EMA
EUROPEAN MEDICINES AGENCY

Shortage mitigation and management at EU level

Joint PCWP/HCPWP meeting – 4 February 2026

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Supply and Availability of medicines and medical devices

EU level approach

- Improving the availability of medicines authorised in the EU is a **key priority** for the European Medicines Regulatory Agencies
- Regulatory authorities - within and outside Europe - are increasingly **working together to prevent shortages** and to limit their impact whenever they occur

- **Regulation (EU) 2022/123[1] implemented starting 2022:**
  - Defines processes/tools for shortages reporting and coordinated responses of EU countries to shortages of critical medicines (during a crisis) and for monitoring of events, including medicine shortages, which might lead to a crisis situation (public health emergencies or major events)
  - Establishes "**Medicines Shortages Steering Group**" (MSSG) supported by the SPOC **Working Party** and a Network of contact points from pharmaceutical companies (i-SPOCs)
  - Foresees the development and implementation of the **European Shortages Monitoring Platform** (ESMP)

KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU

1 Regulation - 2022/123 - EN - EUR-Lex

EU level coordination

Operational group

Single Point of Contact (SPOC) working party

Who is it composed of

- Shortage experts from all Member States and EMA

What does it do

- Monitoring of critical shortages, supply/demand
- EU coordinated actions to address critical shortages
- Escalation to MSSG when appropriate
- Monitoring of events that may lead to a Public Health Emergency (PHE) or Major Event (ME)

Executive group

Medicine Shortages Steering Group (MSSG)

Who is it composed of

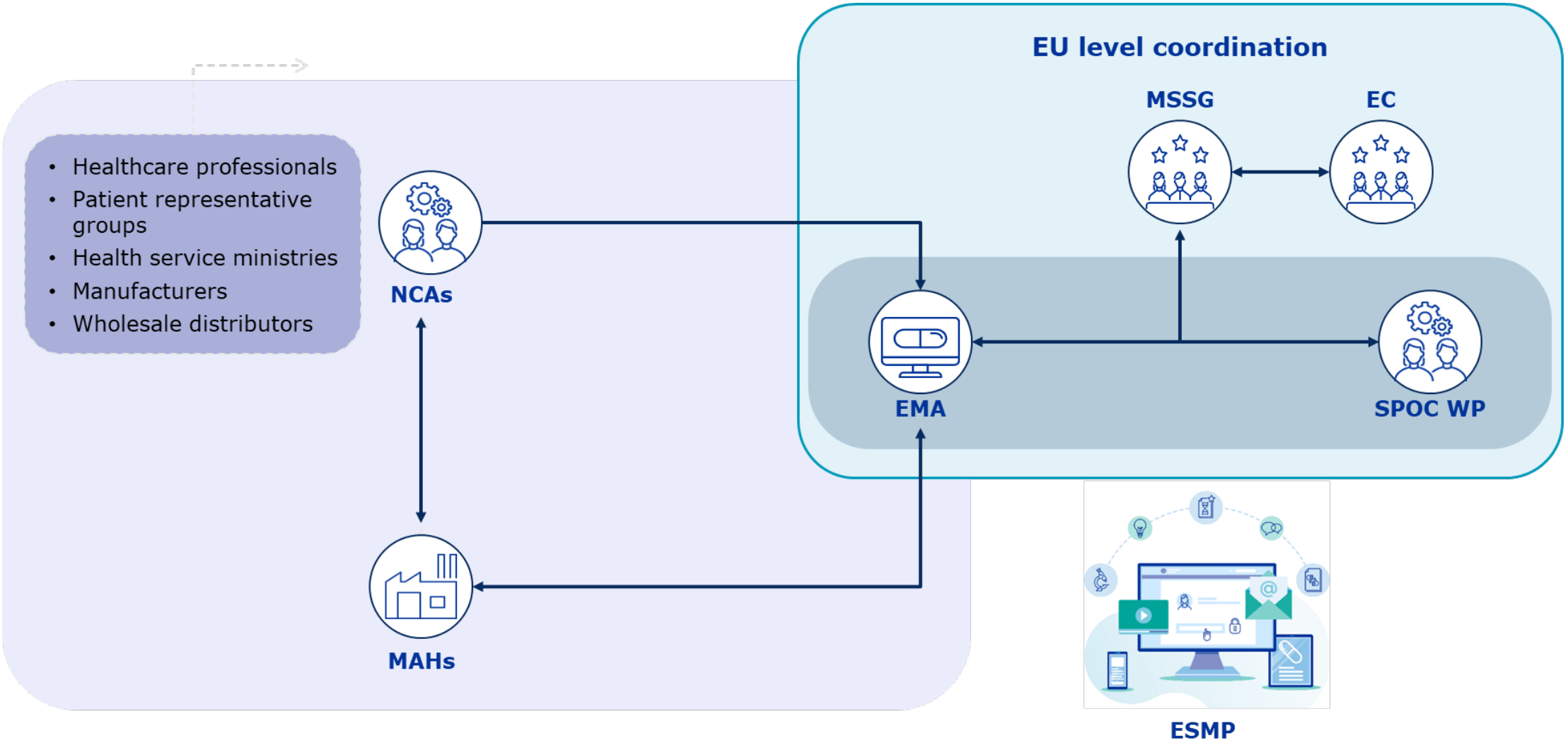
- Heads of national competent authorities from Member States
- European Commission and EMA
- Patient and healthcare professional representatives (observers)

