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SCIENCE MEDICINES HEALTH

Improving the availability of medicines in the EU

SME Info Day, 18 October 2024
15:45 – 16:15

Presented by Sandra Dang and Joao Ferreira
Supply and Availability of Medicines and Devices, EMA

Outline

1. Shortages management in the EU
2. EMA extended mandate: Monitoring and mitigating shortages of critical medicines
3. Availability of medicines: EU level coordination
4. Preparedness activities: HMA/EMA Task Force on Availability Main deliverables, antibiotics example and MSSG “toolkit”
5. Shortages Reporting: Obligations, overview and the European Shortages Monitoring Platform
6. Other important initiatives in the EU re: availability of medicines
7. Conclusions and next steps

Shortages management in the EU

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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

EMA extended mandate: Monitoring and mitigating shortages of critical medicines

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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

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	EMA/HMA Task Force on availability of authorised medicinal products (TF AAM) POLICY GROUP	**Medicine shortages SPOC working party** OPERATIONAL GROUP	**Executive steering group on shortages and safety of medicinal products (MSSG)** EXECUTIVE GROUP
Operates in:	Normal circumstances	Normal circumstances Crisis and preparedness (PHE,ME)	Crisis and preparedness (PHE,ME)
Functions:	• Supply and availability hub • Structural and strategic solutions • Development of guidance and policy	• Monitoring of shortages • Drawing up the list of critical medicines during ME or PHE • Monitoring of demand and stock of critical medicines during ME or PHE	• Opinion on a major event • List of critical medicines • Monitoring of shortages, supply and demand in PHE/ME • Recommendations to MS, industry and EC
Relevant activities:	EU initiative Joint Action CHESSMEN EC Pharma Strategy EMANS 2025	EMA extended mandate	

PHE: Public health Emergency ME: Major event MS: Member states

HMA/EMA Task Force on Availability: Main deliverables 2023

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- HMA/EMA **multistakeholder workshop** on shortages (March 2023)
- Publication of **Good practice guidance for industry** for the **prevention** of medicine shortages (May 2023)
- Development of the **Union list of critical medicines** (December 2023)
- Development of **Shortage Prevention** **and** **Mitigation plans** (SPMP) templates
- Implementation of **Good practice guidance for PC/HCPs organisations** on the **prevention** of shortages of medicines - subgroup established to measure the impact of the guidance
- Monitoring of implementation and review of the **Good practice guidance for communication** to the public on medicines' availability issues (to reflect media role and outcome of surveys)

Bringing shortages activities to life – the example of antibiotics (1/2)

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SITUATION

Reduced production capacity during COVID

+

Increased demand due to respiratory infections

=

November 2022: SPOC WP members highlighted critical shortages of antibiotics (primarily amoxicillin and amoxicillin/clavulanic acid in paediatric formulations)

→ **Shortage impacting 28 EU/EEA countries and regions globally**

Europe lacks critical antibiotics amid strained supply chains

Tuesday 20 December 2022

By The Brussels Times Newsroom

Public broadcasting of Latvia

Acute shortage of antibiotics in Latvia's pharmacies

Alarm over am... shortage in pharm... of children's respirato... infections

Andalusian pharmacies do not have enough stock to meet "50 per cent of demand" although they hope that the shortage will be resolved before the end of the year

The situation was further complicated by high political pressure on EU and national level and increased media attention.

Bringing shortages activities to life – the example of antibiotics (2/2)

