SESSION 1

Monitoring and mitigating shortages of medicines and devices

Introduction by topic lead

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EMA Medicines and Medical Devices Shortages
Outline

1. Shortages management in the EU. The COVID-19 crisis as a tipping point
2. Extended mandate: Key milestones for medicines and devices shortages
3. Monitoring and mitigating shortages of critical medicines and management of major events
4. European Shortages Monitoring Platform (ESMP)
5. Monitoring and mitigating shortages of critical medical devices
6. Conclusion
How does the EU manage shortages?

- Improving the availability of medicines authorised in the EU is a key priority for the European Medicines Regulatory Agencies
  - In the EU, medicine shortages are mainly dealt with at national level by the National Competent Authorities
- Regulatory authorities - within and outside Europe - are increasingly working together to prevent shortages and to limit their impact whenever they occur
- In December 2016, a joint HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF-AAM) was established to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability
Responding to the COVID-19 pandemic

EMA increased its involvement in the handling of shortages and it initiated a number of activities, as follows:

- EMA set up the **EU Executive Steering Group (ESG) on shortages** of medicines caused by major events:
  - EMA, the EC and the Member States developed **regulatory flexibilities** for pharmaceutical companies to prevent/mitigate shortages
  - EMA launched the **i-SPOC (Single Point of Contact) system** in April 2020
  - EMA together with the Member States developed a common framework for **forecasting demand data** in the EU/EEA (**ad hoc Working group** on forecasting demand data)
- EMA continued to use the **EU SPOC network** for sharing information between Member States, EMA and the EC on critical medicine shortages in the context of COVID-19
EXTENDED MANDATE: KEY MILESTONES FOR MEDICINES AND DEVICES SHORTAGES

Implementation of the shortages mandate

1 March 2022
Shortages of critical medicines

2 August 2022
Establishing a list of the main therapeutic groups (hospital care)

2 September 2022
Registration of i-SPOCs from Marketing Authorisation Holders

2 February 2023
Shortages of medical devices/in-vitro diagnostics

2 February 2025
European Shortages Monitoring Platform “Go Live”
MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICINES AND MANAGEMENT OF MAJOR EVENTS

New role for EMA

Regulation (EU) 2022/123 applicable from 1 March 2022

• Monitors events, including medicine shortages, which might lead to a crisis situation (public health emergencies or major events)

• Sets processes/tools for shortages reporting and coordinates responses of EU countries to shortages of critical medicines (during a crisis)

• Establishes “Medicines Shortages Steering Group” (MSSG) – formalises the formerly known ‘EU Executive Steering Group on Shortages Caused by Major Event’ Steering Group to be supported by:

  • Working Party of Single Points of Contacts in the Member States (current EU SPOC Network) and a Network of contact points from pharmaceutical companies (current i-SPOC system)

KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU
MONITORING AND MITIGATING **SHORTAGES OF CRITICAL MEDICINES** AND MANAGEMENT OF MAJOR EVENTS

**Governance**

- HERA
- Health Security Committee
- ECDC
- Emergency Task Force (ETF)
- Executive Steering Group on Shortages of Medical Devices

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

- PCWP
- HCPWP (Observers)
- European Commission
- Member States
- EMA

**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
Role of the Executive Steering Group on shortages and safety of medicines (during a PHE or a major event)

<table>
<thead>
<tr>
<th>Shortages of medicinal products</th>
<th>Establish <strong>lists of critical medicinal products</strong> to be monitored (in consultation with ETF for public health emergencies)</th>
<th>Provide <strong>recommendations and coordinate measures</strong> to prevent or mitigate potential or actual shortages (Art 8.4 &amp; 8.5)</th>
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<tr>
<td>Quality, safety and efficacy of medicinal products</td>
<td>Evaluate information related to the public health emergency or the major event and provide recommendations regarding the <strong>quality, safety and efficacy of the medicinal products</strong> concerned (Art. 5.1)</td>
<td>Provide <strong>recommendations</strong> to the Commission and Member States on any appropriate action that it believes needs to be taken at Union level on the medicinal products concerned (Art. 5.2)</td>
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**MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICINES AND MANAGEMENT OF MAJOR EVENTS**

SPOCs - in the MSs and Industry - for medicines shortages reporting

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<thead>
<tr>
<th>Medicines Shortages SPOC Working Party</th>
<th>Industry SPOC Network</th>
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<tr>
<td>National Competent Authorities</td>
<td>Subset of Marketing Authorisation Holders, according to list of critical medicines</td>
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<tr>
<td>In preparation, and during a public health emergency/major event</td>
<td>ONLY during a public health emergency/major event</td>
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<tr>
<th>Reporting of shortages and events (e.g. Brexit risk of shortages)</th>
<th>Reporting of estimated data on volume of demand</th>
<th>Escalate critical medicine shortages to MSSG (in prep./during crises)</th>
<th>Reporting of shortages</th>
<th>Reporting of active manufacturing sites, marketing status, sales and market share, available stocks</th>
<th>Forecast of demand, plus supply capacity</th>
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<td>Prevention and mitigation plans</td>
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Main actions in 2022

- **MSSG and the Medicine Shortages (SPOC) Working Party**
  - Working procedures and composition
  - March-April 2022

- **Processes for Industry’s/ NCAs’ reporting of shortages, demand/supply data**
  - Methodology for establishing lists of critical medicines
  - By April 2022

- **Monitoring of events**
  - Monitor events by EMA/NCAs, including medicines shortages (e.g. Russia-Ukraine War, impact of increased COVID-19 vaccine manufacturing)
  - By May 2022