What does it do

- Recommendations to the EC, Member States and industry to address critical shortages and strengthen supply chain of critical medicines
- Adopts lists of critical medicinal products for a specific PHE/ME
- Recommendations to the EC, Member States and industry for Public Health Emergency (PHE) or Major Event (ME)

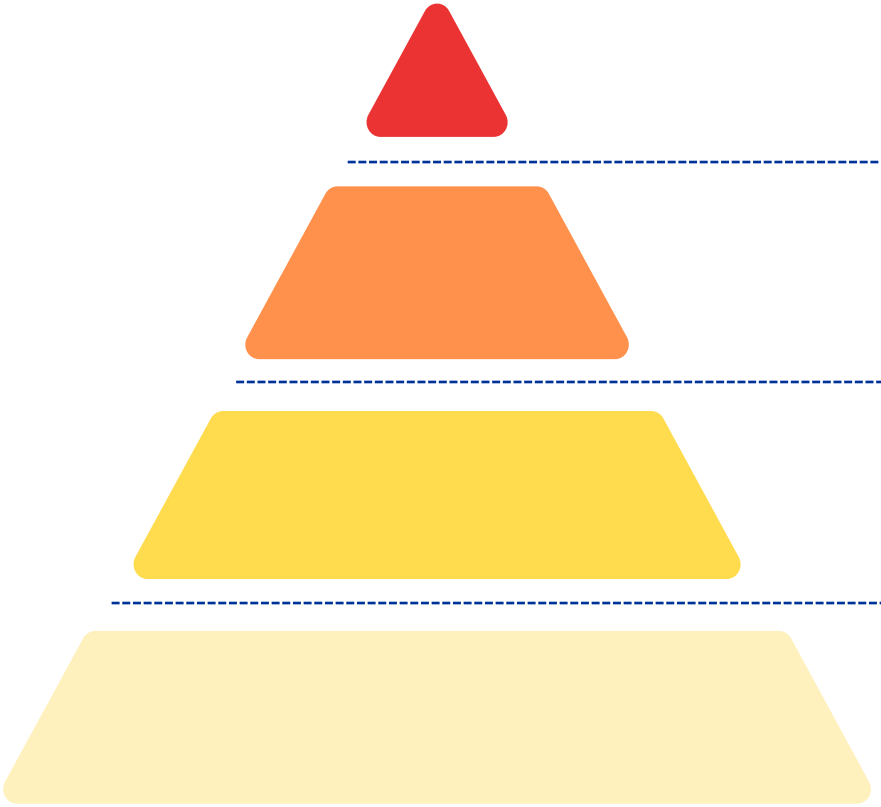
Normal Circumstances, Preparedness and Crisis

National and EU level coordination



NCA= National Competent Authority; MAH= Marketing Authorisation Holder; EC= European Commission

All shortages are different



Critical shortage of a critical medicine: it has a detrimental impact on patients throughout the EU

Critical shortage in the EU: a shortage of a medicine for which no alternative medicine is available, and which cannot be solved at the national level. Coordinated Union level action is considered necessary to resolve that shortage.

