

How Shortages Are handled in the EU

Joint Meeting of CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients' and Consumers' Working Party (PCWP)

Klaus Krutwig
Medicines and Medical Devices Shortages Specialist,
EMA



Shortages management in the EU



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



EMA extended mandate: Monitoring and mitigating shortages of critical medicines

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.

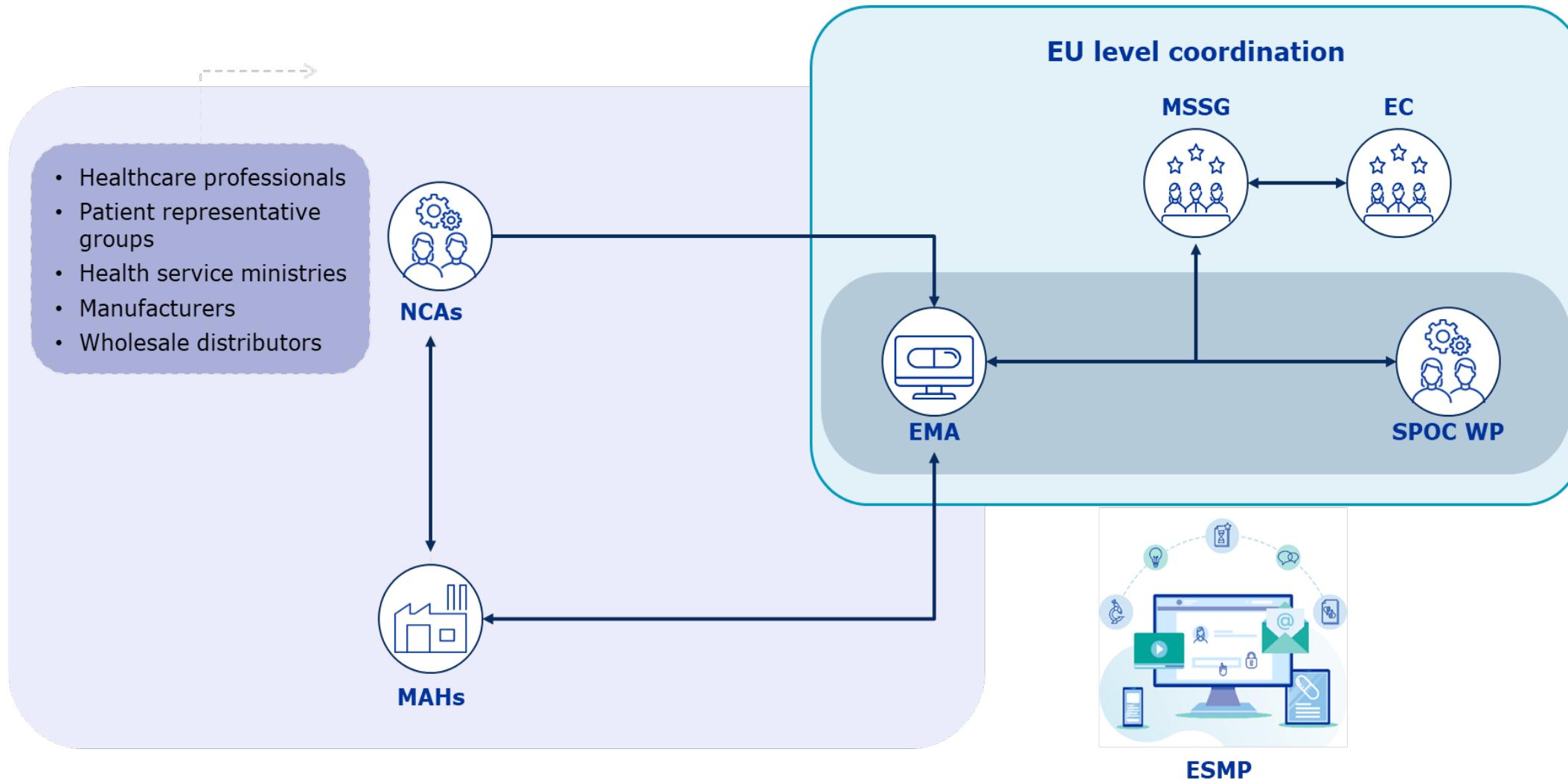
Provides a framework for activities established by the European Medicines Agency to monitor and **mitigate potential and actual shortages of medicines**

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.

