EMA
EUROPEAN MEDICINES AGENCY

Shortage mitigation and management at EU level

Reuniao Anual do Colegio de Especialidade em Assuntos Regulamentares 2026

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The evolution of shortage management in the EU

2012
Quality defects leading to shortages of medicines, publication of **reflection paper**

2016
HMA/EMA Task Force on the **Availability of Authorised Medicines** for Human and Veterinary Use

2019
EU single point of contact (**SPOC**) network

2020
Coordinated efforts to manage **COVID-19 supply** challenges

2022
EMA **mandate extension** implementation (**MSSG/SPOC WP**)

April 2023
Proposal for **reform** of **EU Pharmaceutical legislation**

October 2023
EC **Communication** on addressing **medicines shortages** in the EU

NPL

March 2025
Proposal for the **Critical Medicines Act** (CMA)

March 2026
Agreed **NPL text**

May 2026
Agreed **CMA text**

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Legal framework of TRS-SAM's activities

EMA Extended Mandate

- Preparedness and crisis management.
- Improved coordination at EU level.

New pharmaceutical legislation

Chapter X — Section I: Monitoring and management

Coordinated EU level monitoring and management of **critical shortages at all times.**

Chapter X — Section II: Prevention

Security of supply of medicines on **the Union list of critical medicines**, needed for health systems at all times.

Vulnerability assessment of supply chains of those critical medicines informs:

- MSSG Recommendations to address structural vulnerabilities
- Certain provisions in Critical Medicines Act

Critical Medicines Act

Providing industrial policy solutions to address vulnerabilities and strengthen supply of medicines in the EU.

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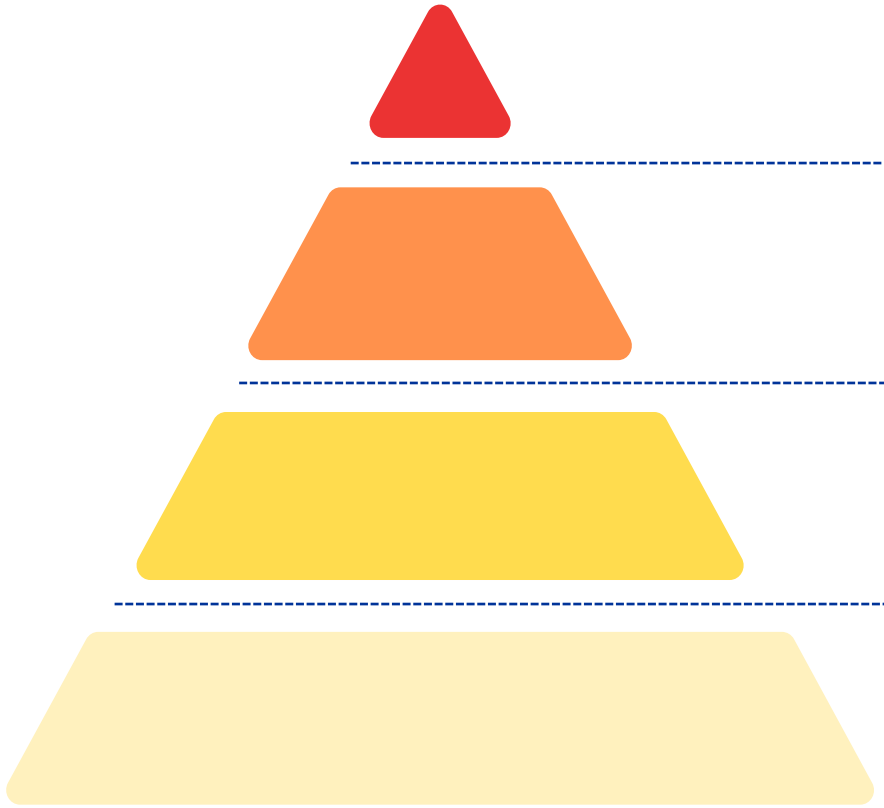
All shortages are different



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

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EU level coordination

Extended Mandate Implemented

Operational group

Medicine Shortages 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
- Monitoring of events that may lead to a Public Health Emergency (PHE) or Major Event (ME)
- Escalation to MSSG when appropriate

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 chains of critical medicines
- Adopts lists of critical medicinal products for a specific PHE/ME and makes recommendations to the EC, Member States and industry

Normal Circumstances, Preparedness and Crisis

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Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

Extended Mandate Implemented

- HERA
- Health Security Committee
- ECDC

- Emergency Task Force (ETF)
- Executive Steering Group on Shortages of Medical Devices (MDSSG)

Co-Chair:
Emer Cooke

Co-Chair:
Karl Broich (DE)

MSSG consists of:

- European Commission (DG SANTE, HERA)
- Member States (often HMA)
- EMA
- PCWP/HCPWP (as observers)

Invited observers — expert advice

Representatives of medicines interest groups:

- Industry associations
- Other relevant actors in the supply chain

Representatives of patients, consumers and health care professionals.