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ACTIVITIES

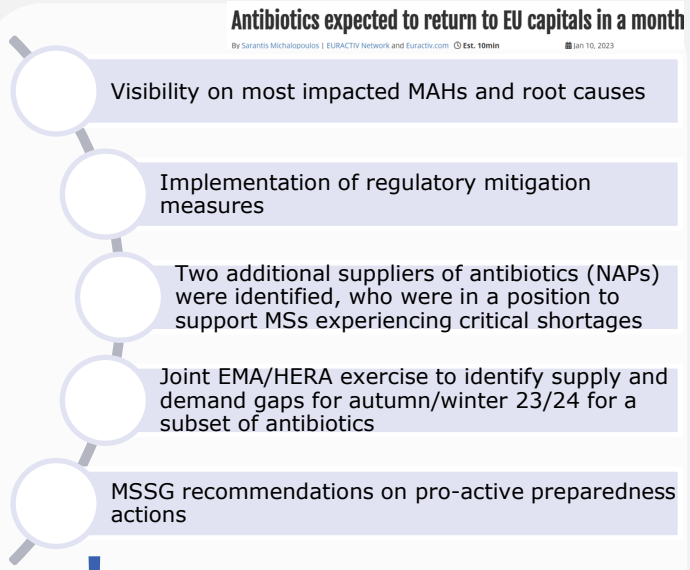
SPOC WP

- Launch of dedicated subgroup to investigate shortage causes and extent of situation
- Engagement with 12 MAHs to agree on possible mitigation measures
- Cooperation with DG SANTE/HERA, EDQM, exchange with international regulators, trade associations

MSSG

- Sharing best practices (incl. toolkit on mitigating measures)
- Letter to scientific committees to use regulatory flexibilities
- MAH presentation to MSSG
- Other: Public communication, shortages catalogue

OUTCOME



Autumn/winter 23–24: Supply situation considerably improved with only few critical shortages, which were addressed in cooperation with MAHs

MSSG toolkit of recommendations to tackle critical shortages

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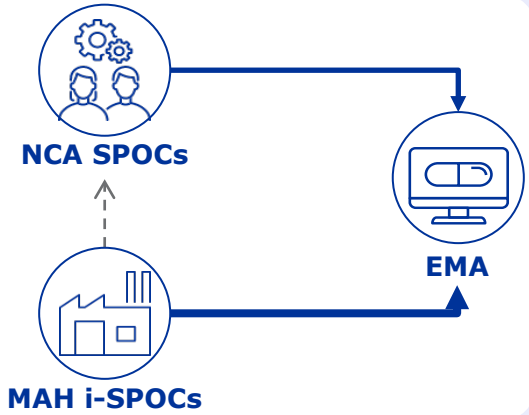
- **European and International cooperation -** MSSG, SPOC WP, EU institutions, international regulators
- **Communication -** Shortage catalogue, DHPCs, public statements, recommendations on alternatives
- **Stakeholder engagement -** MAH presentations to MSSG, liaison with supply chain stakeholders
- **Increased supply -** Increase production capacity, reallocation, importation of unauthorised products, magistral formulations, supply chain diversifications
- **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)

Source: MSSG recommendations toolkit (europa.eu)

MAH Shortages Reporting Obligations



In **normal circumstances**, MAHs will report shortages of centrally authorised products.

- **Shortage information**
- **Shortage prevention and mitigation plans**
- **Shortage impact assessment**
- **Alternative therapies**

Submissions are triggered by a potential or actual shortage and MAHs need to keep the information up-to-date.

During an **MSSG-led preparedness exercise**, MAHs follow the same submission process as during a crisis situation for a subset of products subject to close monitoring.

In a **crisis situation**, MAHs submit data on nationally and centrally authorised products in scope of a critical medicines list for a particular public health emergency.

- **Shortage information**
- **Shortage prevention and mitigation plans**
- **Marketing status**
- **Market share, sales volume** and **sales forecast**
- **Manufacturing information** including production plan, capacity and alternative sites
- **Alternative therapies**

Submissions are triggered by an MSSG announcement and frequency of reporting is defined by the MSSG.

Relevant legal texts:

Article 13(4) of Regulation (EC) No 726/2004: *"MAHs are required to inform EMA if their CAP ceases to be placed on the market of a Member State, either temporarily or permanently".*

Article 23a) and 27a) of Directive 2001/83/EC, as amended: *"If the product ceases to be placed on the market of a MS, either temporarily or permanently, the MAH shall notify the NCA no less than two months before the cessation of placing on the market"*

Article 10, Regulation 2022/123: Outlines obligations on marketing authorisation holders in crisis situations

