

## 9.2 Introduction to shortages topic

### Monitoring and mitigating shortages of medicines — current activities

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# EU-level coordination structures and activities

## SPOC Working Party and MSSG

- Continuous **reporting, monitoring and discussion** of 1) critical shortages and 2) events to understand impact on medicines and **to prevent and mitigate shortages**
- Minutes of [SPOC WP](#) and [MSSG](#) meetings are publicly available. The [MSSG annual activity report](#) is also publicly available.

Preparedness activities	Voluntary Solidarity Mechanism
<p>Monitoring of antibiotic supply situation for upcoming <b>autumn/winter season 2025/26</b></p> <ul style="list-style-type: none"><li>• Outreach to key MAHs to obtain an overview of the <b>expected supply situation for a set of key antibiotics</b>.</li><li>• Liaising with <b>international regulators</b> in the southern hemisphere.</li><li>• Re-launch of <b>social media campaign</b> promoting prudent use of antibiotics.</li></ul>	<ul style="list-style-type: none"><li>• Continues to be a successful tool to identify supply of medicines in case of critical shortage, as a last resort</li><li>• The mechanism supports Member States, industry, healthcare professionals and patients by identifying available stocks and coordinating efforts in certain situations</li></ul> <p>13 VSM procedures concluded to date, all successfully*</p> <p>Examples include: Etoposide, Quetiapine, Olanzapine</p> <p><small>*Support could be found via the impacted MAH, alternative MAHs or other Member States</small></p>

# Critical shortage management

## MSSG recommendations to manage and mitigate critical shortages

Recommendation of **application of certain flexibilities** to prevent or mitigate critical shortages of medicinal products.

Examples: facilitation of the **reallocation of stock** for medicinal products, **exemptions** from national labelling requirements or **extension of shelf-life**.

## Medicine Shortage Communication (MSC)

Communication to healthcare professionals on medicine shortages, adopted by MSSG in late 2024.

Replaces Direct Healthcare Professionals Communication (DHPC) when a shortage is not linked to a quality, safety or efficacy issue.

MSCs published for shortages linked to:

- **withdrawal** of a marketing authorisation for commercial decisions;
- **disruptions in manufacturing or supply**;
- **unexpected increased demand**.

Examples:

- [MSC on Visudyne](#) (published Sept 2025)
- [MSC on Victoza](#) (published Sept 2025)

[Link to general EMA MSC webpage](#)

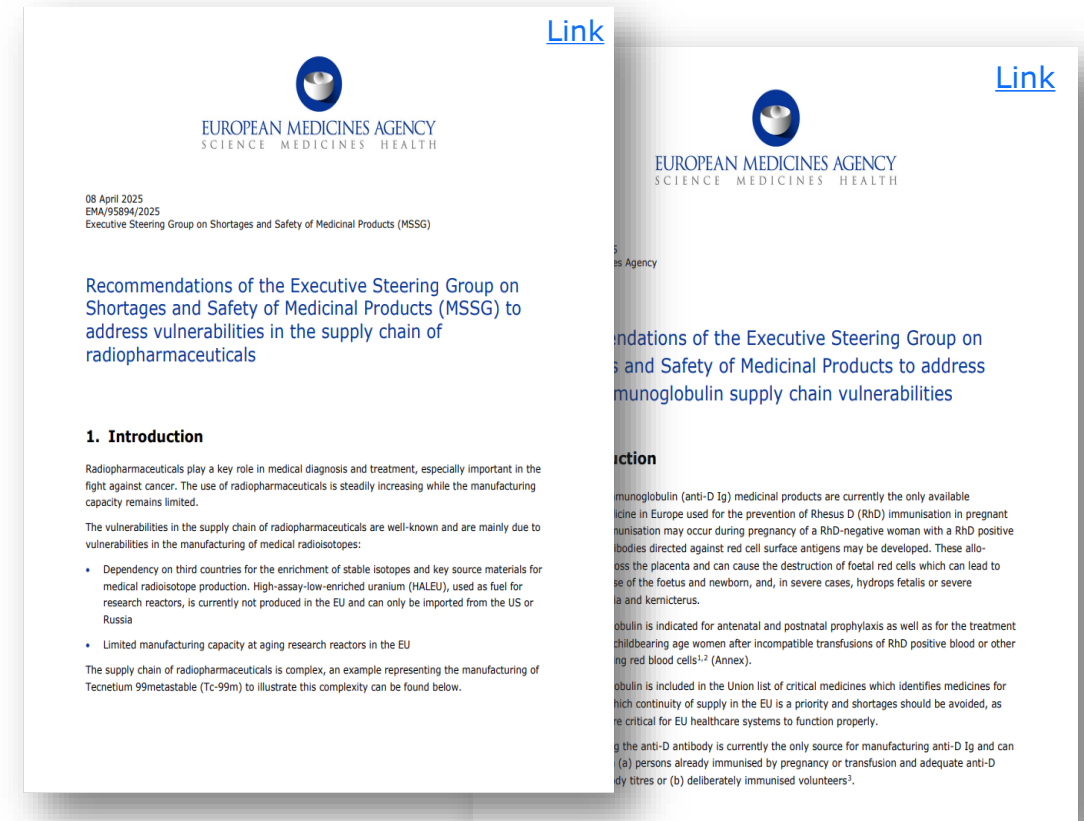
# MSSG recommendations on strengthening supply chains of critical medicines

Recommendations issued by MSSG to strengthen security of supply of certain medicines, based on identified supply chain vulnerabilities:

- **Anti-D immunoglobulins**
- **Radiopharmaceuticals**

Close interaction with relevant stakeholders was key to informing drafting of these recommendations:

- Experts from relevant organisations
- Experts from EMA Working Parties
- Healthcare Professionals and Patient representatives



# Next presentations

## Ongoing critical shortages

Update on ongoing **coordinated management of critical shortages**, under SPOC Working Party/MSSG.

## Union list of critical medicines

**Medicines** for which continuity of supply is a priority, as they are **critical to the proper functioning of EU healthcare systems at all times**.

## Shortage Prevention and Mitigation Plans (SPPs/SMPs) and Vulnerability Assessment Methodology

- **Pilot exercise** to test and optimise templates and guidance in anticipation of the proposed pharmaceutical legislation.
- **SMPs** will be key to inform the management of medicine shortages.
- **SPPs** will be key to inform the evaluate the resilience of supply chains of medicines on Union List and to identify vulnerabilities to support continued supply of those medicines.



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