



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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

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IT monitoring and reporting system: Feasibility study  
*Ad hoc* working group on critical medical device shortages

ISG meeting

Presented by Pedro Ferreira and Monica Dias



## □ **Aim of the Feasibility study**

- Identification of an IT System that to be used for reporting, monitoring, analyzing and evaluating shortages of critical medical devices during PHEs.
- Several options are being considered regarding functional viability, cost and implementation timelines.



# Monitoring and mitigating shortages of critical medical devices

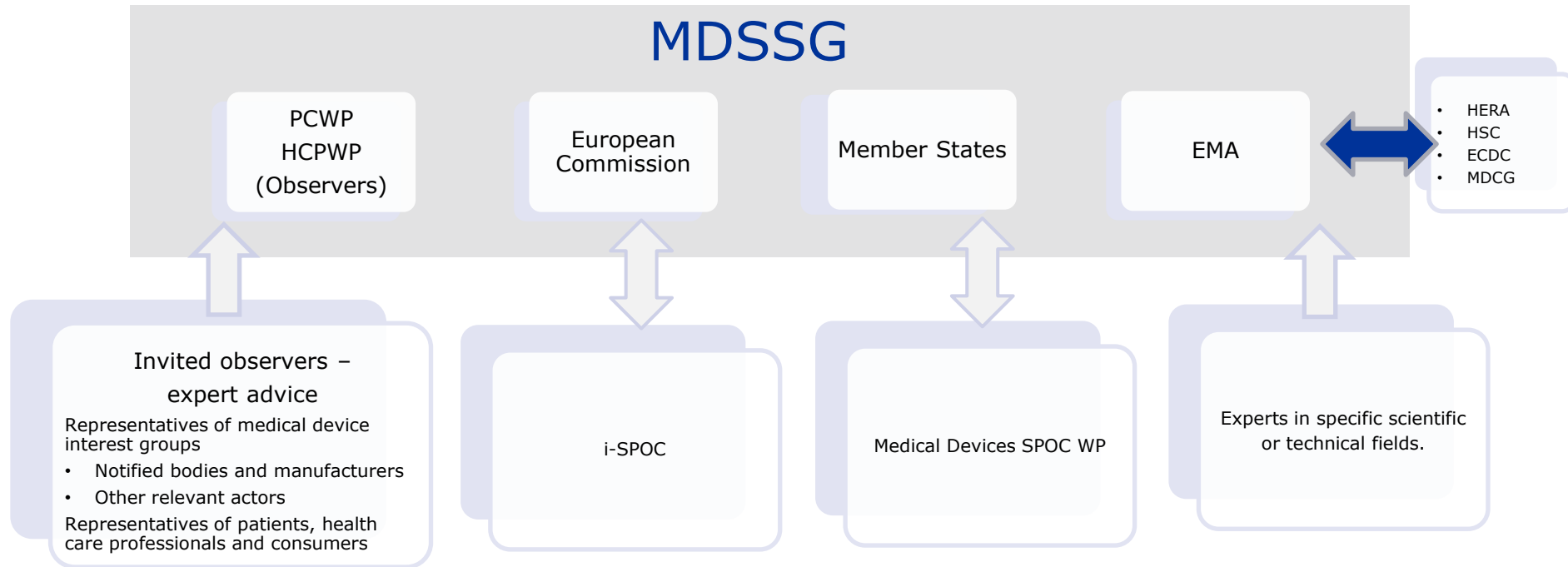
Implementation date: 2 Feb 2023

*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

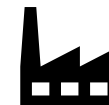


# Single Points of Contact in the MSs and economic operators & notified bodies



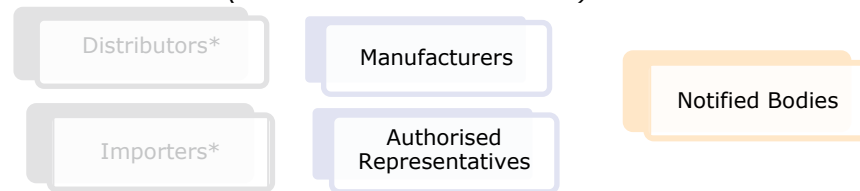
## Medical Devices Shortages SPOC WP

- **Operational group**
- consists of one representatives from each NCAs responsible for shortage monitoring and management of medical devices
- **Role:** reporting on volumes of demand and forecasts of demand (for devices in PHE **critical medical devices list**)



## Single points of contact

(for devices in the critical list)



*\*where appropriate*

- **Mandatory reporting**, 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** - information on status, number of applications & capacity to process applications



# EMA extended mandate: main actions for the implementation

**Establishment** of a **drafting group** to support the preparatory work for the monitoring of shortages

**Establishment of interactions with relevant existing groups responsible for medical devices**

- Set up interactions with economic operators and other relevant actors

**Preparatory work for the monitoring of shortages** (list of critical devices)

- Establish methodology to create list of categories of critical devices
- Establish procedures and processes for reporting of shortages of devices, demand and supply data

Preparatory work for formal establishment of the Medical devices Shortages Steering Group (**MDSSG**) and the Medical Device shortages SPOC WP

**Identification of existing data sources for medical devices**

- Set up interactions with NCAs to facilitate information exchange

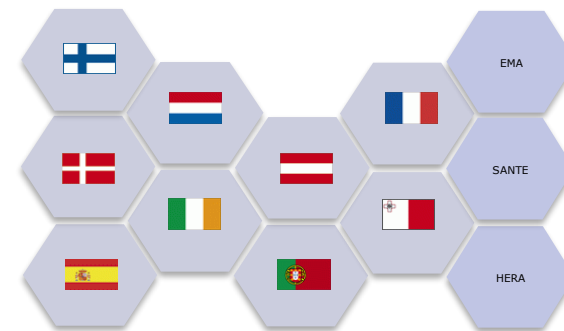
Develop **electronic monitoring and reporting systems for devices**

- Leverage from EMA IT developments for medicines
- leverage from national IT systems until integration in EUDAMED is possible

# 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





## Next steps

- Ad hoc drafting group on shortages of critical medical devices to progress the preparatory for the implementation of the mandate in February 2022;
- Implementation of the IT framework to allow the submission of demand and supply;
- Strengthen the integration with industry associations in the medical devices sector as well as with Notified Bodies.





# Any questions?

## Further information

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