



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Monitoring and mitigating shortages of critical medical devices in the context of a public health emergency

Industry Standing Group (ISG) meeting, 22 November 2022



Monitoring and mitigating shortages of critical medical devices

Implementation date: 2 Feb 2023

*Within the provisions of **Regulation (EU) 2022/123**, EMA has a central role in monitoring and mitigating shortages of critical medical devices in the context of a public health emergency (PHE).*

The **Executive Steering Group on Shortages of Medical Devices** (MDSSG) will be set up as part of the agency responsible for:

- Adopting a list of categories of critical medical devices, i.e. the PHE **critical medical devices list**. The list will be updated whenever necessary until the termination of the PHE.
- Defining the set of info to be provided, **monitor the supply of and demand for medical devices** included on the PHE critical medical devices list, with a view to identifying any actual or potential shortages of those medical devices.
- Report and provide recommendations (and coordinate) on measures to **prevent or mitigate potential or actual shortages**, and **provide aggregated data and forecasts of demand**.

Ad-hoc drafting group on critical medical device shortages initiated

- First meeting held 6 October 2022
- **Mandate:** drafting group will support ensuring the successful implementation of key elements of the Regulation (EU) 2022/123, including the establishment of the Executive Steering Group on Shortages of Medical Devices (MDSSG)
- Established on a **temporary basis** until March 2023
- **Membership:**
 - composed of experts chosen on the basis of their specialised knowledge in supply and demand aspects of medical devices
 - Expertise will be provided by the Member States, EC and EMA.
- Meetings approximately every 3 weeks

Ad-hoc drafting group on shortages of critical medical device

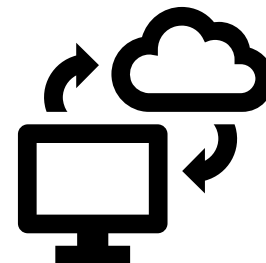
Main tasks of the drafting group:

- Share experiences from the COVID-19 pandemic
- Support the preparatory work for the establishment of the MDSSG and its supporting Working Party
- Development of a draft methodology to create a list of categories of critical devices, processes for reporting of shortages of critical medical devices, demand and supply data.
- Support interactions with industry associations, notified bodies and other relevant groups



Implementation of IT framework

- Registration of critical medical devices Economic Operator Single Point of Contact (EO-SPOC) to follow process established for medicines i-SPOC
 - Submission via EMA's IRIS platform
 - Only for Economic Operators whose products are included in a list of critical medical devices to address an ongoing public health emergency
- IT tool needed to capture submissions of required supply and demand data for critical medical devices
 - Feasibility project concluded September 2022
 - EMA proceeding with implementation of solution provided by European Commission
- Target for implementation Q2 2023
 - First webform in development (Economic Operators)
 - National Competent Authority and Notified Body webforms to follow





Next steps

- Ad hoc drafting group on shortages of critical medical devices to continue supporting preparations for the implementation of the mandate in February 2023;
- Implementation of the IT framework to allow the submission of demand and supply data;
- Strengthen the interactions with industry associations in the medical devices sector as well as with Notified Bodies.



Any questions?

Further information

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