



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SESSION 1

Monitoring and mitigating shortages of medicines and devices

Introduction by topic lead

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An agency of the European Union



Outline

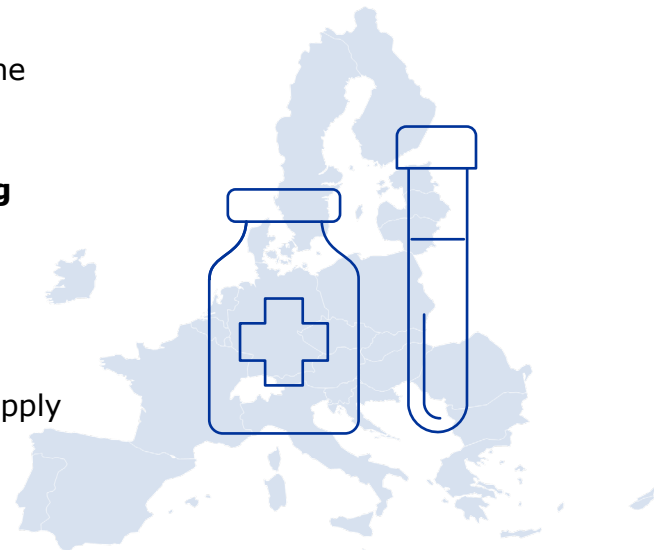
- 1 Shortages management in the EU. The COVID-19 crisis as a tipping point
- 2 Extended mandate: Key milestones for medicines and devices shortages
- 3 Monitoring and mitigating shortages of critical medicines and management of major events
- 4 European Shortages Monitoring Platform (ESMP)
- 5 Monitoring and mitigating shortages of critical medical devices
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SHORTAGES MANAGEMENT IN THE EU

THE COVID-19 CRISIS AS A TIPPING POINT

How does the EU manage shortages?

- Improving the availability of medicines authorised in the EU is a key priority for the **European Medicines Regulatory Agencies**
 - In the EU, medicine shortages are mainly dealt with at national level by the National Competent Authorities
- Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur
- In December 2016, a joint **HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF-AAM)** was established to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability



SHORTAGES MANAGEMENT IN THE EU THE COVID-19 CRISIS AS A TIPPING POINT

Responding to the COVID-19 pandemic

EMA increased its involvement in the handling of shortages and it initiated a number of activities, as follows:

- EMA set up the **EU Executive Steering Group (ESG) on shortages** of medicines caused by major events:
 - EMA, the EC and the Member States developed **regulatory flexibilities** for pharmaceutical companies to prevent/mitigate shortages
 - EMA launched the **i-SPOC** (Single Point of Contact) **system** in April 2020
 - EMA together with the Member States developed a common framework for **forecasting demand data** in the EU/EEA (**ad hoc Working group** on forecasting demand data)
- EMA continued to use the **EU SPOC network** for sharing information between Member States, EMA and the EC on critical medicine shortages in the context of COVID-19



EXTENDED MANDATE: KEY MILESTONES FOR MEDICINES AND DEVICES SHORTAGES

Implementation of the shortages mandate



MONITORING AND MITIGATING **SHORTAGES OF CRITICAL MEDICINES** AND MANAGEMENT OF MAJOR EVENTS

New role for EMA



Regulation (EU) 2022/123 applicable from **1 March 2022**

- Monitors events, including medicine shortages, which might lead to a crisis situation (public health emergencies or major events)
- Sets processes/tools for shortages reporting and coordinates responses of EU countries to shortages of critical medicines (during a crisis)
- Establishes “**Medicines Shortages Steering Group**” (MSSG) – formalises the formerly known ‘*EU Executive Steering Group on Shortages Caused by Major Event*’ Steering Group to be supported by:
 - **Working Party of Single Points** of Contacts in the **Member States** (current EU SPOC Network) and a Network of contact points from pharmaceutical companies (current i-SPOC system)