Critical shortage in a Member State: critical shortage in a Member State means a shortage of a medicinal product, for which there is no appropriate alternative medicinal product available on the market in that Member State.

A shortage: a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State.

Additional difference: **Nationally Authorised Products** (NAPs) and **Centrally Authorised Products** (CAPs)

Source: Addressing medicine shortages in the EU today, tomorrow and beyond, European Commission

How does it work in practice – critical shortages in a member state

Member states submits notification of critical shortage of EMA

EMA circulates the shortage notification to SPOC WP and asks for criticality assessment

All other member states respond with relevant information on criticality, availability of alternatives and any other relevant info (using a shared workspace)

If shortage is critical in multiple member states, EMA will request that submitting NCA bring the topic for discussion at the SPOC WP

EMA works on mitigating or preventing the shortage (discussions with manufacturers, contacting alternative suppliers, understanding supply chain situation across EU/EEA, publishing relevant communications, etc)

Escalation to MSSG, if necessary

How does it work in practice – shortages notified directly to EMA

EMA receives notification of shortage from MAH or other source (usually centrally authorised products via ESMP)

EMA reviews and triages the notification and determines whether additional follow up needed (e.g. if multiple countries seriously affected, or medicine is sole treatment for critical illness etc)

If shortage is considered concerning, EMA discusses with MAH to understand root cause and overall shortage situation.

EMA requests criticality assessment from SPOC WP.

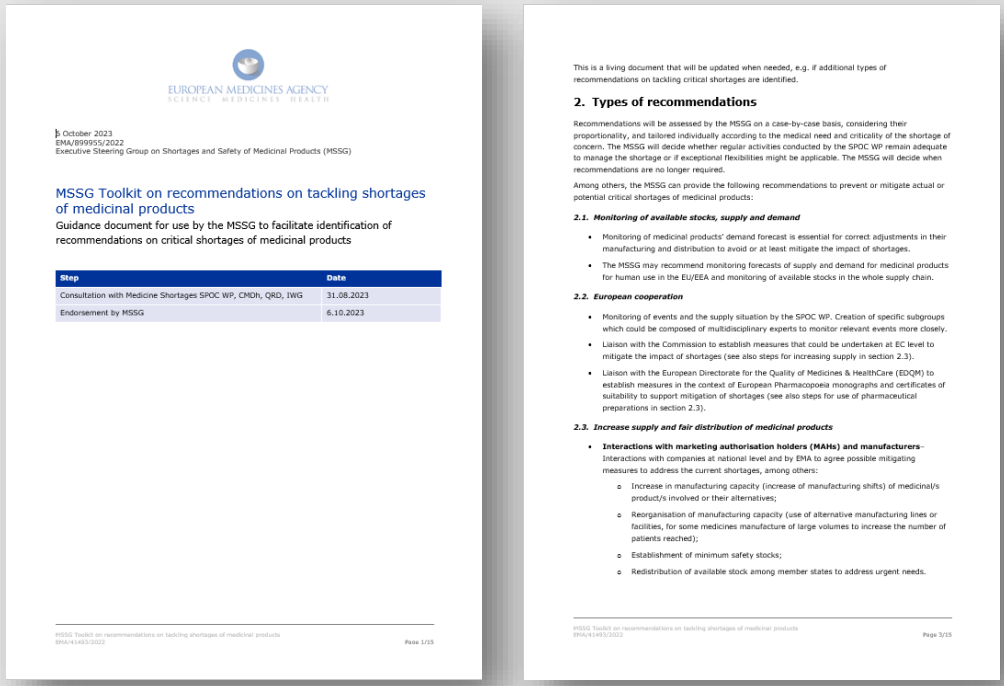
If shortage is considered critical for multiple member states, the topic is brought to the next SPOC WP for further discussion and possible action/escalation

EMA works to mitigate shortage impact, liaising with MAHs, NCAs, and other stakeholders as needed.