Shortages Reporting: Overview

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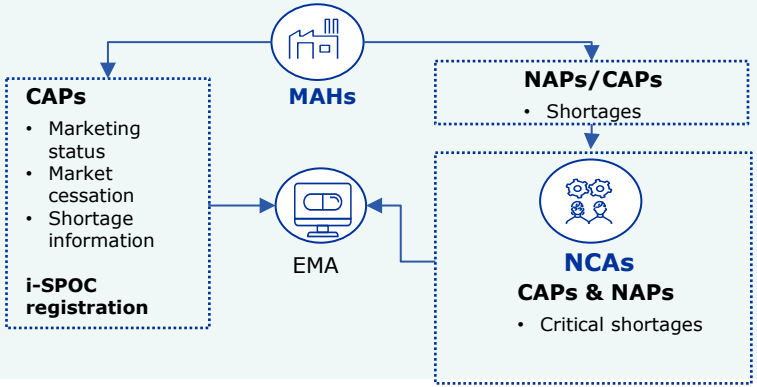
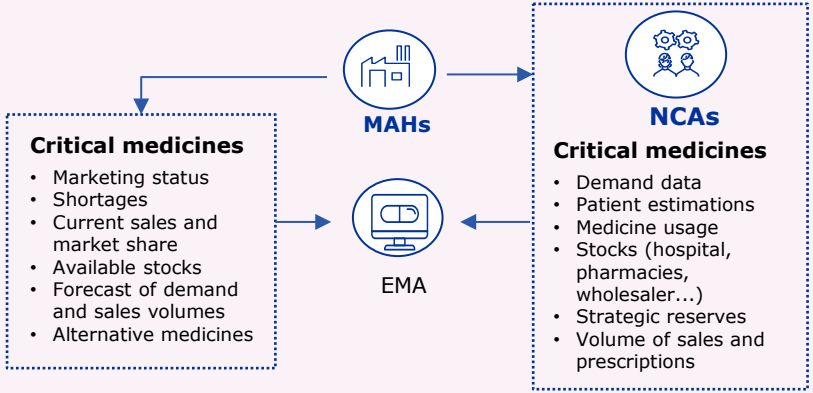
NORMAL CIRCUMSTANCES

Monitoring of shortages that can lead to PHE/ME



PUBLIC HEALTH EMERGENCY/ MAJOR EVENT

Critical medicines (crisis specific)



Roles and responsibilities for MAHs

1. Reporting of potential or actual CAP medicine shortages for SMEs to EMA:

If root cause is related to GMP-noncompliance or quality problems
→ Send an email to qdefect@ema.europa.eu and AvailablitySPOC@ema.europa.eu , clearly indicate if the problem identified is likely to lead to a shortage.

If root cause is other non-GMP-related issues (e.g. unexpected increase in demand, supply capacity)
→ Complete Annex 1 of Guidance for MAHs on the detection and notification of shortages and send this by email to AvailablitySPOC@ema.europa.eu

2. iSPOC registration:
MAH are required to register single points of contact (i-SPOCs) to report supply issues for critical medicines, as per Regulation (EU) 2022/123, Article 10.

The European Shortages Monitoring Platform (ESMP)

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Data collection

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

Analysis & Reporting

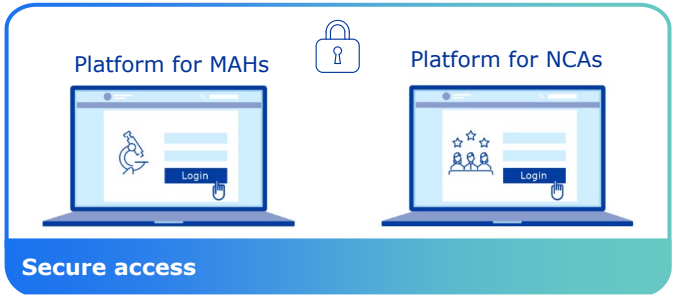
- Matching supply & demand
- Reporting findings and results
- Public reports

Shortages management

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

Data integration

- PMS integration of CAPs and NAPs
- RMS integration
- Interoperability with NCA and Industry systems



More information:

- ESMP webpage
- ESMP Essentials webinar event page, incl. recording and Q&A document
- ESMP Stakeholder engagement plan
- ESMP essentials: Industry and network reporting requirements
- FAQs on the ESMP
- ESMP Implementation guide for MAHs
- i-SPOC registration

ESMP vision & key changes

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Vision

ESMP will enable ***information exchange for better prevention, identification and management of shortages, and communication between EMA****, and Stakeholders in the supply chain medicinal products,* ***in order to ensure medicines are available for patients during PHEs/MEs****.*

