



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Monitoring and mitigating **shortages of medicines** and management of public health emergencies/major events

23-24 April 2024 The Supply of Plasma-Derived Medicinal Products in the Future of Europe

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An agency of the European Union





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Monitoring and mitigating **shortages of medicines** and management of public health emergencies/major events



Regulation (EU) 2022/123

- 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 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 of the **European Shortages Monitoring Platform** (ESMP) by Feb 2025



KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU



Crisis and preparedness (PHEs, MEs)



Normal Circumstances



EMA extended mandate



EC Pharma Strategy



EMANS 2025



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

Executive group

- Opinion on a major event
- List of critical medicines
- Monitoring of shortages, supply and demand in PHE/ME
- Recommendations to MS, industry and EC



Medicine Shortages SPOC Working Party

Operational group

- Monitoring critical shortages and events that could lead to a major event or public health emergency and reporting these to the MSSG (war in Ukraine, antibiotics, thrombolytics)
- Drawing up lists of critical medicines during a major event and during a public-health emergency at the request of MSSG

EMA/HMA Task Force on availability of authorized medicinal products (TF AAM)

(TF AAM)

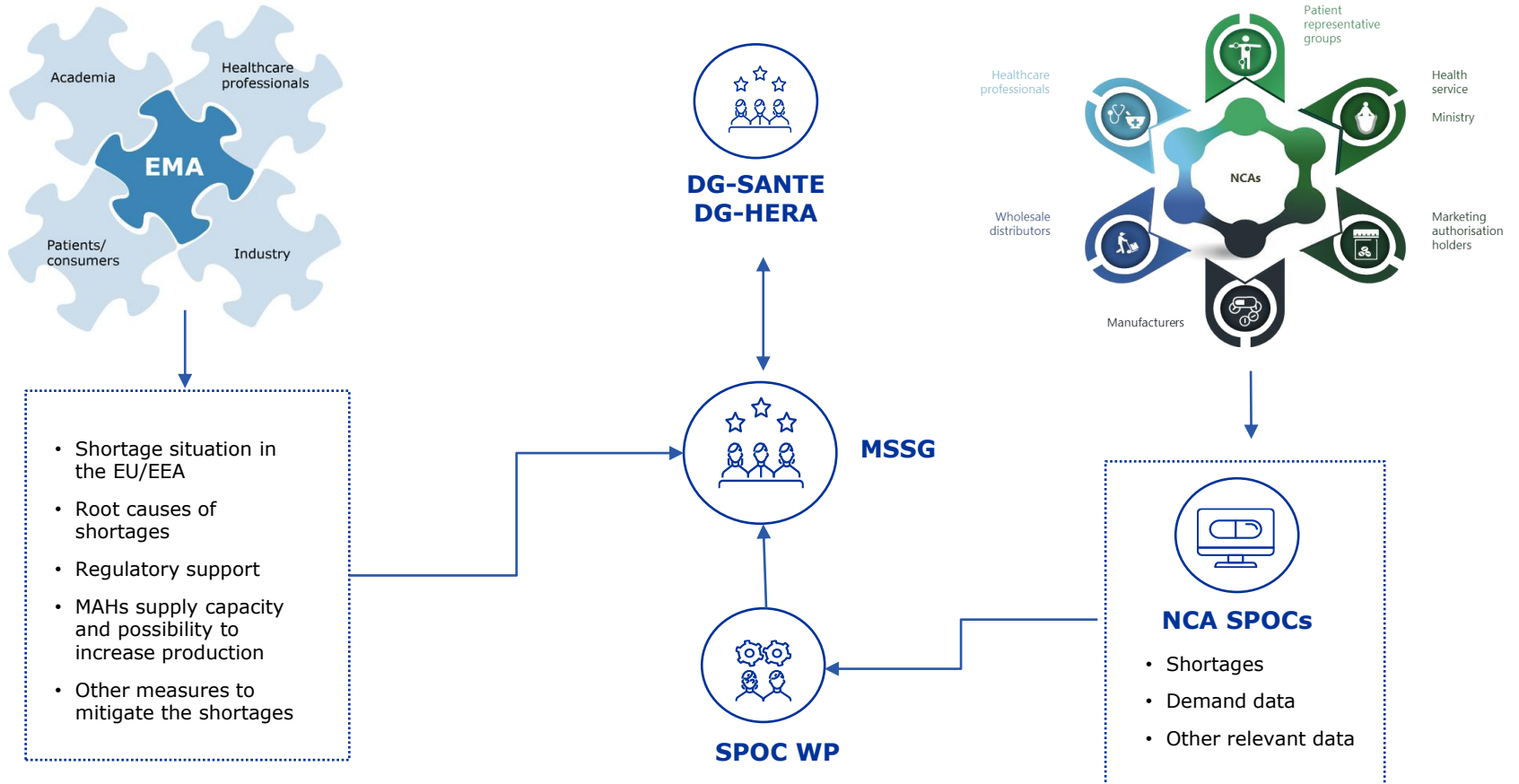
Policy group

- Supply and availability hub
- Structural and strategic solutions
- Development of guidance and policy



Joint Action on Shortages

Preparedness activities: interactions with stakeholders





Union list of Critical Medicines



Objectives & scope

1. Ensuring medicines considered most **critical for health systems** are always available.

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

3. Enable Short- to Medium^{1*} and long-term^{2*} **Supply Security measures**



1. Suppliers' diversification or increase production within the EU,
2. Investment incentives,
3. Additional regulatory obligations for companies,
4. Procurement with strong contractual obligations for delivery.

1) October 23 - EC Communication in addressing critical shortages of medicines in the EU (short-/medium-term proposals): https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5190