Industry Single Point of Contact (i-SPOC) Network

Medicines Shortages SPOC Working Party

Experts in specific scientific and technical fields

[Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) | European Medicines Agency (EMA)]

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Shortage management 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 is needed (e.g. if multiple countries seriously affected, or medicine is sole treatment for critical illness, etc.)

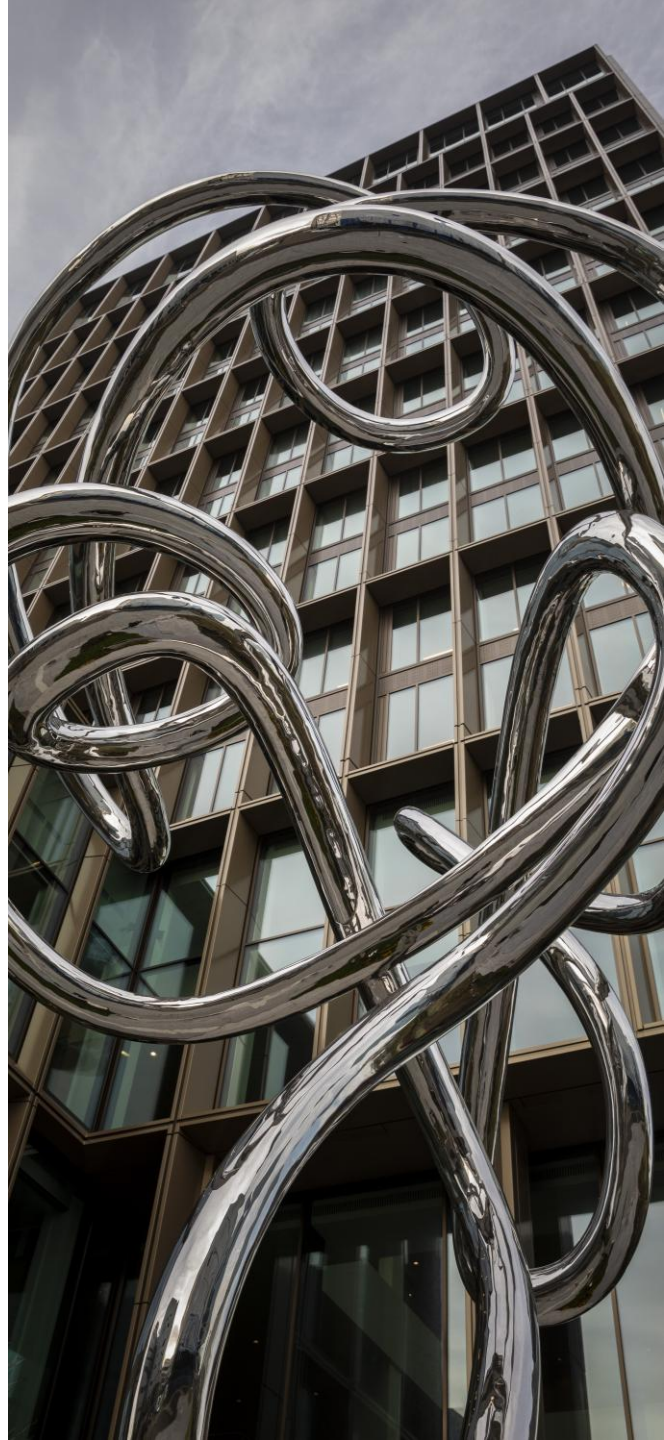
If shortage is considered concerning, EMA discusses with MAH to understand root cause and overall shortage situation.