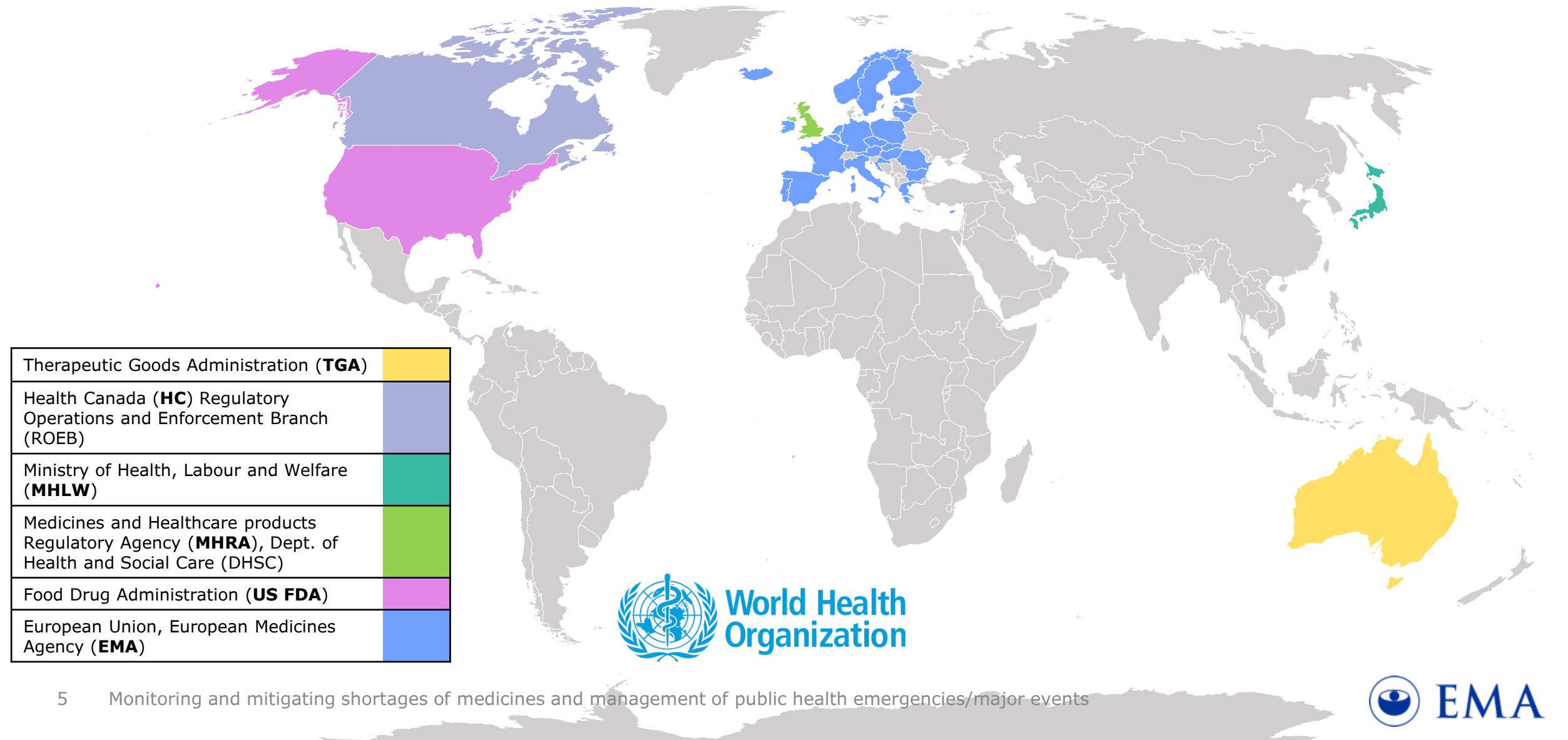
Established the **"Medicines Shortages Steering Group"** (MSSG) supported by the **SPOC Working Party** and a Network of contact points from pharmaceutical companies (MAH i-SPOCs)

Establishment of the **European Shortages Monitoring Platform** (ESMP) in January 2025

National and EU level coordination



International collaboration: Drug Shortages Global Regulatory (DSGR) Working Group