Escalation to MSSG, if necessary

MSSG toolkit of recommendations to tackle critical shortages

- **European and International cooperation** — MSSG, SPOC WP, EU institutions, international regulators
- **Communication** — Shortage catalogue, letters to healthcare professionals, public statements, recommendations on alternatives
- **Stakeholder engagement** — industry presentations to MSSG, liaison with supply chain stakeholders
- **Increased supply** — Increase production capacity, reallocation, importation of unauthorised products, magistral formulations
- **Controlled distribution** — Rationing measures, limiting online sale, restrictions on sale in community pharmacies
- **Regulatory flexibilities** — Labelling exemptions, extension of shelf life, accelerating supply-critical variations, liaison with EDQM* (CEP acceleration)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October 2023
EMA/899955/2022
Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

MSSG Toolkit on recommendations on tackling shortages of medicinal products

Guidance document for use by the MSSG to facilitate identification of recommendations on critical shortages of medicinal products

Step	Date
Consultation with Medicine Shortages SPOC WP, CMDh, QRD, IWG	31.08.2023
Endorsement by MSSG	6.10.2023

This is a living document that will be updated when needed, e.g. if additional types of recommendations on tackling critical shortages are identified.

2. Types of recommendations

Recommendations will be assessed by the MSSG on a case-by-case basis, considering their proportionality, and tailored individually according to the medical need and criticality of the shortage of concern. The MSSG will decide whether regular activities conducted by the SPOC WP remain adequate to manage the shortage or if exceptional flexibilities might be applicable. The MSSG will decide when recommendations are no longer required.

Among others, the MSSG can provide the following recommendations to prevent or mitigate actual or potential critical shortages of medicinal products:

2.1. Monitoring of available stocks, supply and demand

- Monitoring of medicinal products' demand forecast is essential for correct adjustments in their manufacturing and distribution to avoid or at least mitigate the impact of shortages.
- The MSSG may recommend monitoring forecasts of supply and demand for medicinal products for human use in the EU/EEA and monitoring of available stocks in the whole supply chain.

2.2. European cooperation

- Monitoring of events and the supply situation by the SPOC WP. Creation of specific subgroups which could be composed of multidisciplinary experts to monitor relevant events more closely.
- Liaison with the Commission to establish measures that could be undertaken at EC level to mitigate the impact of shortages (see also steps for increasing supply in section 2.3).
- Liaison with the European Directorate for the Quality of Medicines & HealthCare (EDQM) to establish measures in the context of European Pharmacopoeia monographs and certificates of suitability to support mitigation of shortages (see also steps for use of pharmaceutical preparations in section 2.3).

2.3. Increase supply and fair distribution of medicinal products

- **Interactions with marketing authorisation holders (MAHs) and manufacturers**– Interactions with companies at national level and by EMA to agree possible mitigating measures to address the current shortages, among others:
  - Increase in manufacturing capacity (increase of manufacturing shifts) of medicinal/s product/s involved or their alternatives;
  - Reorganisation of manufacturing capacity (use of alternative manufacturing lines or facilities, for some medicines manufacture of large volumes to increase the number of patients reached);
  - Establishment of minimum safety stocks;
  - Redistribution of available stock among member states to address urgent needs.

MSSG Toolkit on recommendations on tackling shortages of medicinal products

*EDQM- European Directorate for the Quality of Medicines & HealthCare
CEP - Certification of suitability to the monographs of the European Pharmacopoeia

Prevention of medicine shortages: long term measures

Moving from a reactive to a proactive approach

Prevention of shortages of critical medicines cannot be addressed through regulatory (MSSG) recommendations alone.

Inclusion on Union list/ Vulnerability Assessment

Will inform provisions in the **Critical Medicines Act**

Longer term measures
Strategic Projects; Public Procurement; Collaborative Procurement, State aid, International partnerships

Critical medicines are available to treat patients in the EU at all times

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Thank you

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