

# Monitoring of supply for immunoglobulins

Monitoring, prevention and  
mitigating shortages of critical  
medicines

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Improving the availability of medicines authorised in the EU is a key priority for the **European Medicines Regulatory Network (EMRN)**



Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur



The joint **HMA/EMA Task Force on the Availability of Authorised Medicines** for Human and Veterinary Use (TF-AAM) provides **strategic support** to tackle disruptions in medicine supply and ensure availability



The EMA's role in **crisis preparedness and management** in reference to availability of medicinal products has increased significantly following the outbreak of the Covid-19 pandemic. **Regulation 2022/123** formalises the structures and processes established during the pandemic.



Provides a framework for activities established by the European Medicines Agency to monitor and **mitigate potential and actual shortages of medicines**



Sets **processes/tools for shortages reporting** and coordinates **responses** of EU countries to shortages of critical medicines during crisis and for monitoring of events which might lead to a crisis situation

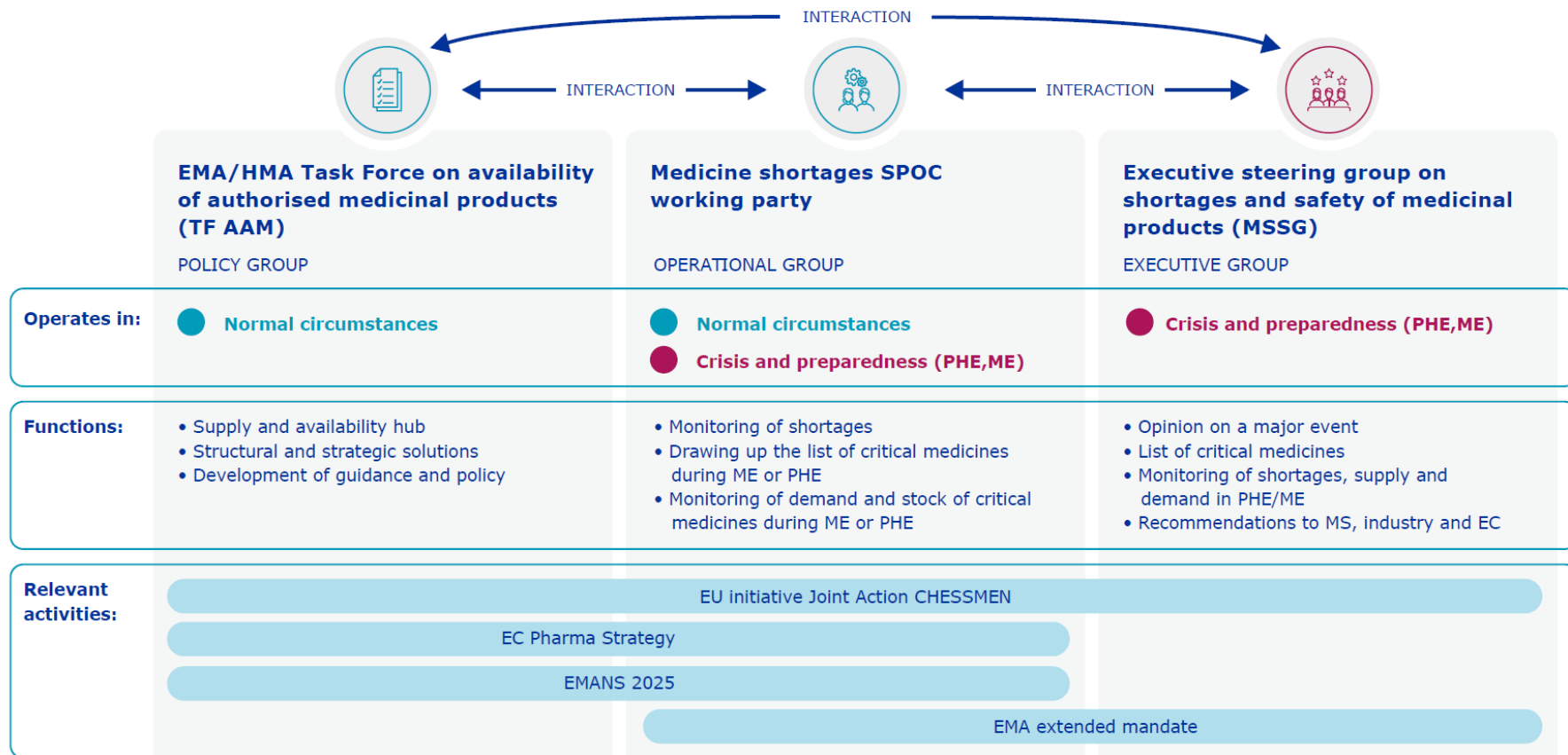


Established the “**Medicines Shortages Steering Group**” (MSSG) supported by the **SPOC Working Party** and a Network of contact points from pharmaceutical companies (MAH i-SPOCs)

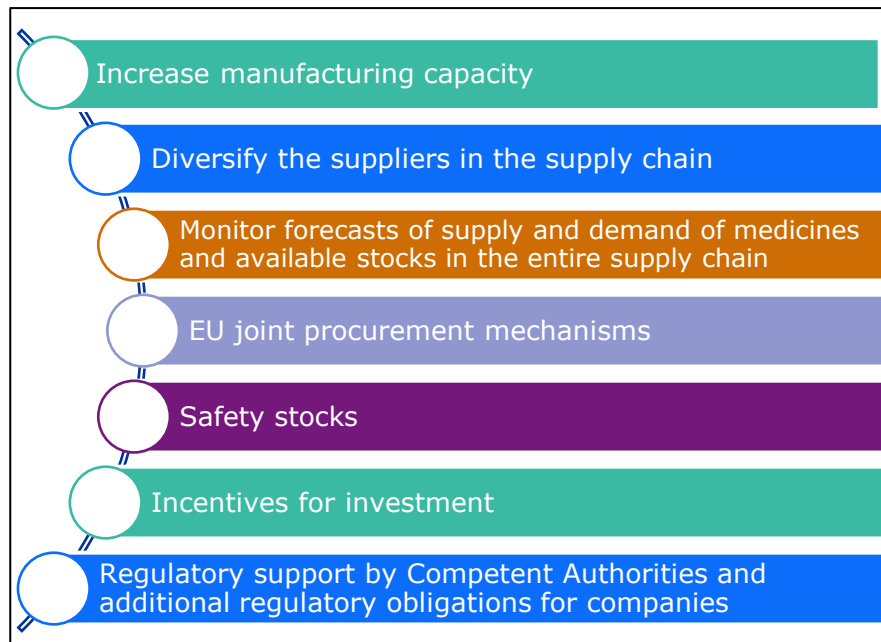


Foresees the development of the **European Shortages Monitoring Platform** (ESMP) by February 2025