- **Monitoring of shortages (list of critical medicines)**
  - List of COVID-19 critical medicines
  - Match supply and demand data
  - By May 2022

- **Enhanced transparency outputs**
  - Publication: List of main therapeutic groups/critical medicines, shortages information

- **Electronic monitoring and reporting systems for EMA/Industry/NCAs**
  - European Shortages Monitoring Platform (3-year deadline for implementation)
    - Feasibility study

**CONTINUOUS STAKEHOLDER ENGAGEMENT**
European shortages monitoring platform (ESMP)

Implementation date: 2 February 2025

- Article 13 of Regulation 2020/0321 foresees the development of an **IT platform** to facilitate collection of information on **shortages, supply and demand** for medicinal products, including information on marketing status and marketing cessations, from both Industry’s and Member States’ SPOCs

- **Scope**: monitoring, prevention and management
  - Shortages of medicinal products (on the **critical** medicines lists) during a **PHE** or a **major event**
  - Actual and potential medicines shortages (in a given Member State), that **can lead to** a Major event or a PHE

**KEY BENEFIT**

Providing a centralised EU platform to report, monitor, prevent and manage medicine shortages
European shortages monitoring platform (ESMP)

**PREPAREDNESS**
Monitoring of shortages that can lead to PHE/ME

- CAPs
  - Marketing status
  - Market cessation
  - Shortages

- MAHs

- ESMP (EMA)

- SPOC WP
  - Subset of NAPs
    - Marketing status
    - Market cessation
    - Shortages

**PUBLIC HEALTH EMERGENCY/MAJOR EVENT**
Critical medicines (crisis specific)

- i-SPOCS

- Critical medicines
  - Marketing status
  - Shortages
  - Sales and market share, available stocks, forecast of demand
  - Alternative medicines

- NAPs/CAPs

- MAHs

- ESMP (EMA)

- SPOC WP

- Critical medicines
  - Demand data
  - Volume of sales and prescriptions
EUROPEAN SHORTAGES MONITORING PLATFORM (ESMP)

Development requirements

Implementation date: **2 February 2025**

- **Draw up an implementation plan**
- **Develop technical and functional specifications in collaboration with MSSG**
- **Ensure compliance with ISO standards, and Commerially Confidential Information (CCI) protection**
- **Develop standardised reporting terminology and guidance**
- **Ensure data interoperability with national IT systems**
- **To ensure access to the information for the EC, the EMA, NCAs**
MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES

New role for EMA

Implementation date: 2 February 2023

• New task for EMA during public health emergencies (only)

• Sets up Executive Steering Group on Shortages of Medical Devices (MDSSG) for:
  • Adopting a list of categories of critical medical devices
  • Monitor the supply of and demand for medical devices (included on the PHE critical medical devices list)
  • Report and provide recommendations on measures to prevent or mitigate potential/actual shortages

• Steering Group will be supported by Working Party of SPOCs (Member States) and, a sub-network of SPOCs from Economic Operators and Notified Bodies
MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES

Governance

Executive Steering Group on Shortages of Medical Devices (MDSSG)

- PCWP
- HCPWP (Observers)

European Commission

- Invited observers – expert advice
  - Representatives of medical device interest groups
    - Notified bodies and manufacturers
    - Other relevant actors
  - Representatives of patients, health care professionals and consumers

- i-SPOC Network
  - (MD manufacturers, authorised reps., NBs and importers/distributors)

Member States

- Medical Devices Shortages SPOC WP

EMA

- Experts in specific scientific and technical fields

• HERA
• MDCG
• Health Security Committee
• ECDC
MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES

SPOCs - in the MSs and Industry* - for medical devices shortages reporting

**Medical Devices Shortages SPOC Working Party**
Member States
During a public health emergency ONLY

- Reporting of estimated data on volume of demand and forecasts
- Escalate critical medicine shortage issues to MDSSG (during a PHE only)

**Industry* SPOC Network**
According to list of critical medical devices
During a public health emergency ONLY

- Reporting of shortages
- Sales and market share, available stock
- Forecast of demand, plus supply capacity
- Prevention and mitigation plans
- Information from Notified Bodies

* Medical device manufacturers (or their authorised reps.), Notified Bodies and importers/distributors (as appropriate)
MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES

Main actions in 2022

- Establishment of a drafting group to support the preparatory work
- Preparatory work for the monitoring of shortages (list of critical devices): methodology and procedures
- Establishment of interactions with relevant existing groups responsible for medical devices
- Identification of existing data sources for medical devices
- Preparatory work for establishment of the Medical devices Shortages Steering Group (MDSSG) and the Medical Devices shortages SPOC WP
- Develop electronic monitoring and reporting systems for devices
Conclusion

• The new Regulation (EU) 2020/123 has become applicable on 1 March 2022 for the monitoring and mitigation of shortages of **critical medicinal products**

• The Agency is currently transitioning from the *ad hoc* structures and processes put in place at the start of the pandemic, to those foreseen in the Regulation

• The Agency is starting the preparatory work to ensure a smooth and efficient delivery of the **ESMP** in early 2025

• For **critical medical devices**, preparatory work is ongoing to set up the necessary structures and processes by 2 Feb 2023. The Agency is also establishing the necessary interactions with stakeholders in the field of medical devices

• New mandate provides tools to prevent shortages of medicines and ensure supply in emergencies, and for the first time will extend monitoring to devices in emergencies