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



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Shortage management in practice — critical shortages in a member state

Member states submits notification of critical shortage to 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

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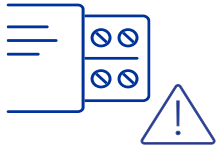
Example of shortage tackled at EU level: Metalyse

What it is used for

Dissolve blood clots during a heart attack or stroke



Causes of shortage

- Rising number of patients
- Manufacturing capacity constraints

Context

Complex manufacturing process

What EMA/EU did

- Goal: increase supply and prevent disposal of usable stocks
- Action
  - Allowed use beyond the expiration date, based on new data confirming this approach was safe
  - Communicated with healthcare professionals and the public
  - Approved a new manufacturing site in Austria with an accelerated process

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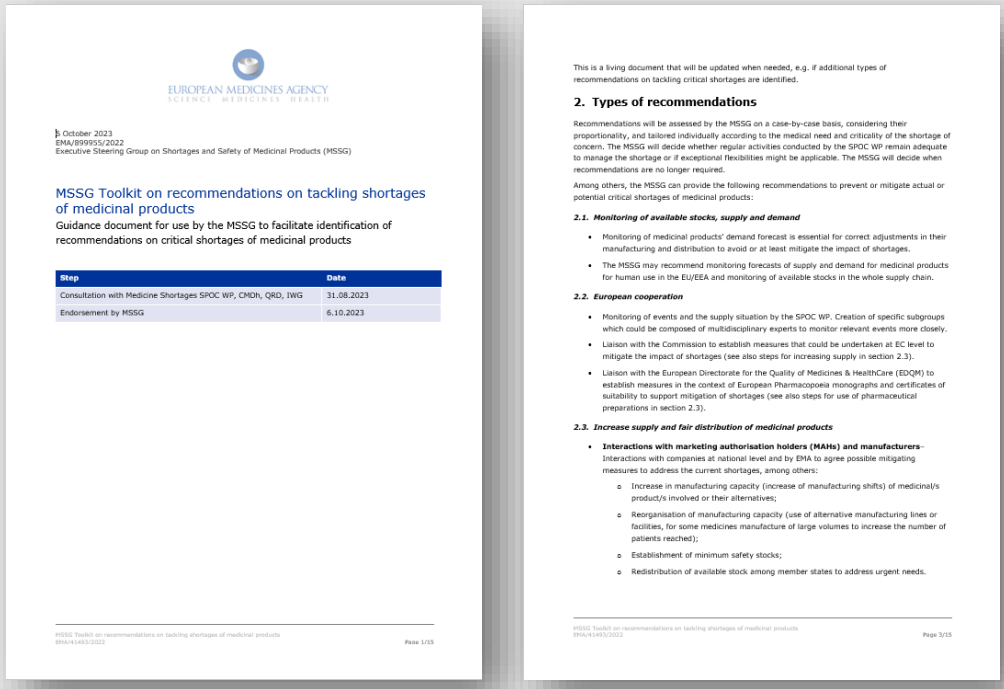
MSSG toolkit of recommendations to tackle critical shortages

- **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

MSSG Toolkit on recommendations on tackling shortages of medicinal products
EMA/41493/2022 Page 1/15

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
EMA/41493/2022 Page 3/15

[MSSG Toolkit on recommendations on tackling shortages of medicinal products, published October 2023]

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

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Voluntary Solidarity Mechanism

The solidarity mechanism is a **voluntary** mechanism which allows a Member State to request assistance from other Member States in **obtaining stocks*** of a medicine during critical shortages.

This mechanism should be used as the **last resort** when the MSs have exhausted all other possibilities.

EMA provides dedicated support to the triggering Member States with the submission of the request and any follow up actions.

Results:

- Pilot ran from March 2024 to September 2025
- Updated procedure published in November 2025
- 13 VSM procedures successfully completed in 2024 and 2025

** Different types of stock can be used (MAH, wholesaler, national safety stock)*

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Prevention of shortages

NPL
In progress

Moving from a **reactive** to a **proactive** approach

Union list of critical medicines

Vulnerability Assessment

Will inform industrial policy measures under the new **Critical Medicines Act**

MSSG recommendations, however, prevention of shortages of critical medicines cannot be addressed through regulatory alone.

Long term measures e.g. financial support for strategic projects that address vulnerabilities, procurement requirements that favour EU manufacturing and promote diversification

To ensure critical medicines are available to treat patients in the EU at all times

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Union list of critical medicines, Shortage Prevention and Mitigation Plans and the Vulnerability Assessment

NPL
In progress

Union list of critical medicines (ULCM)

- Details the **medicines considered critical** for the proper functioning of healthcare systems across the Union.
- Version 2 was published on the EMA website in December 2024 and will be subject to **annual reviews** to ensure that any changes in usage or availability of the active substances included are appropriately reflected.