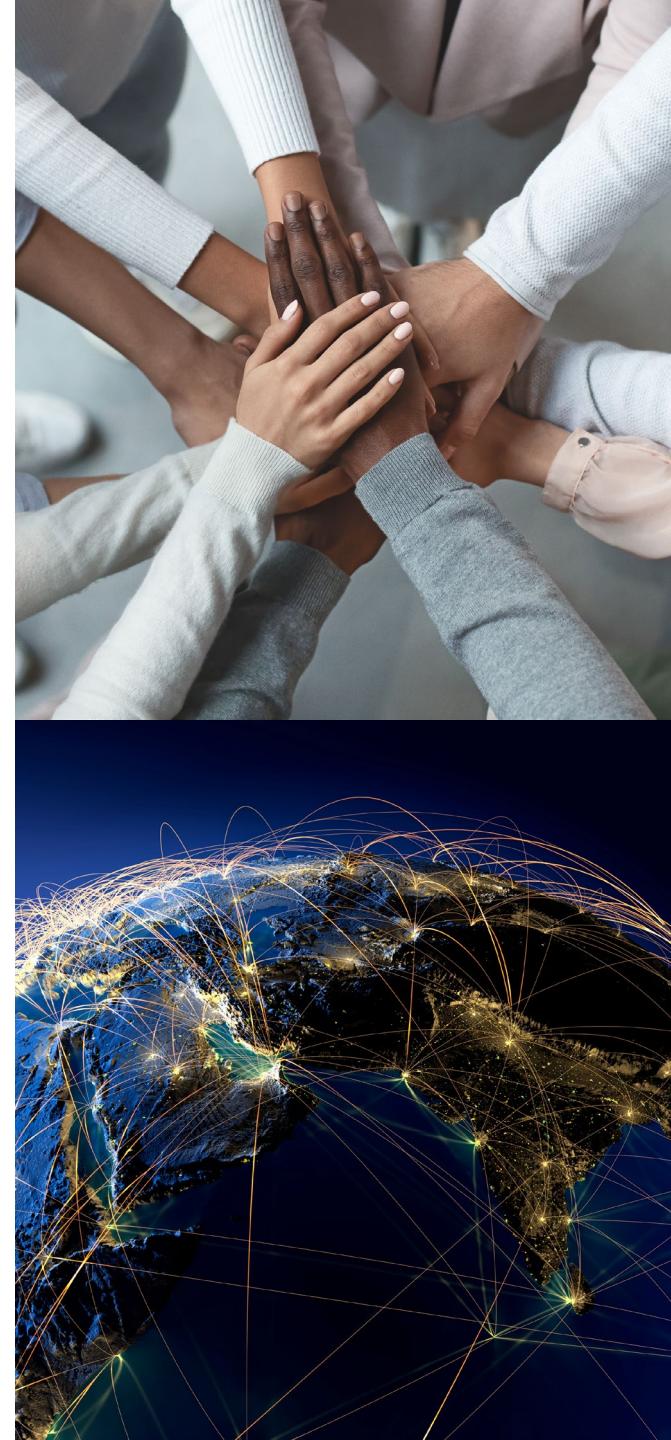


Mission & scope

The Drug Shortages Global Regulatory Working Group is an **international forum of medicine regulators**, established to **share** information about **shortages** of medicines with a **global impact** and the actions taken in each jurisdiction to prevent, monitor and mitigate their impact. In addition, relevant policy measures and best practices to address shortages are discussed.

In previous years, the Working Group's exchange of information helped address medicines' shortages during the **COVID-19 pandemic**. Further global issues in which **international cooperation is key** relate to shortages of **antibiotics** and **Glucagon-Like Peptide-1 receptor agonists (GLP-1 RA)**

The Working Group meets on a **quarterly basis**, with the possibility of subgroup meetings, and regular exchanges on shortages related topics.