Key changes

Accelerate the decision-making process

Increase efficiency and predictability

Mitigate impact on patients

Development timeline

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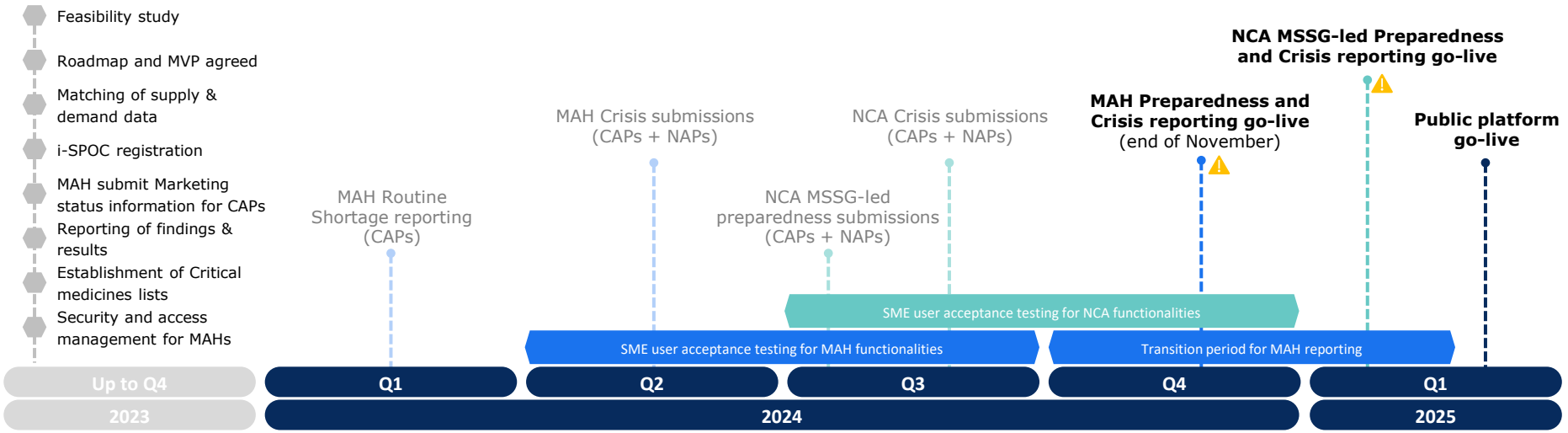

Legend:

- Public delivery
- Development completed
- PMS dependency
- MAH functionalities
- NCA functionalities

Save the date!

Upcoming online-training for all CAP MAHs on the routine shortage reporting functionality of the ESMP (tentatively 20 November)

ESMP MVP

Pharmaceutical Reform

- Security of supply and shortage prevention and management is a key focus
- Foresees a stronger coordinating role for EMA, and more powers for Member States and the European Commission
- Expansion of the scope of the European Shortages Monitoring Platform (ESMP)

European Commission Communication on tackling medicine shortages in the EU

- Prevention and mitigation of critical shortages at EU level
  - Accelerating and anticipating the pharmaceutical reform in cooperation with the Member States
  - EU guidance on procurement of medicines to strengthen security of supply to be issued by the Commission
- Structural measures to support long-term security of supply
  - Critical Medicines Alliance (CMA)
  - International partnerships for supply

Conclusion and next steps

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- 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.
- IT development work on European Shortages Monitoring Platform **ESMP** is underway to ensure delivery of different functionalities by **late 2024/2025.**
    - Please ensure registration of an i-SPOC and kindly keep your i-SPOC contact up to date
    - **Save the date**: Upcoming online-training for all CAP MAHs on the routine shortage reporting functionality of the ESMP (tentatively 20 November)
- **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** will further reinforce security of supply for critical medicines and prevention of shortages.

Thank you for your attention

Further information

For any shortage related queries or questions, please reach out to availabilitySPOC@ema.europa.eu

