EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Industry Standing Group (ISG) meeting, 21 March 2023

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Agenda

- Overview about the main tasks of the Executive Steering Group on Shortages of Medical Devices (MDSSG)
- Key activities related to the implementation of the Regulation (EU) 2022/123
- Overview of the development of the IT system for Critical Medical Device Shortages
- Discussion

Monitoring and mitigating shortages of critical medical devices

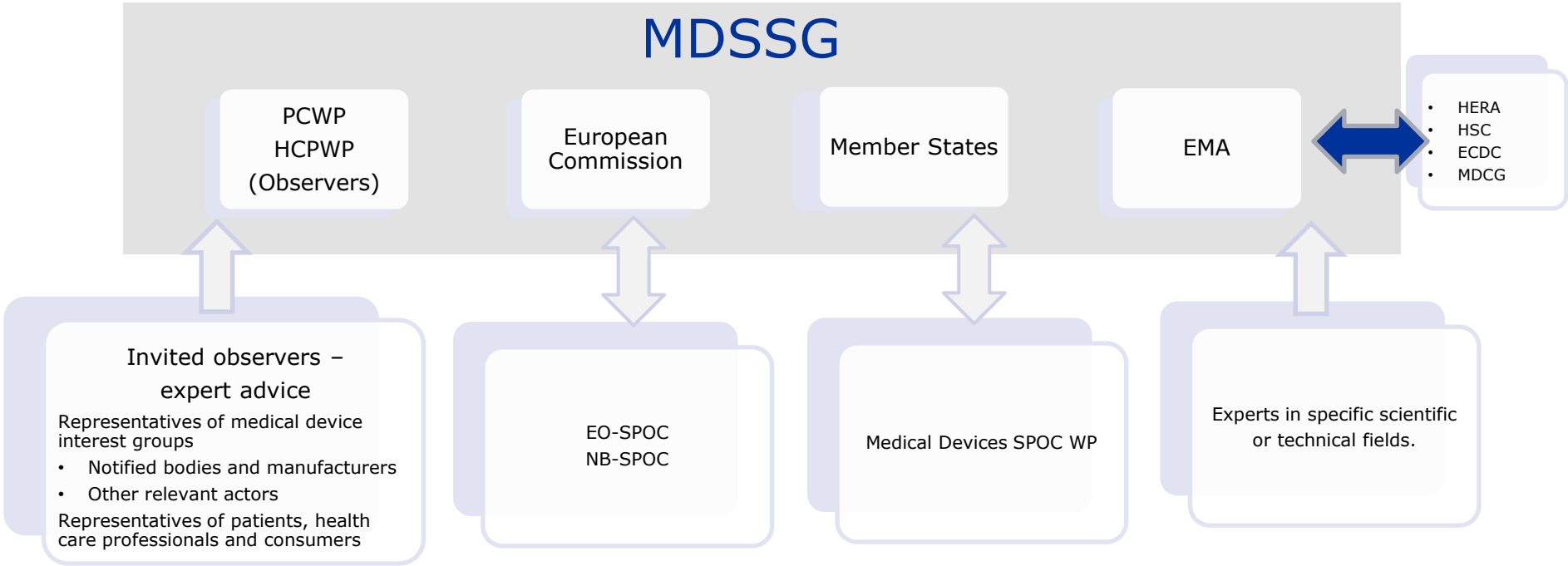
Implementation date: 2 Feb 2023

*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**.

Executive Steering Group on Shortages of Medical Devices



Key activities related to the implementation of the Regulation

- ❑ Ad-hoc drafting group on critical medical device shortages
  - Mandate: drafting group **supports the implementation of key elements** of the Regulation (EU) 2022/123
    - Established on a temporary basis; Meetings approximately every 3 weeks
    - Establishment of methodologies, preparation of documents and supporting the IT system development
- ❑ Establishment of the MDSSG
  - First administrative meeting of the MDSSG on 15 March 2023
- ❑ Establishment of the HERA-EMA JICF Working Group on data collection in January 2023
  - Detailed discussions with stakeholders and gathering feedback on technical elements (e.g. IT system)
- ❑ Preparatory activities for the establishment of the SPOC WP
  - The Working Party, as an operational group will continue the activities currently undertaken by the Ad Hoc Drafting Group on shortage of critical devices
  - Nominations for **NCA representative to the Working Party** will be launched shortly to Heads of the Competent Authorities responsible for medial devices in the Member States

IT solution for critical medical devices in a public health emergency

Manufacturers authorized representatives, importers, distributors as appropriate

Economic operators SPOCs

Information on critical medical devices, including:

- Details of the manufacturer, medical device & if applicable notified body
- Details on the shortage
- Sales and market share data
- Available stocks
- forecast of supply, including information on the potent vulnerabilities in the supply chain
- Forecast of demand
- Quantities already delivered & projected deliveries
- Shortage prevention and mitigation plans

Notified Bodies SPOCs

Information on critical medical devices

- Capacity to **process** applications and **carry out** and complete conformity assessments
- Number of applications received and information on the relevant conformity assessment procedures
- Where conformity assessments are ongoing, **the status** of the conformity assessment and **possible critical issues** on the final outcome of the assessment and **which need to be considered** in order to complete the conformity assessment process.