Availability of medicines: EU level coordination



Operational group

Medicine Shortages SPOC Working Party

- Monitoring and mitigation at all times
- List of critical medicines during a PHE/ME
- Monitoring of demand and stock during a PHE/ME

Subgroups:

SPOC WP SG on GLP1-RAs

SPOC WP SG on immunoglobulins

SPOC WP SG on definition of shortage

SPOC WP SG on crisis monitoring

SPOC WP SG on EMANS 2028



Executive group

Executive Steering Group on Shortages and Safety of medicinal products (MSSG)

- Monitoring of events, including shortages
- Recommendations
- List of main therapeutic groups of medicines, list of critical medicines for PHE/ME
- Monitoring of shortages, supply, and demand during PHE/ME
- Recommendations and opinion on ME

Working Groups:

MSSG WG on ESMP

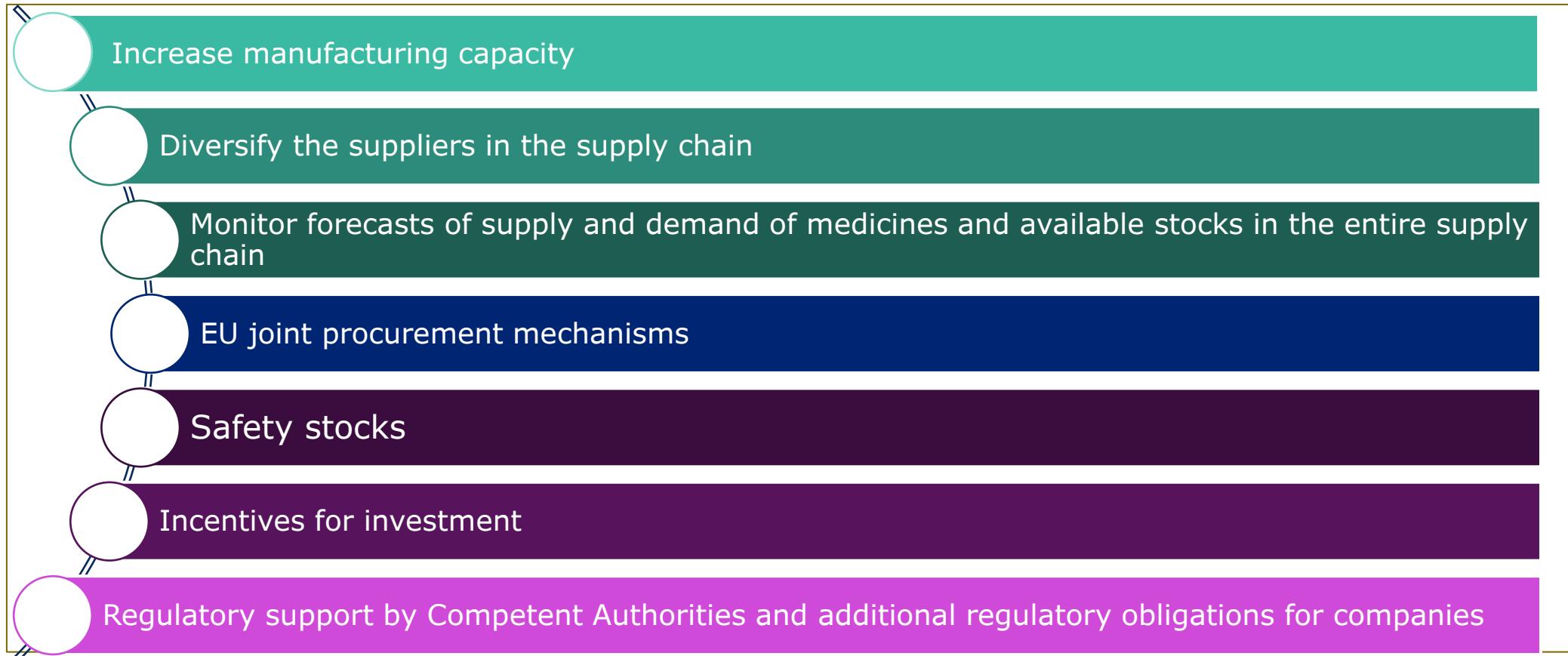
MSSG WG on Vulnerability Assessment Methodology

MSSG WG on VSM and policy

Normal Circumstances, preparedness and Crisis

MSSG recommendations to strengthen supply chains of critical medicinal products

Guidance document to facilitate the identification of regulatory measures to strengthen supply chains of critical medicinal products in the Union list