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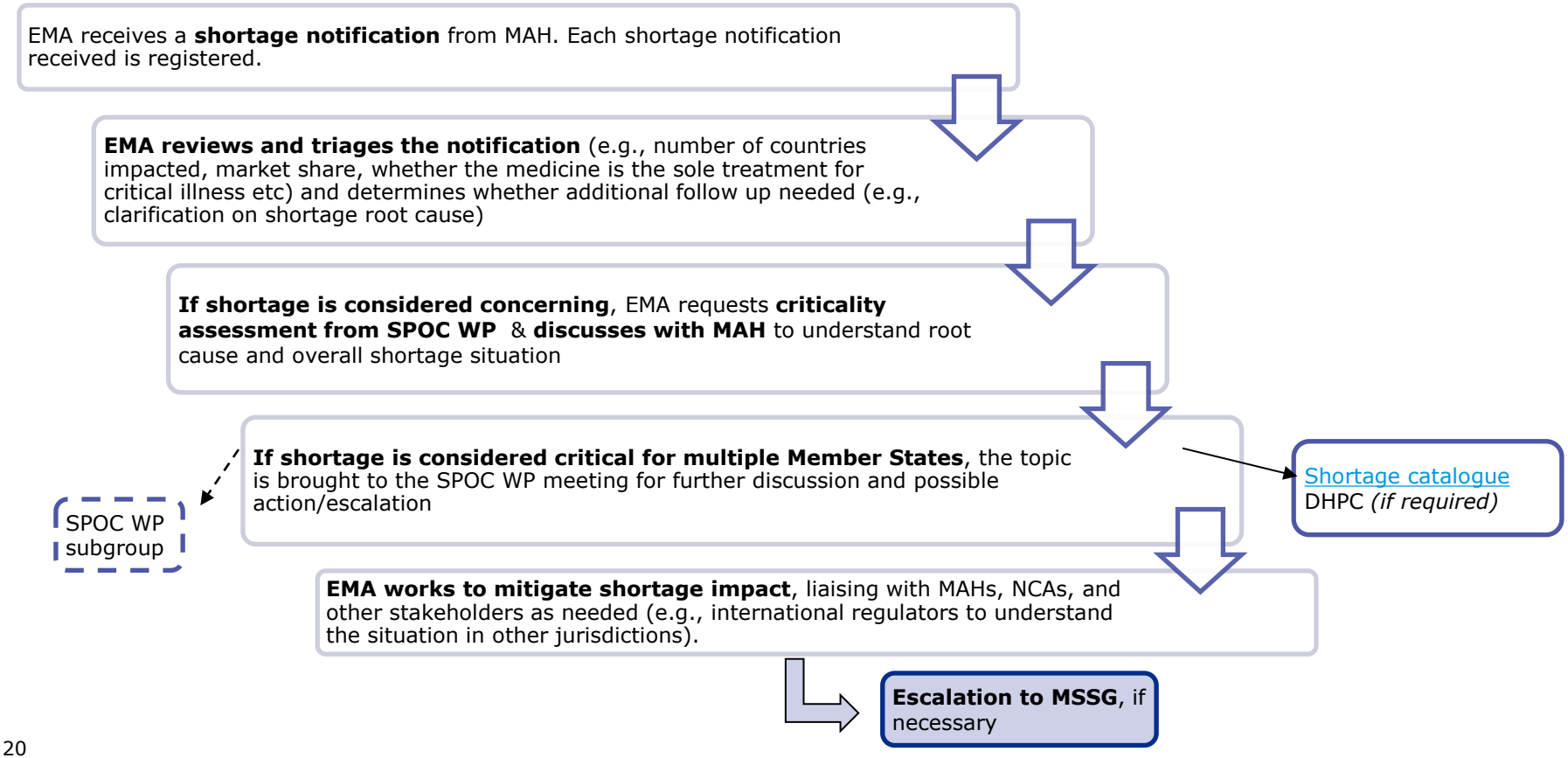
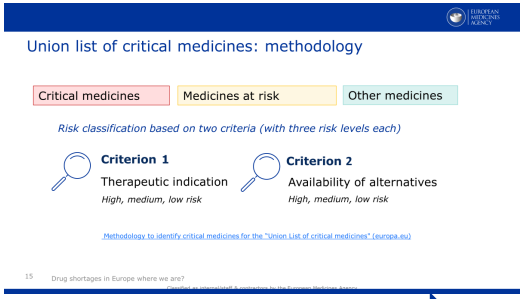
Back-up



Union list of critical medicines



March-July 2021

- **EC Structured Dialogue** (SD) on security of medicines supply takes place

October 2022

- Publication of EC **SD staff working document***

June 2023

- TF-AAM endorsed final **methodology** and agreed **process** to set up the list

12 December 2023

Release of first version of the 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 (europa.eu)

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"*