Union list of critical medicines | European Medicines Agency (EMA)

Vulnerability Assessment (VA)

- Methodology to identify **vulnerabilities in the supply chains** of critical medicines on the Union list published in November of 2025.
- Outcome of the VA will inform both **MSSG recommendations** set out in **proposed pharmaceutical legislation** and certain provisions of proposed **Critical Medicines Act**.
- First set of **19 INNs** to be assessed in 2026 to inform policy decisions.

Shortage Prevention (SPP) and Mitigation (SMP) Plans

- **SMPs** will be key to inform the management of medicine shortages.
- **SPPs** will be key to ensure marketing authorisation holders have appropriate systems and processes in place to ensure continued and secure supply of medicines.
- The SPP and SMP templates are being updated to address the findings of the pilot (closed September 2025) and to align with the NPL.

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European Shortages Monitoring Platform overview

Extended Mandate Implemented

NPL In progress

PREVENTION

Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration

MONITORING

Analysis & reporting

- Matching supply & demand
- Reporting findings and results
- Public reports

Case management

- Maintain critical medicinal product lists
- Evaluate and manage medicines shortages

MANAGEMENT

Data integration

- EMA data management (SPOR, IAM, IRIS integration)
- Interoperability with NCA and Industry systems

Platform for MAHs

Platform for NCAs

Secure access

Platform for general public

Open access

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International Cooperation

Drug Shortages Global Regulatory Working Group

- International cooperation and alignment on shortage mitigation and prevention strategies
- EMA chairs group in 2025–2026

Bilateral exchanges with e.g. FDA, Heath Canada, TGA, etc.

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

International Coalition of Medicines Regulatory Authorities (ICMRA)

- Cooperation and coordination

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Thank you

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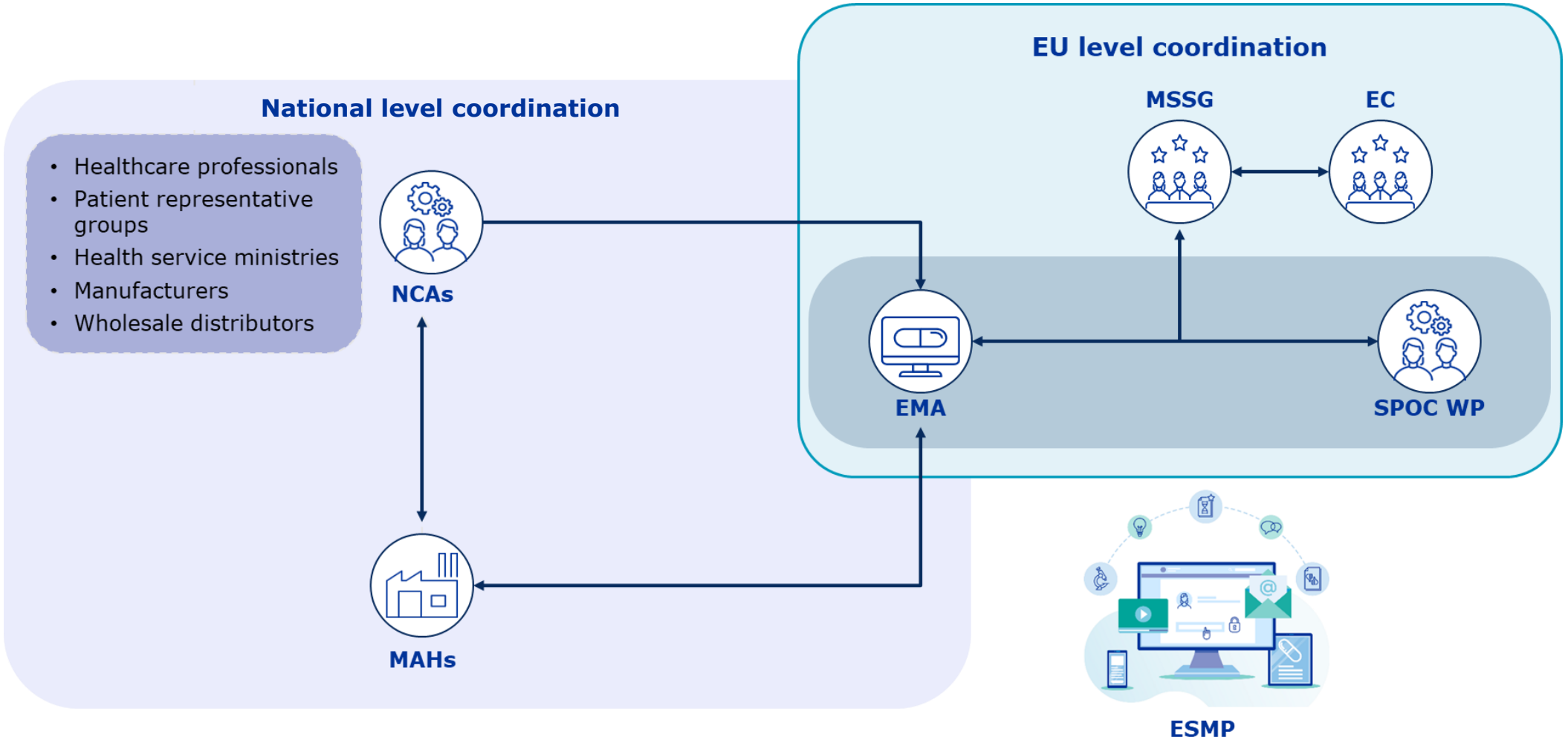
National and EU level coordination