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

Mitigating the impact of critical medicine shortages

MSSG Solidarity Mechanism

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

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

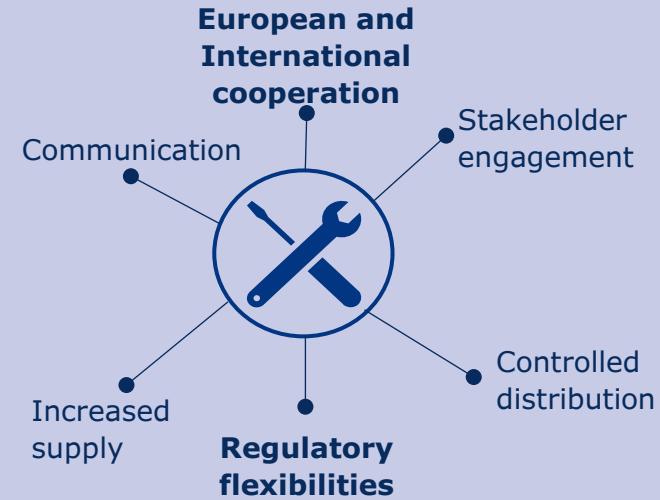
7 VSM procedures concluded in 2024, all successfully

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 \(europa.eu\)](http://europa.eu)

MSSG Toolkit



Regulatory flexibilities

- Labelling exemptions
- Extension of shelf life
- Accelerating supply-critical variations
- Liaison with EDQM (CEP acceleration)

[MSSG recommendations toolkit \(europa.eu\)](http://europa.eu)

Case study: Initiatives for monitoring and addressing the supply of PDMPs



Medicine shortages SPOC working party

Surveys mapping shortages and availability issues of IV/SC human normal immunoglobulins and investigating root causes

Subgroup of the SPOC WP on supply and availability of immunoglobulins set up in February 2022.

Discussions and presentations in SPOC WP meetings on supply and availability of immunoglobulins



Executive steering group on shortages and safety of medicinal products (MSSG)

Shortages of immunoglobulins have been discussed in the SPOC WP since 2019 and **brought to the attention of the MSSG**

MSSG is currently developing a set of **recommendations for Rho(D) immune globulins/ Anti-D immunoglobulins.**

Other activities

Breakout session on immunoglobulins supply as part of a two-day EMA/HMA multistakeholder workshop on shortages on 1 March 2023.

Publication of a shortage catalogue entry for normal human immunoglobulins on 3 June 2024.

Foster information exchange via regular meetings with the EC SoHO team, EDQM and ECDC, as well as blood cluster meetings ((with FDA and HC) to discuss issues of common interest

The screenshot shows a page from the European Medicines Agency (EMA) website. The title is "Shortage of human normal immunoglobulins". The page contains the following information:

- What are human normal immunoglobulins used for?** Human normal immunoglobulins are highly purified proteins extracted from donated human blood. They contain mainly immunoglobulin G (IgG), a class of antibody with a wide range of activity against pathogens that can cause infection.
- Reason for shortage** There have been shortages of several medicines containing human normal immunoglobulins, particularly by injection, in the European Union (EU) and the European Economic Area (EEA). The cause of the shortages are multifactorial and include an unexpected increase in demand. These shortages affect medicines authorised across the EU/EEA as well as several medicines authorised at national level. They are expected to occur throughout 2024.
- Member States affected** The following countries are affected by the shortages: Austria, Belgium, Croatia, France, Hungary, Italy, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.
- Monitoring of shortage** EMA's SPOC working party is closely monitoring the supply situation and engaging with the marketing authorisation holders to identify measures to mitigate the impact of the supply shortage.