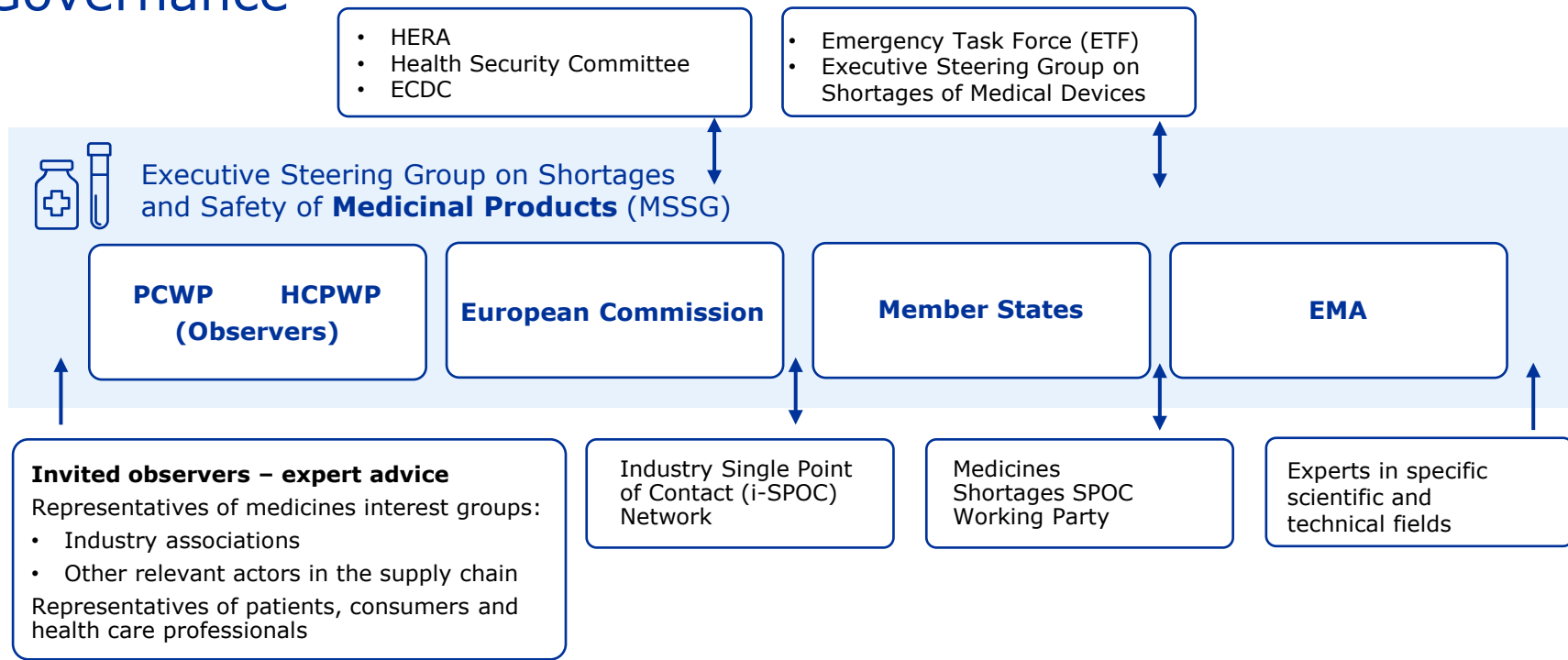


KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU

MONITORING AND MITIGATING **SHORTAGES OF CRITICAL MEDICINES** AND MANAGEMENT OF MAJOR EVENTS

Governance



MONITORING AND MITIGATING **SHORTAGES OF CRITICAL MEDICINES** AND MANAGEMENT OF MAJOR EVENTS

Role of the Executive Steering Group on shortages and safety of medicines (during a PHE or a major event)

Shortages of medicinal products

Establish **lists of critical medicinal products** to be monitored (in consultation with ETF for public health emergencies)

Provide **recommendations and coordinate measures** to prevent or mitigate potential or actual shortages (Art 8.4 & 8.5)


Quality, safety and efficacy of medicinal products

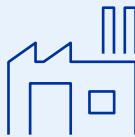
Evaluate information related to the public health emergency or the major event and provide recommendations regarding the **quality, safety and efficacy of the medicinal products** concerned (Art. 5.1)

Provide **recommendations** to the Commission and Member States on any appropriate action that it believes needs to be taken at Union level on the medicinal products concerned (Art. 5.2)

