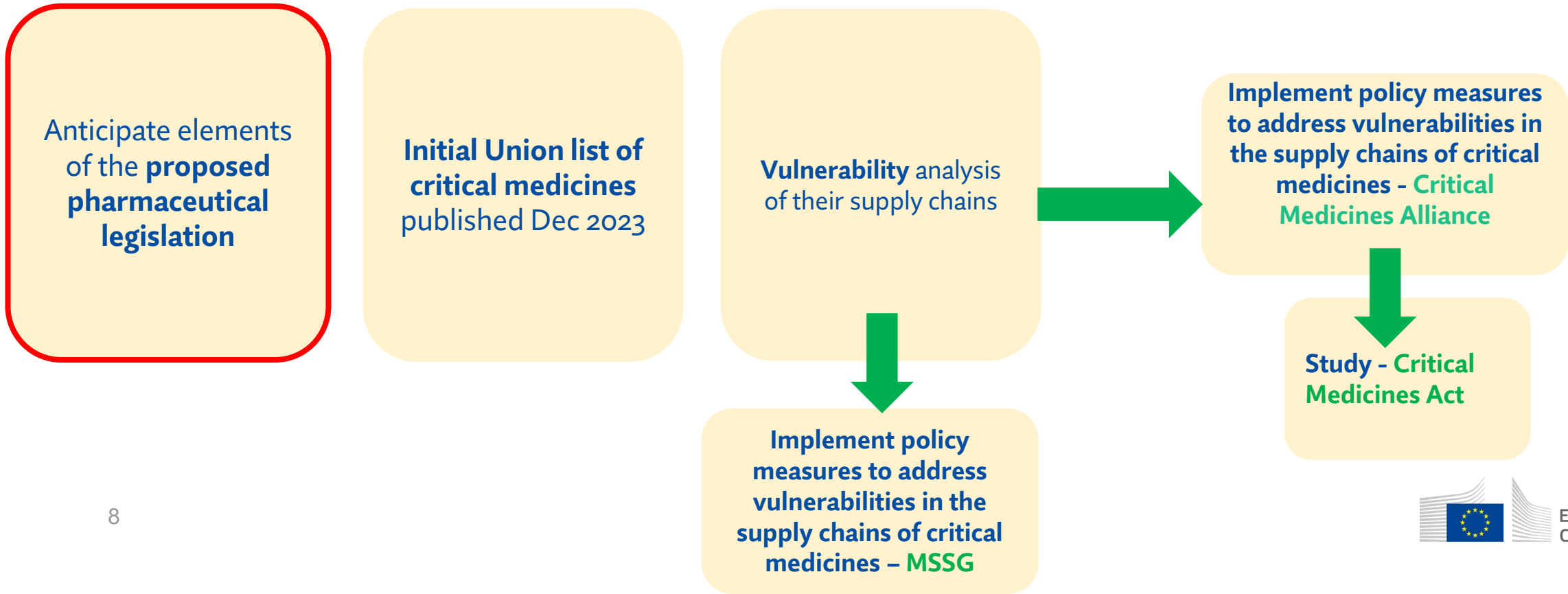
Guidance on public procurement (NCAPR), early 2024

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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