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SCIENCE MEDICINES HEALTH

EMA Mandate extension - high level status updates Emergency task force

Industry Standing Group (ISG) meeting, 21 June 2022

Presented by Marco Cavaleri – ETF cochair and Head of Health Threats and Vaccines Strategy

EMA role in public health emergencies

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Regulation (EU) 2022/123

- Role of the **Emergency Task Force** is set in legislation and strengthened building on past experience (H1N1v, Ebola)
- ETF to operate after declaration of public health emergency by WHO or EC & for preparedness during non-emergency periods

1 March, date of implementation of the Regulation

Adopted ETF composition

- Composition built on previous ETF for continuity of expertise
- Nominees proposed by the various entities
- Management Board adopted ETF composition on **16 March**

Adopted ETF procedural rules

- New ETF adopted its Rules of Procedure (RoP) on **31 March**
- RoP approved by Management Board & Commission on 21 April

New ETF is operational

- New ETF started operating based on new mandate on **22 April**

The new Emergency Task Force (ETF)

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- ETF established with formal legal mandate as an **advisory and support body on medicines for public health emergencies and preparedness**
- Regulation sets out objectives and composition, but allowing flexibility & membership based on expertise
- **Strengthened** existing ETF responsibilities building on successful experience during past emergencies & COVID-19

Scientific advice and support to clinical trials

- assessed **directly** by ETF
- free of charge & fast-track for clinical trials and protocols
- **support study conduct**

Scientific reviews

- **systematic** assessment of evidence on medicines

ETF recommendations

- **on medicines not yet authorised**
- on scientific or **public health matters**

Preparedness activities for future emergencies

- **Monitor outbreaks and epidemics** that could become serious threats and development of countermeasures
- **Provide scientific advice** on, and develop strategy and requirements for, medicines with potential to address future emergencies
- **Maintain an overview of medicines in development for future emergencies**, and up- to-date information on potential radiological, chemical or bioterrorism agents
- **Coordinate activities** with relevant EU bodies including European Health Emergency Preparedness and Response Authority (DG HERA), ECDC and WHO

ETF composition for COVID-19

Co-Chairs: EMA chair, CHMP vicechair

Representatives from groups based on expertise:

Scientific Committees (CHMP, PRAC, PDCO, CMDh) **and EMA Representatives**

14

Working Parties' experts on vaccinology, biologics, infectious disease treatment, biostatistics, inspection, clinical trials, scientific advice assessment

19

Patients and Healthcare professionals identified by PCWP and HCPWP to bring the views of their respective communities

4

Clinical trial experts from various EU Member States (Clinical Trials Advisory Group (CTAG) and Clinical Trials Coordination Group (CTCG))

4

Additional experts and observers from academia, EU national or international regulators, EU bodies

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Medicines shortages and Medical Devices

Industry Standing Group (ISG) meeting, 21 June 2022

Presented by Monica Dias, EMA Head of Supply and Availability of Medicines and Devices Workstream

EMA extended mandate in the area of shortages

1

Monitoring and mitigating shortages of critical **medicinal products**

2

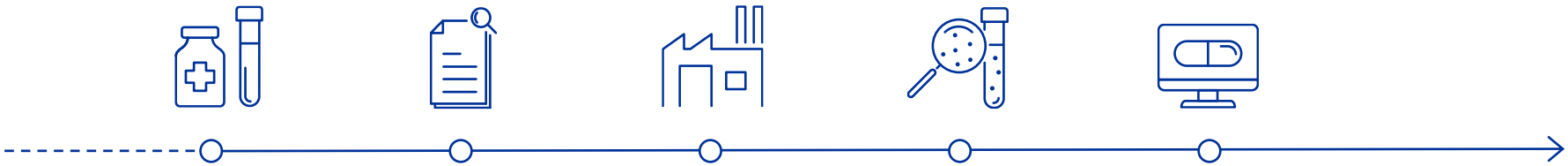
Setting up, maintenance and management of the **European Shortages Monitoring Platform** (ESMP)

3

Monitoring and mitigating shortages of critical **medical devices**

EXTENDED MANDATE: KEY MILESTONES FOR MEDICINES AND DEVICES SHORTAGES

Implementation of the shortages mandate



1 March 2022

Shortages of critical medicines

2 August 2022

Establishing a list of the main therapeutic groups (hospital care)

