EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

5th Industry Standing Group (ISG) meeting
26th June 2023, 09:00-13:30 CEST, virtual

Presented by
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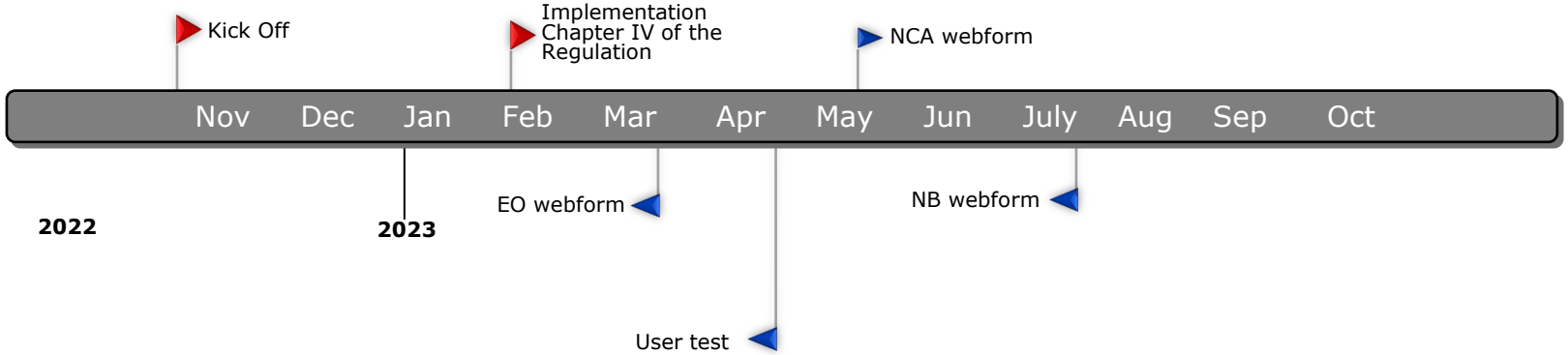
Critical Medical Device Shortages (CMDS)

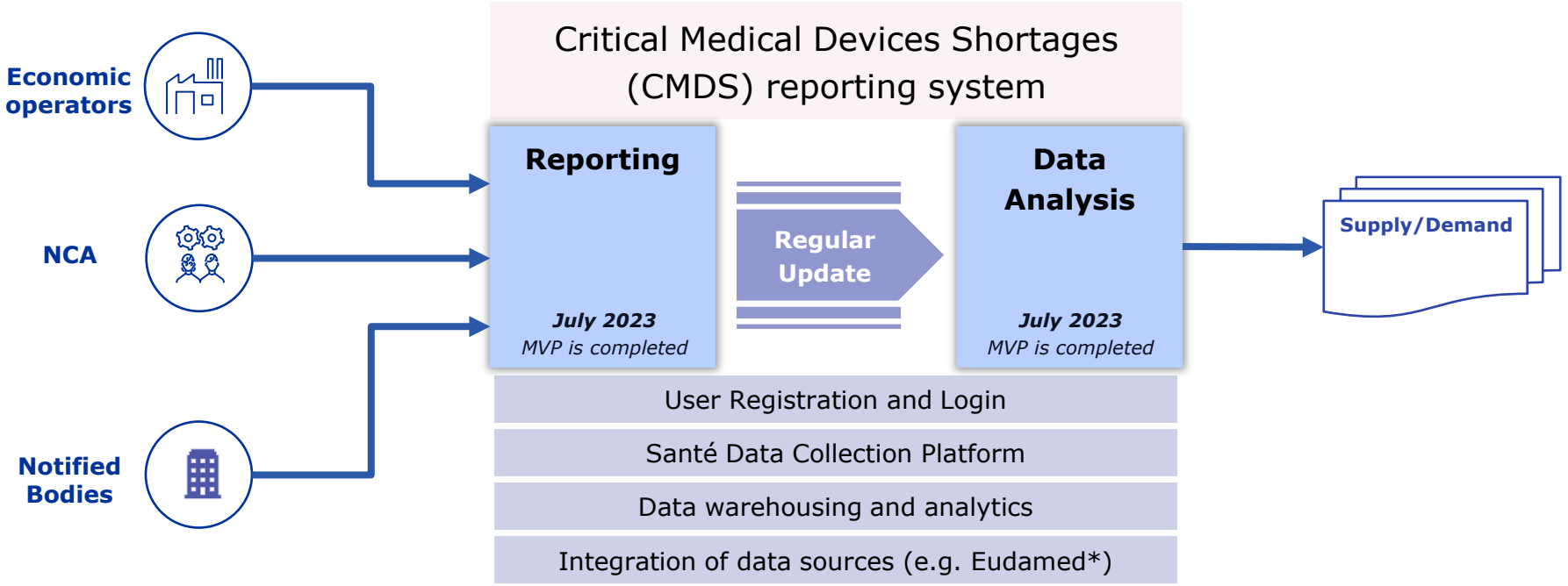
- The development of the **CMDS** for monitoring and reporting of shortages of critical medical devices started in November 2022 and will be **finalised in July 2023**