MONITORING AND MITIGATING **SHORTAGES OF CRITICAL MEDICINES** AND MANAGEMENT OF MAJOR EVENTS

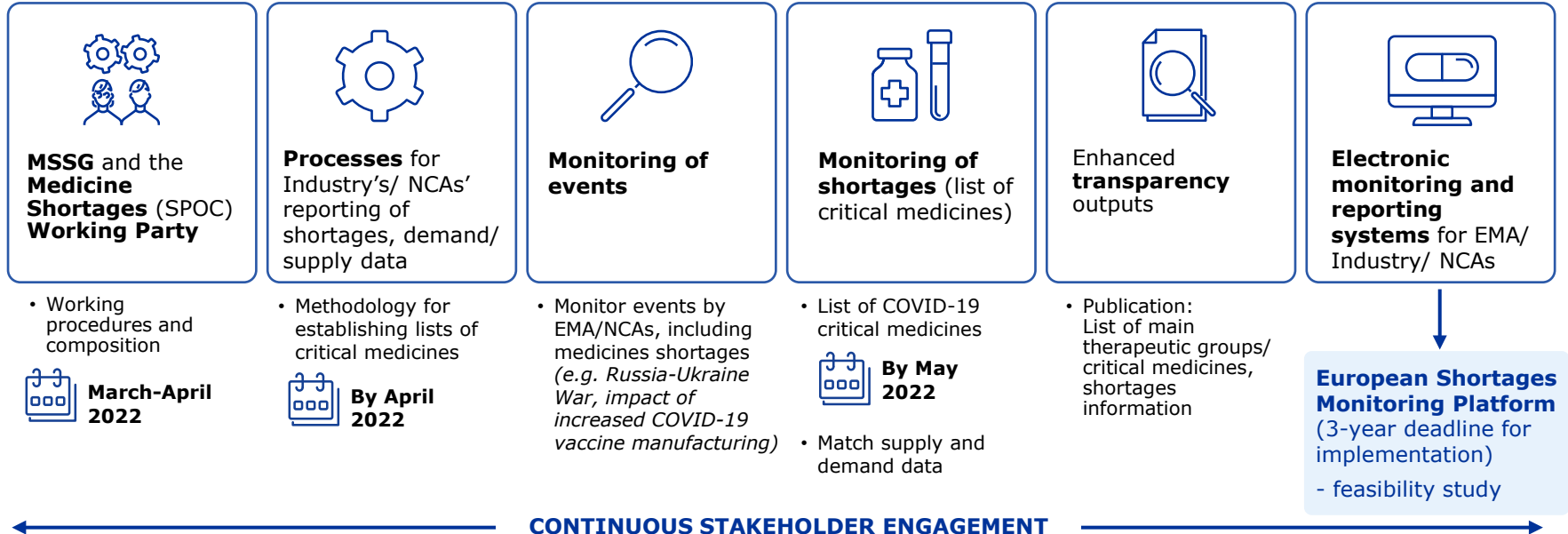
SPOCs - in the MSs and Industry - for medicines shortages reporting

 Medicines Shortages SPOC Working Party National Competent Authorities In preparation, and during a public health emergency/ major event		
Reporting of shortages and events (e.g. Brexit risk of shortages)	Reporting of estimated data on volume of demand	Escalate critical medicine shortages to MSSG (in prep./ during crises)

 Industry SPOC Network Subset of Marketing Authorisation Holders, according to list of critical medicines ONLY during a public health emergency/major event		
Reporting of shortages	Reporting of active manufacturing sites, marketing status, sales and market share, available stocks	Forecast of demand, plus supply capacity Prevention and mitigation plans

MONITORING AND MITIGATING **SHORTAGES OF CRITICAL MEDICINES** AND MANAGEMENT OF MAJOR EVENTS

Main actions in 2022



European shortages monitoring platform (ESMP)



Implementation date: **2 February 2025**

- Article 13 of Regulation 2020/0321 foresees the development of an **IT platform** to facilitate collection of information on **shortages, supply** and **demand** for medicinal products, including information on marketing status and marketing cessations, from both Industry's and Member States' SPOCs
- **Scope:** monitoring, prevention and management
 - Shortages of medicinal products (on the **critical** medicines lists) during a **PHE or a major event**
 - Actual and potential medicines shortages (in a given Member State), that **can lead to** a Major event or a PHE