# Availability of medicines: EU level coordination

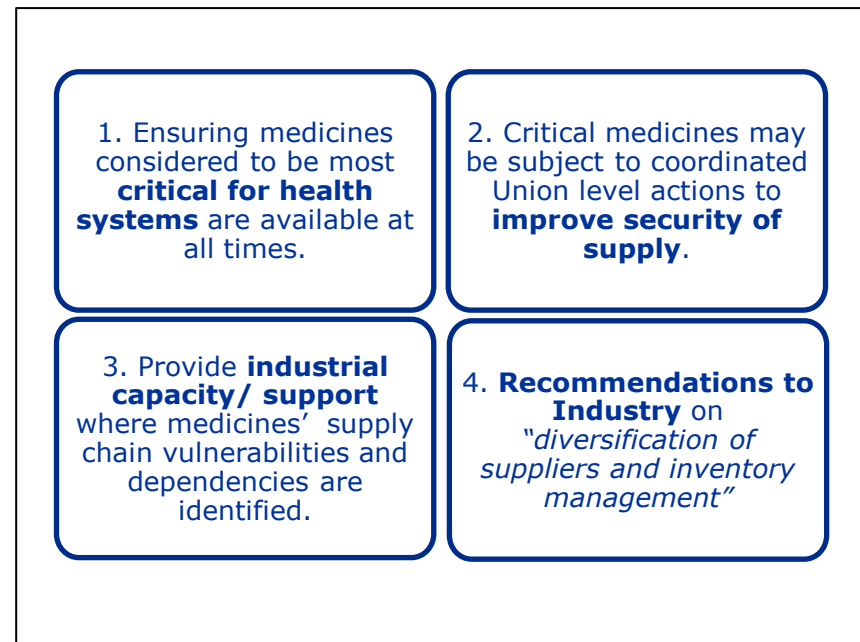


## Recommendations to strengthen supply chains of critical medicinal products



[MSSG recommendations to strengthen supply chains of critical medicinal products](#)

## Union List of critical medicines



[First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU | European Medicines Agency \(EMA\)](#)

## International cooperation

### Global Regulatory Working Group on Drug Shortages

- Meets every quarter and share information about relevant drug supply issues (exchange of information and support each other)
- International cooperation on Drug Shortage Reporting, Signal Detection and Signal Assessment
- International cooperation and alignment on shortage mitigation and prevention strategies

### Bilateral exchanges with e.g. FDA, HC, TGA, etc

- Shortages of concern to both regions
- Exchanges of best practices to mitigate and prevent shortages

## MSSG Solidarity Mechanism

The VSM is used as a **last resort** to **temporarily alleviate critical shortages in a Member State**.



Allows a MS to **request assistance** from other Member States in obtaining stocks of a medicine **during critical shortages**

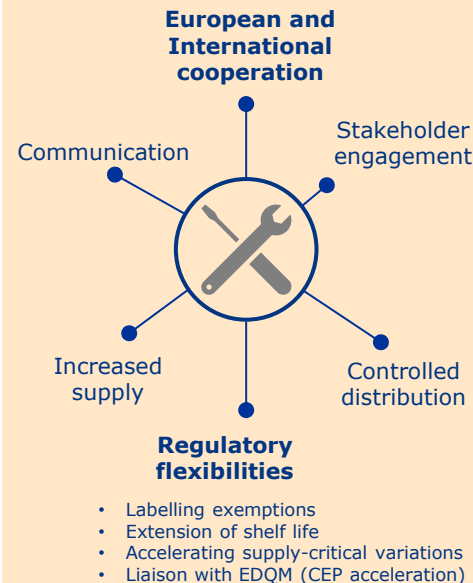
4 VSM procedures concluded, all successfully

Conditions:

1. EMA already notified of the shortage (SPOC WP)
2. No or insufficient therapeutic alternatives available
3. Insufficient quantities to treat critical indications
4. No or insufficient relief from short-term measures
5. Urgency (e.g., < 1 month supply)

[MSSG Solidarity mechanism process \(europa.eu\)](https://european-council.europa.eu/media/en/press-room/pages/press-room-detail.aspx?lang=en&id=12345)

## MSSG Toolkit



[MSSG recommendations toolkit \(europa.eu\)](https://european-council.europa.eu/media/en/press-room/pages/press-room-detail.aspx?lang=en&id=12345)

- The MSSG, supported by the SPOC WP, continues to ensure a robust response to medicine supply issues under **preparedness activities or during a major events/public-health emergencies**. It coordinates urgent actions within the European Union (EU) to manage medicine supply issues.
- **Shift** from a reactive (**management**) approach to a proactive (**prevention**) approach to ensure supply of medicines.
- **New EU pharmaceutical legislation** proposal currently under negotiation, together with the initiatives foreseen in the **European Commission Communication on tackling medicine shortages in the EU, including the CMA** will further reinforce security of supply for critical medicines and prevention of shortages.
- EMA continues to monitor shortages of immunoglobulins through the SPOC WP and the MSSG is currently developing a set of recommendations for Rho(D) immune globulins/ Anti-D immunoglobulins.



# Any questions?

## Further information

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