2) April 2023 - Proposal for Regulation (long-term proposals): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0193>

Methodology: criteria

Categorization of medicines in three groups

Critical medicines

Medicines at risk

Other medicines

Risk classification based on two criteria (with three risk levels each)



Criterion 1

Therapeutic indication
High, medium, low risk



Criterion 2

Availability of alternatives
High, medium, low risk







Categorization according to a risk matrix





Union list of critical medicines - Immunoglobulins

  		
EMA/528805/2023		
6 December 2023		
Union list of critical medicines - version 1		
ATC level 5	ATC description	Date of inclusion
<input type="checkbox"/>	The Anatomical Therapeutic Chemical code: a unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO).	<input type="checkbox"/>
J06BA01	HUMAN NORMAL IMMUNOGLOBULIN (extravascular use)	1 December 2023
J06BA02	HUMAN NORMAL IMMUNOGLOBULIN (intravascular use)	1 December 2023
J06BB01	HUMAN ANTI-D IMMUNOGLOBULIN	1 December 2023
J06BB02	HUMAN TETANUS IMMUNOGLOBULIN	1 December 2023
J06BB05	HUMAN RABIES IMMUNOGLOBULIN	1 December 2023
See websites for contact details		
Heads of Medicines Agencies www.hma.eu European Medicines Agency www.ema.europa.eu European Commission www.commission.europa.eu		
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- The current list reflects the outcome of the review of 600 active substances and combinations of active substances from existing national lists of critical medicines.
- It will be updated and extended in 2024 after the review of medicines that are not included in those national lists.
- [Availability of critical medicines](#)



Conclusion and next steps

- EMA continues to monitor shortages of immunoglobulins through the SPOC WP
- EMA will continue to facilitate regular dialogue with MAHs to obtain a detailed overview of the availability of immunoglobulins and to discuss potential support measures to prevent or mitigate shortages in the EU/EEA.
- The union list of critical medicines to be a living document, subject to continuous review and potential update.
- The list is contributing to the EC's exercise to analyse the supply chain of critical medicines to determine potential vulnerabilities and identify regulatory measures (MSSG) and/or industrial policy measures (CMA) to address those.



Any questions?

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