NB-SPOC Notifications

NCA SPOC Notifications

EO-SPOC Notifications

IT solution (EMA)

NCA SPOCs

Information on critical medical devices

- Available and estimated **data on volume of demand and demand forecasts.**
- **Any information** which provides evidence of an **actual or potential shortages** of medical devices

Reporting in analogy to Medicines

Critical Medical Devices Shortages (CMDS)

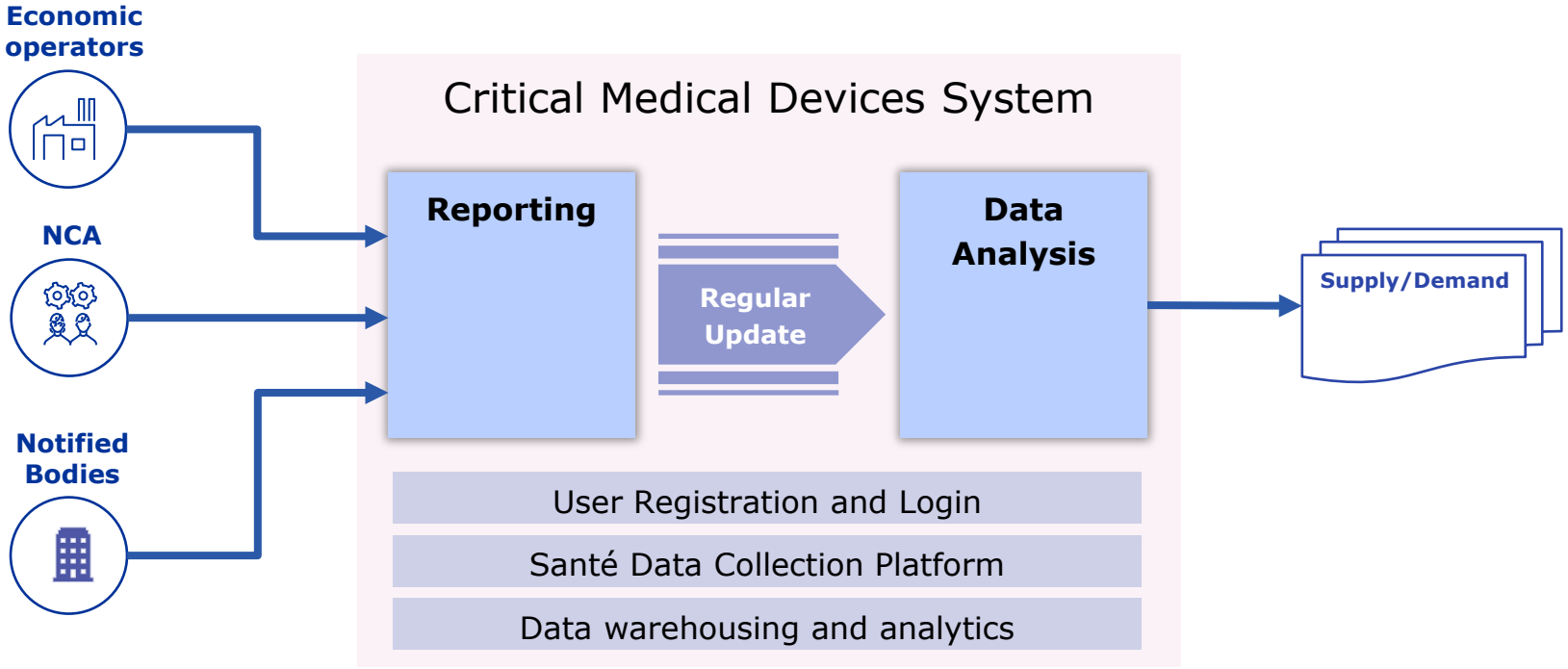
- The development of the **CMDS** for monitoring and reporting of shortages of critical medical devices started in November 2022 and will be finalised in July 2023;

- The reuse of IT components hosted by DG SANTE and the definition of the Minimum Viable Product were the main drivers for streamlining and reducing development time;