Union list of critical medicine

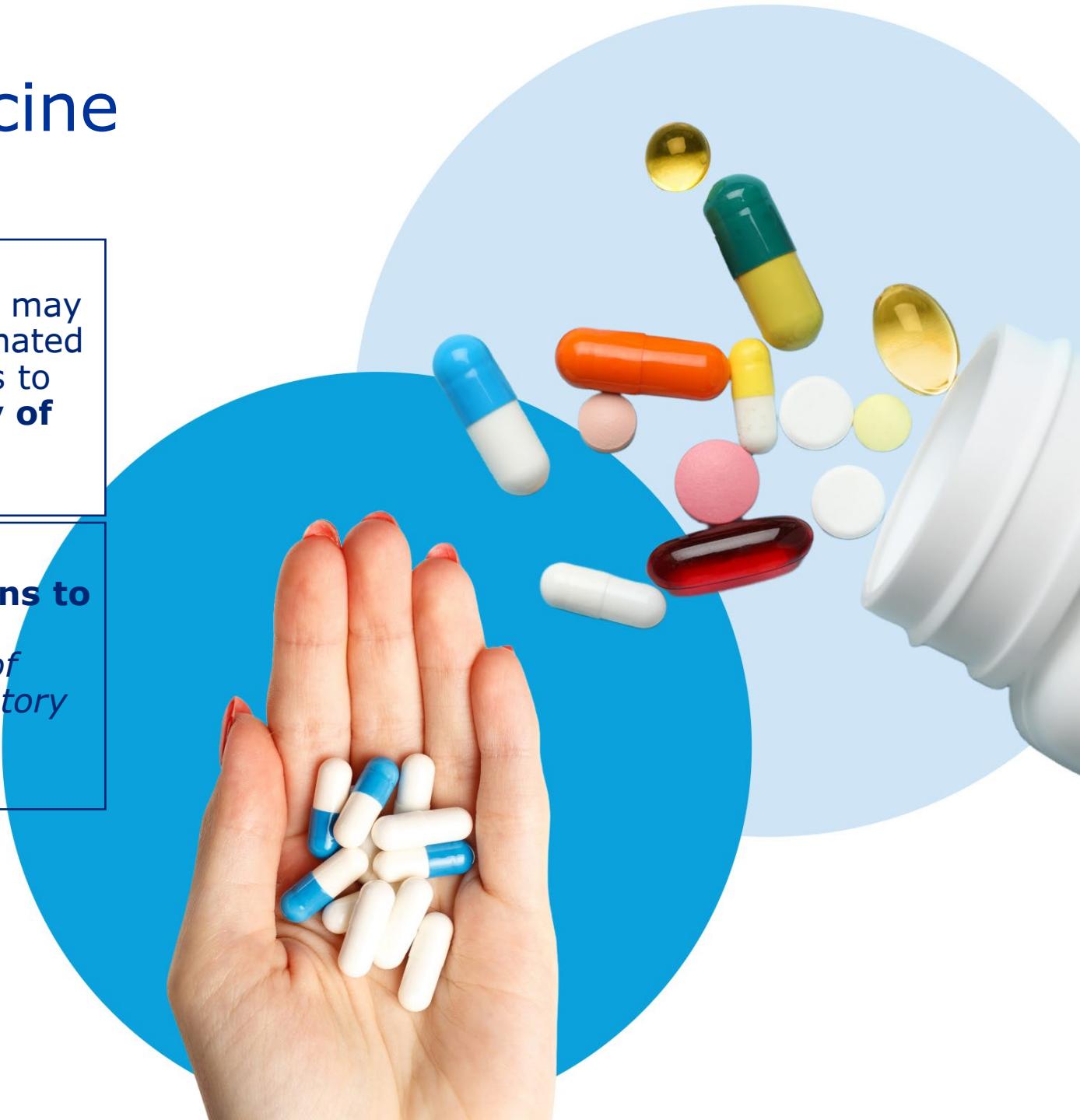
1. Ensuring medicines considered to be most **critical for health systems** are available at all times.

2. Critical medicines may be subject to coordinated Union level actions to **improve security of supply**.

3. Provide **industrial capacity/ support** where medicines' supply chain vulnerabilities and dependencies are identified.

4. **Recommendations to Industry** on *“diversification of suppliers and inventory management”*

[Union list of critical medicines](#)



Security of supply of critical medicines

Reform of the EU pharmaceutical legislation

Proposal for a new Directive and a new Regulation, which revise and replace the existing general pharmaceutical legislation

Union list of critical medicines

Preventing issues with the supply and availability of critical medicines at European level

Vulnerability analysis

Resilience of critical medicines supply chains

MSSG recommendations

Targeted Recommendations of the MSSG to address supply chain vulnerabilities of critical medicines

