



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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

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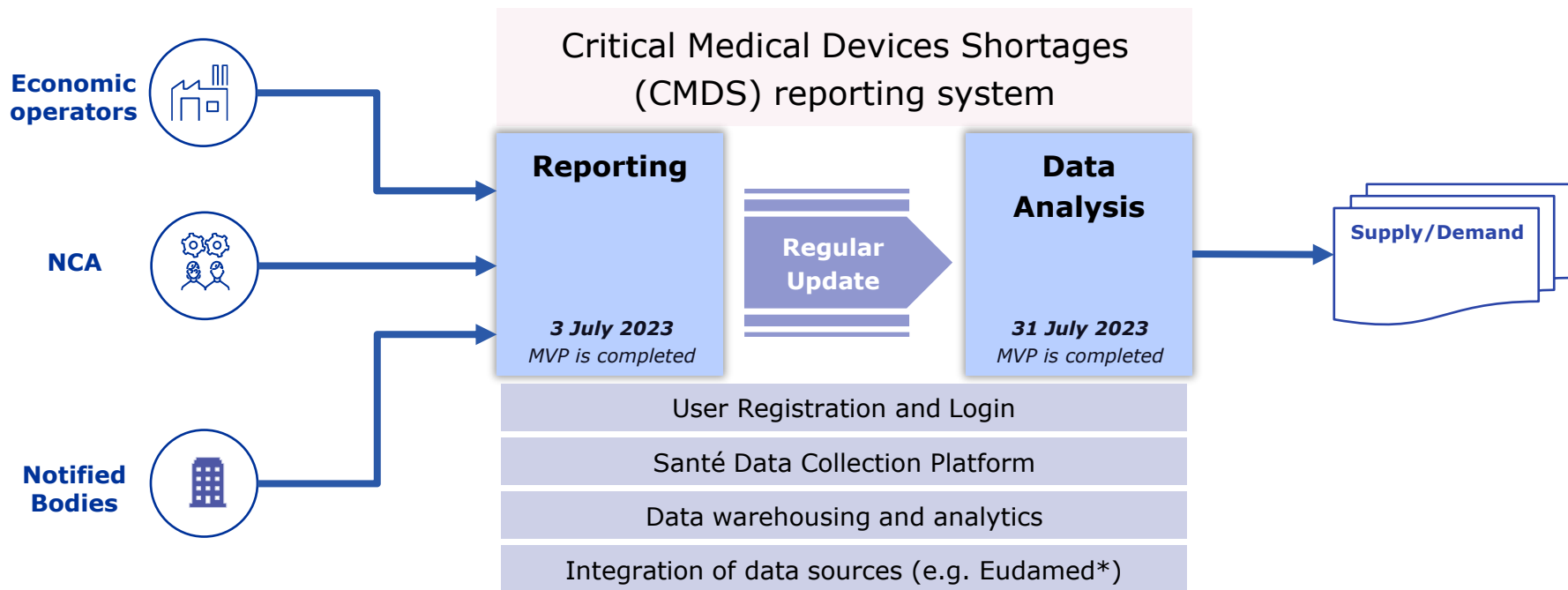
ISG Meeting 21 September 2023

Presented by Pedro Pina Ferreira, Monitoring VS Owner, EMA, and Klaus Kruttwig, CMDS Product Owner, EMA

An agency of the European Union



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





# Current status of the Minimum Viable Product 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 took place in Q3 2023 to identify opportunities for improvement

## Notified Bodies



- Webform was finalized on 3 July 2023
- Further user testing will take place in Q4 2023 to identify opportunities for improvement

## Data Analysis



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



# Executive summary of the user test performed in the EMA-HERA JICF working group on data collection



6

**Companies/Associations provided feedback**



4

**User tests completed and feedback interviews conducted**

## Key Highlights

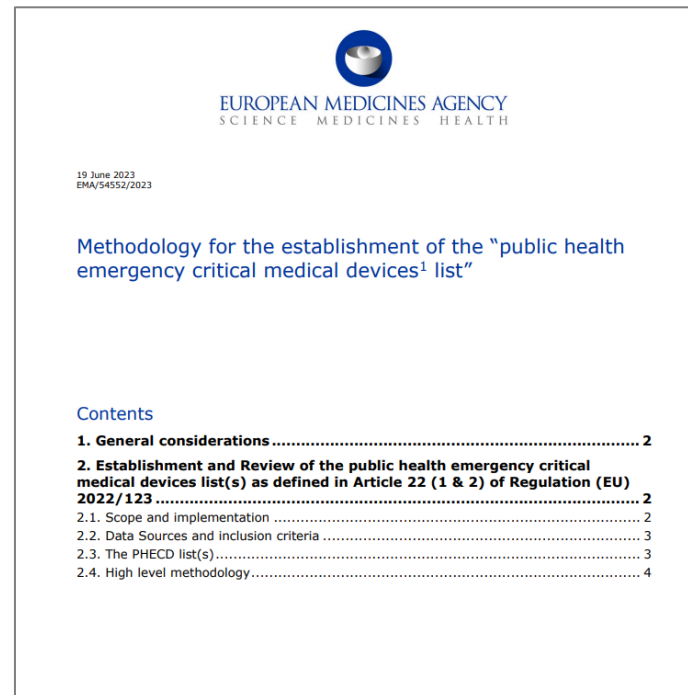
- 1 Participants provided key **suggestions** on **the overall design** and **clarity of documentation**. No technical issues were raised.
- 2 **All participants** involved in the interviews confirmed that they used the guidance document. Positive feedback and **additional suggestions** on the guidance document were provided.
- 3 **All participants rated the usability** of the EO-webform **as high**.
- 4 **The overall design** of the webform can be significantly improved, for example by including specific information from the user guide directly in the webform.



# Publication of the Methodology for the establishment of the “public health emergency critical medical devices list

- In the context of a public health emergency the MDSSG shall establish a list or lists of categories of critical medical devices which it considers to be critical during the public health emergency (public health emergency critical devices list’ (PHECD list)).
- The document\* was adopted by the MDSSG on 19 June 2023 and describes the methodology for the establishment of such lists by the MDSSG.

\*[Methodology-establishment-public-health-emergency-critical-medical-devices-list\\_en.pdf](#)





## Conclusion

- The MDSSG and MD SPOC WP were established and the methodology for the establishment of the “public health emergency critical medical devices list” adopted by the MDSSG;
- The development of CMDS for monitoring and reporting of shortages of critical medical devices was finalised in July 2023;
- Relevant economic operators were invited for a user test of the economic operators webform via the EMA-HERA JICF working group on data collection. Relevant feedback was received and taken into consideration to further improve CMDS;
- The user test with NCAs started in September 2023 and will be followed by a user test with Notified Bodies in Q4 2023.



# Any questions?

## Further information

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