- 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 Agency will focus on the collection of information from manufacturer and authorised representatives via the CMDS.



IT system to collect information on critical medical devices during public health emergencies



* Once fully functional

Current status of the Minimum Viable Product (MVP) of the IT system

Economic Operators

- Webform finalized
- User testing with relevant economic operators took place to identify opportunities for improvement

NCA

- Webform finalized
- Further user testing will take place in Q3 2023 to identify opportunities for improvement

Notified Bodies

- Webform will be finalized on 3 July 2023
- Further user testing will take place in Q3 2023 to identify opportunities for improvement

Data Analysis

- Data analytics reporting will be finalized by the end of July 2023
  - Match supply and demand data on an EU aggregated level
  - Shortage information and root causes

The development of the **IT system** for monitoring and reporting of shortages of critical medical devices will be finalised in July 2023 and is subject to further improvements under the Agile framework.

User test of the webform relevant for economic operators

Scope of the test

- Participation in a user test of the webform was requested to gather feedback and inform the future development of CMDS.

- Manufacturers and authorised representatives were invited to participate in this test.
  - Test the system with sample data and provide feedback
  - Provide feedback on the user guide
  - Participate in the dedicated meetings and contribute to the discussion
  - Discuss potential improvements of the different functionalities

<u>The testing did not require the submission of any operational data for the purpose of this user test.</u>

1. Meeting of the EMA-HERA -JICF working group and call for nominations launch
   19 April 2023
2. Demonstration of webform and usability test launch with participating economic operators
   16 May 2023 **(Start of the test: 23 May 2023)**
3. Usability test closure
   16 June 2023
4. Collection of feedback
   Starting 12 June 2023
6. Presentation and discussion of results
   date TBD

Conclusions and next steps

- EMA will further strengthen the interactions with industry associations in the medical devices sector as well as with Notified Bodies;
- Relevant economic operators were invited for a user test of the economic operators webform via the EMA-HERA JICF Working Group; Further discussion on data analysis will continue;
- Interactions with the NBCG-Med have been facilitated to implement the webform relevant for notified bodies;
- User tests with NCAs and notified bodies are planned for Q3 2023;
- The development of MVP of the IT system for monitoring and reporting of shortages of critical medical devices will be finalised in July 2023 and is subject to further improvement under the Agile framework.

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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Annex

Summary of the relevant Articles from the Regulation (EU) 2022/123 for the development of the IT system

Article 26.1 Regulation (EU) 2022/123: The Agency may request:
The manufacturers of medical devices, or their authorised representatives, as applicable, and, if appropriate, importers and distributors, referred to in the first subparagraph, **shall submit the requested information** through the single points of contact referred to in Article 25(2), point (a), **using the monitoring and reporting systems established pursuant to Article 25(1), point (b).** They shall provide updates where necessary.

Article 27.1(a) Regulation (EU) 2022/123: The Agency may request a Member State to:
Submit the set of information referred to in Article 22(2), including available information about needs related to the medical devices included in the public health emergency critical devices list, and available and estimated data on volume of demand and demand forecasts for those medical devices, through the respective single point of contact referred to in Article 25(2), point (a), and using the monitoring and reporting methods and systems established pursuant to Article 25(1), point (b);

Article 25.1(b) Regulation (EU) 2022/123: The Agency shall:
Develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, that facilitate interoperability with existing IT tools and Eudamed, once it is fully functional, and provide the adequate support to national competent authorities for monitoring and reporting;