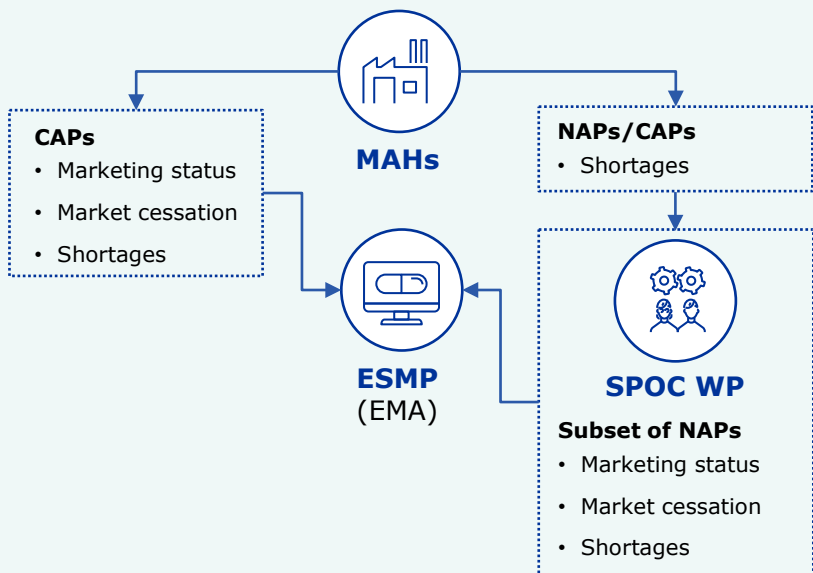
KEY BENEFIT

Providing a centralised EU platform to report, monitor, prevent and manage medicine shortages

European shortages monitoring platform (ESMP)

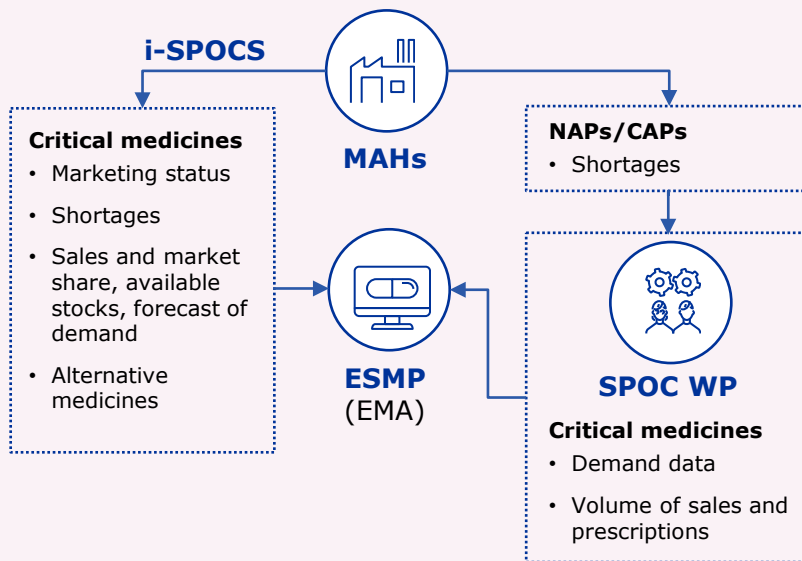
PREPAREDNESS

Monitoring of shortages that can lead to PHE/ME



PUBLIC HEALTH EMERGENCY/ MAJOR EVENT

Critical medicines (crisis specific)



Development requirements



Implementation date: **2 February 2025**



Draw up an **implementation plan**



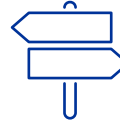
Develop technical and functional **specifications in collaboration with MSSG**



Ensure **compliance** with ISO standards, and Commercially Confidential Information (CCI) protection



Develop standardised reporting terminology and **guidance**



Ensure data interoperability with national IT systems



To ensure **access** to the information for the EC, the EMA, NCAs

MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES

New role for EMA



Implementation date: **2 February 2023**

- New task for EMA during public health emergencies (only)
- Sets up **Executive Steering Group on Shortages of Medical Devices** (MDSSG) for:
 - Adopting a list of categories of critical medical devices
 - Monitor the **supply of and demand** for medical devices (included on the PHE critical medical devices list)
 - Report and provide recommendations on measures to **prevent or mitigate** potential/actual shortages
- Steering Group will be supported by **Working Party of SPOCs (Member States)** and, a sub-network of SPOCs from Economic Operators and Notified Bodies