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

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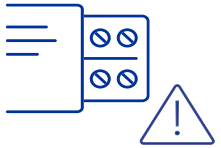
Example of shortage tackled at EU level: Visudyne

What it is used for

Macular degeneration due to age and a severe type of myopia called choroidal neovascularisation



Cause of shortage

Technical issue with the machine used to fill vials

↓

Reduced manufacturing capacity

↓

Worldwide shortages

Context

- One manufacturer makes the active ingredient worldwide
- Making the final medicine is complicated and requires several ingredients

What EMA/EU did

- Provided support to company to establish new supply chain
- Worked with company to distribute stocks fairly between EU countries, based on past demand

What national authorities did

Expert committees or national guidance to allocate available supply to patients who need it most

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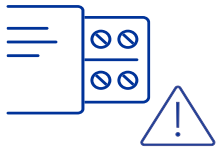
Example of shortage tackled at EU level: NovoSeven

What it is used for

Treat bleeding and prevent bleeding after surgery



Cause of shortage

Capacity constraints and issues with the packaging process

What EMA/EU did

- Temporarily allowed distribution with a package leaflet in English
- Communicated with healthcare professionals and patients

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Example of SPOC initiative: SPOC Flash report

SPOC WP Flash report dashboard

Ongoing critical shortages

Medicinal product	Current status
Visudyne (verteporfin)	high
Zypadhera (olanzapine)	high
Beriglobin (human normal immunoglobulin)	high
Quetiapine containing medicinal products	medium
Insulin containing medicinal products	medium
GLP-1 receptor agonists	medium
Risperidone	low
Oncology medicinal products from MAH Teva, Accord	low

Monitoring level: high; medium; low

Potential shortages

Medicinal product
Lamzede (velmanase alfa)
Nexviadyme (avalglucosidase alfa)
Azactam (aztreonam)
Cystadrops (cysteamine)

Recently resolved shortages

Medicinal product	Resolved on
Pegasys (peginterferon alfa-2a)	06/2025
Ec	
Zi	
Cy	

2 Flash report updated on 21 November 2025

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Ongoing shortages

high — The shortage affects multiple EU/EEA Member States. There are either no suitable alternatives or only a few available. The situation is approaching or has reached a stock-out, and last resort mechanisms are being considered (VSM).

Visudyne CAP
MAH: Cheplapharm (verteporfin, for injection)

Indication

- 'Wet' form of age-related macular degeneration (AMD) - disease which affects the central part of the retina (called the macula) at the back of the eye.
- Choroidal neovascularisation caused by pathologic myopia (a severe type of short-sightedness where the eyeball continues to grow, becoming longer than it should be).

Root cause and current status

Ongoing since May 2020 due to reduced manufacturing capacity and now manufacturing issues with establishment of new supply chain. Reduced and controlled deliveries based on agreed methodology, monthly updates to EMA/SPOC WP. Shortage catalogue entry updated in Sept 2025. MSC published 17 Sept 2025 (2 previous DHPCs 2021, 2022).

Ongoing actions and next steps

New supply chain is planned to be established by July 2026, and shortages are expected to continue until then, with restricted allocations to continue up to Q1 2027. Continued close engagement with the MAH, with monthly reports. SPOC WP subgroup to be reestablished.

3 Flash report updated on 21 November 2025 — Critical medicine — EMA

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- Distributed monthly to MSSG and SPOC WP
- Facilitates clear communication of ongoing/potential critical communication at EU level

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