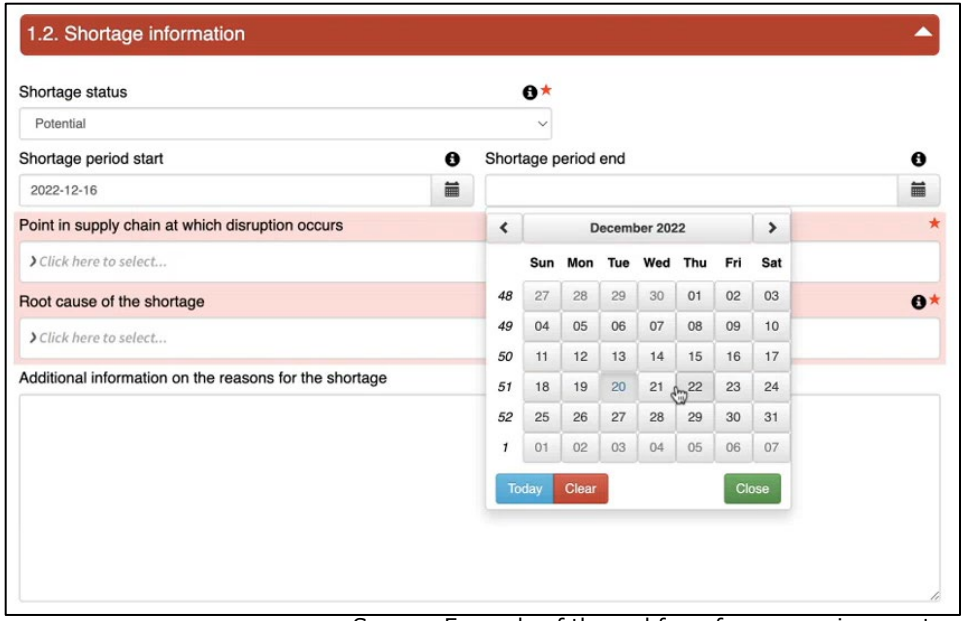
- The **CMDS** consists of two main components - **Reporting** (e.g., shortages, sales data, demand, forecast) developed by DG SANTE and **Data Analysis**, developed by EMA, and will become available accordingly:
  - **March** : Reporting for Economic Operators
  - **May** : Reporting for National Competent Authorities
  - **June** : Data analysis functionality
  - **July** : Reporting for Notified Bodies

- Communication activities are planned and will be implemented from middle of March 2023 onwards.

IT solution for critical medical devices



Early view of the webform for economic operators (EO)

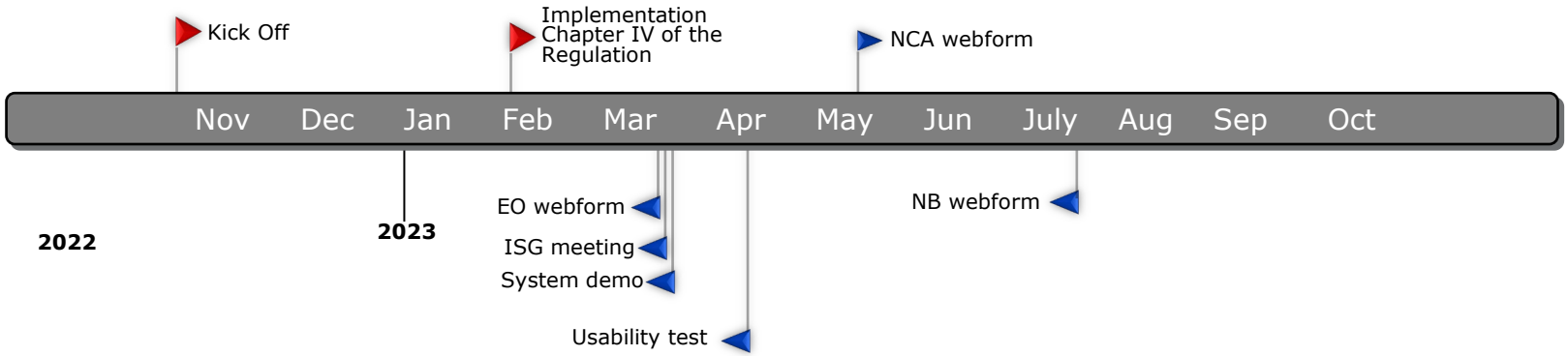


Source: Example of the webform for economic operators

- Information on the shortage status and root cause of a shortage will be collected.
- Combination of multi-selection fields and free-text information facilitates information gathering

➢ invitation to the EMA quarterly system demo - Q1 2023 on 22 March 2023

Timelines and milestones for the EO webform



- Communication material, including user guide is currently in development
- A selected number of relevant economic operators will be invited to the usability test.
- The final implementation of the CMDS will be finalised in July 2023

Next steps

- Ad hoc drafting group on shortages of critical medical devices to continue supporting activities for the implementation of the mandate and to transition to the SPOC WP;
- Continue the implementation of the IT framework to allow the submission of demand and supply data for critical medical devices;
- 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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