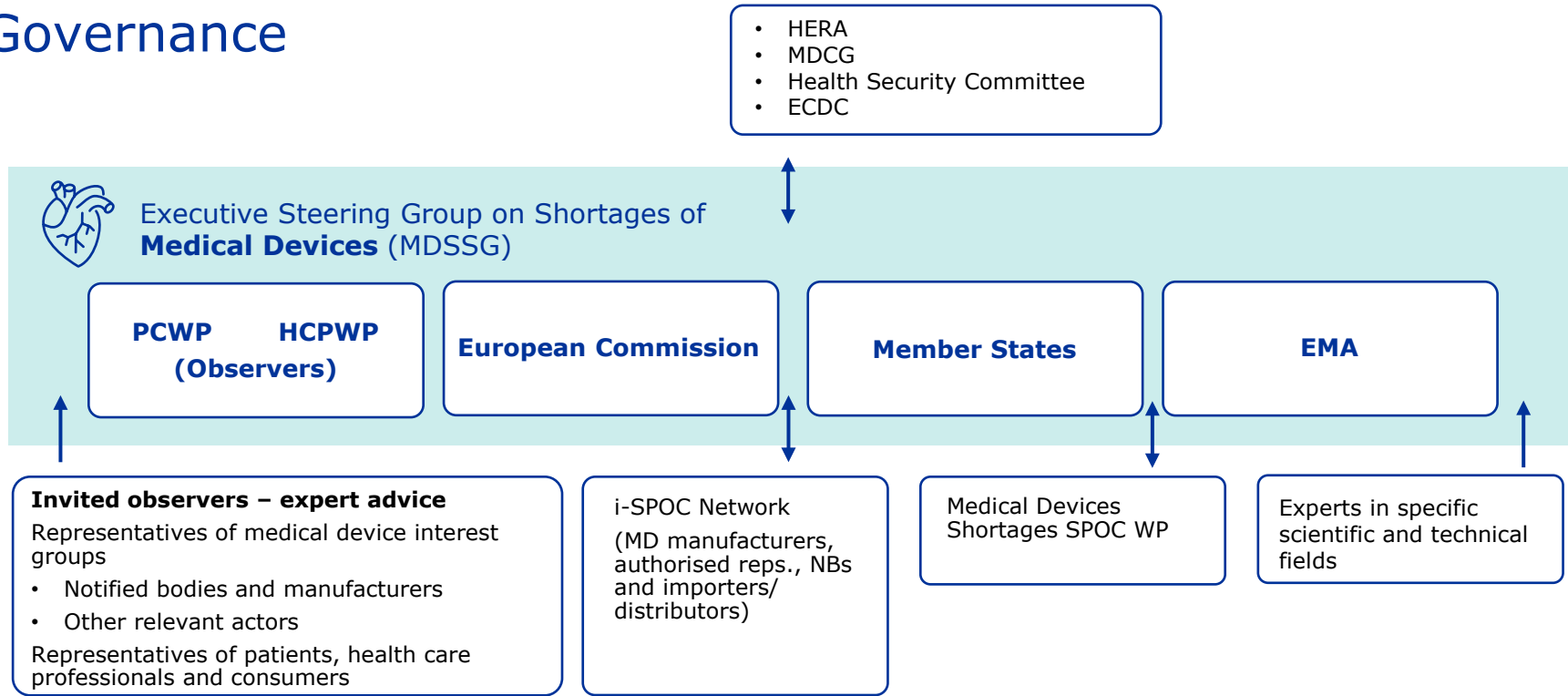


KEY BENEFIT

More coordination in preventing and mitigating medical devices shortages in the EU


MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES


Governance



MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES

SPOCs - in the MSs and Industry* - for medical devices shortages reporting

 Medical Devices Shortages SPOC Working Party Member States During a public health emergency ONLY	
Reporting of estimated data on volume of demand and forecasts	Escalate critical medicine shortage issues to MDSSG (during a PHE only)

 Industry* SPOC Network According to list of critical medical devices During a public health emergency ONLY		
Reporting of shortages	Sales and market share, available stock	Forecast of demand, plus supply capacity Prevention and mitigation plans Information from Notified Bodies

* Medical device manufacturers (or their authorised reps.), Notified Bodies and importers/distributors (as appropriate)

MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES

Main actions in 2022



Establishment of a drafting group to support the preparatory work



Preparatory work for the monitoring of shortages (list of critical devices): methodology and procedures



Establishment of interactions with relevant existing groups responsible for medical devices



Identification of existing data sources for medical devices



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



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

Conclusion

- The new Regulation (EU) 2020/123 has become applicable on 1 March 2022 for the monitoring and mitigation of shortages of **critical medicinal products**
- The Agency is currently transitioning from the *ad hoc* structures and processes put in place at the start of the pandemic, to those foreseen in the Regulation
- The Agency is starting the preparatory work to ensure a smooth and efficient delivery of the **ESMP** in early 2025
- For **critical medical devices**, preparatory work is ongoing to set up the necessary structures and processes by 2 Feb 2023. The Agency is also establishing the necessary interactions with stakeholders in the field of medical devices
- New mandate provides tools to prevent shortages of medicines and ensure supply in emergencies, and for the first time will extend monitoring to devices in emergencies