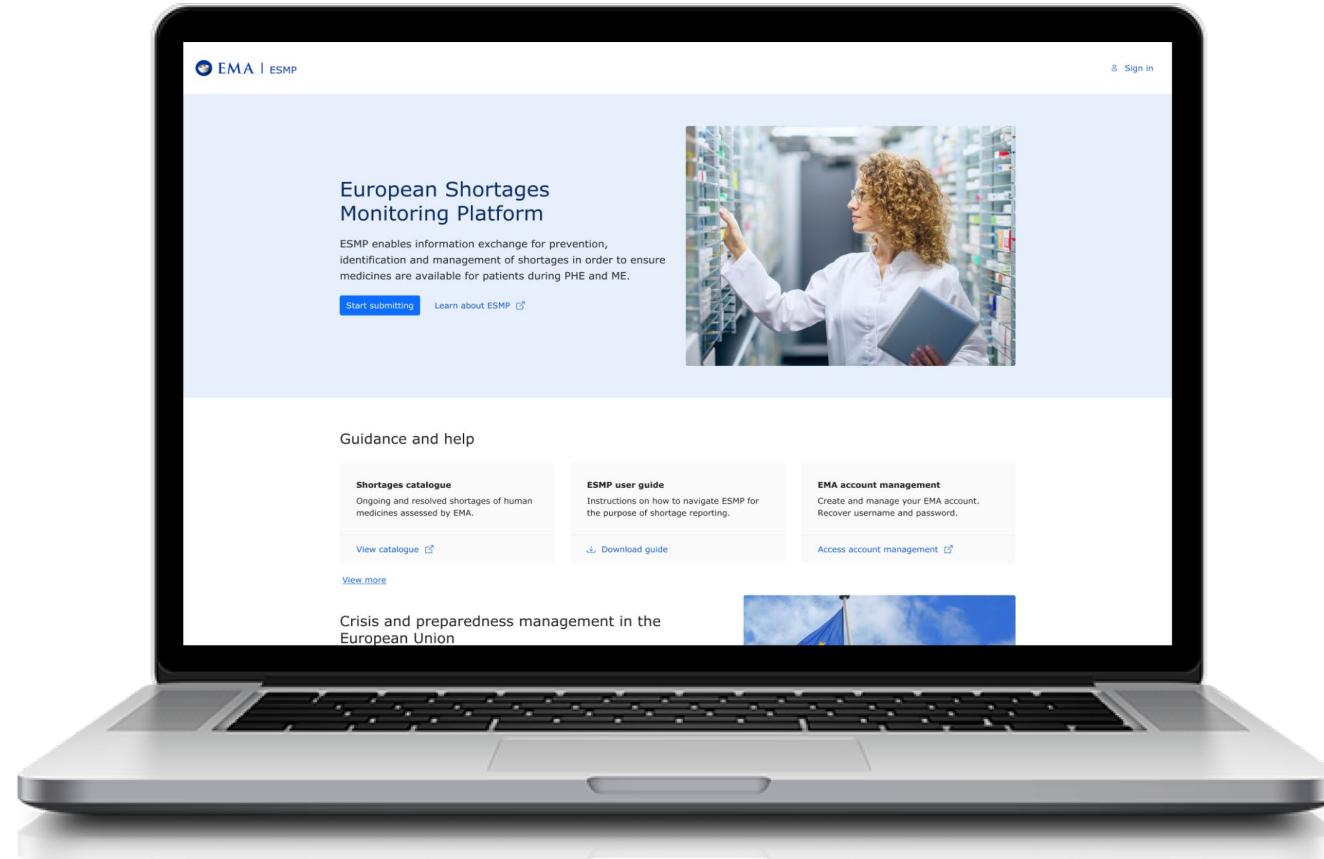
Critical Medicines Act (CMA)

Provisions in CMA will ensure industrial policy measures and complement the MSSG recommendations

The European Shortages Monitoring Platform (ESMP)

The ESMP is a harmonised, transparent, and collaborative IT platform for ensuring medicines are available when and where they are needed most.

- designed to improve the **prevention, monitoring, and management** of medicines **shortages** across the EU/EEA
- It centralises and automate **data collection on medicine shortages**, giving access to real-time and comprehensive information.



Conclusions

- The MSSG, supported by the SPOC WP, continues to ensure a robust response to medicine supply issues under **preparedness activities and 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 Critical Medicines Act** will further reinforce security of supply for critical medicines and prevention of shortages.
- EMA continues to monitor critical shortages of medicines, including through the SPOC WP.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

klaus.krutwig@ema.europa.eu

Follow us