2 September 2022

Registration of i-SPOCs from Marketing Authorisation Holders

2 February 2023

Shortages of medical devices/in-vitro diagnostics

2 February 2025

European Shortages Monitoring Platform "Go Live"

MONITORING AND MITIGATING **SHORTAGES OF CRITICAL MEDICINES**

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)

European shortages monitoring platform (ESMP)

New platform for EMA

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 **Public Health Emergency (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

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

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EMA Mandate extension - high level status updates Medical Devices experts panel

Industry Standing Group (ISG) meeting, 21 June 2022

Presented by Silvy da Rocha Dias – Expert Panels and Groups (EPG) Head of Office *ad interim*

Handover Roadmap of the Expert Panels from JRC to EMA

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Q2 2021

Role of the Expamed secretariat

Expanded EMA mandate for the coordination and administration of CECP and PECP

Q3 2021

Expert database management

Review of the EC policy on the management of competing interests for MD

Q4 2021

Expert selection

Managing pool of applications of experts and assignment into thematic panels based on workload

End Q4 2021

Expert engagement and payments

Assignment of rapporteurships and assessment team

Q1 2022

Final transfer steps

Preparatory work for official handover 1st March 2022

Terms of references and Rules of procedure

Legal provisions that have led to the process design

Conflict of interest declaration (CoI)

CoI evaluation based on the EMA policy, however with some adaptation

Call for expression of interest

Open call for applications and appointment of experts by the EC

IT tools

Internal workflow for CECP and PECP, CIRCABC for dossier management with notified body

Handover activities

Training, knowledge transfer and expert onboarding

Organisation of the expert panels

SECRETARIAT → **EMA**

Overall coordination, supervision and support

Screening panel (1)

70 experts

- In charge of **decision** whether to provide scientific opinion (CECP)

Thematic expert panels (11)

- In charge of **scientific opinions (CECP) and views (PECP)**

Expert panels sub-groups

- Established in agreement with the **Secretariat** (permanent or ad-hoc basis)

Coordination Committee

- Chairs & Vice- Chairs of all expert panels
- Supports efficient and uniform operation of the panels

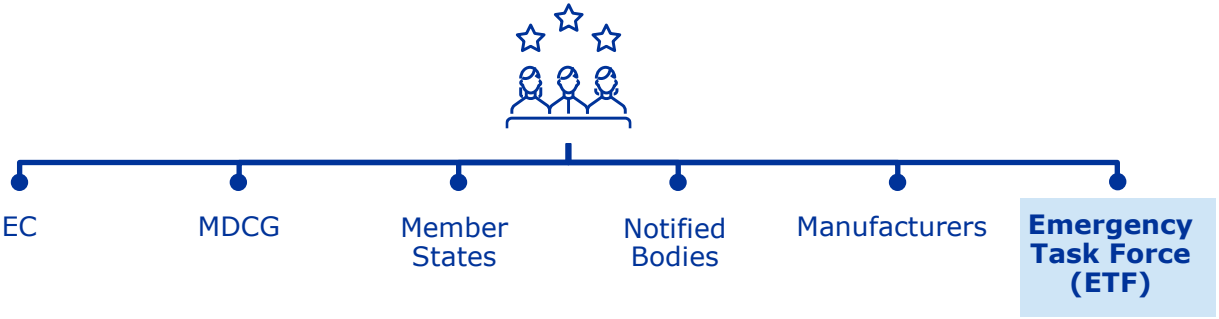
~130 experts for panels; ~ 120 experts in the central list

Role of the expert panels

Focus: Provide opinion on notified bodies' assessment of clinical evaluation of certain high-risk medical devices and views on the performance evaluation of certain high-risk *in vitro* diagnostics

To further implement:

- Advisory role on technical, scientific and clinical matters
- Contribution to the development of common specifications for clinical evaluation of device categories, guidance documents or international standards
- Contribute to the identification of concerns and emerging issues on safety and performance of medical devices
- Play a relevant role in preparedness and management of public health emergencies with the ETF



EMA’s extended mandate on the expert panels

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- The Agency is well-positioned to provide support to the expert panels as it has many years of **experience** supporting 7 Committees for the medicines’ regulation and many scientific advisory groups, *ad hoc* expert groups and working parties.
- The Agency **has already experience in some areas of medical devices** managing several assessment and consultation procedures on:
  - Medicinal products used in combination with a medical device
  - Medical devices with an ancillary medicinal substance
  - Medical devices made of substances that are systemically absorbed
  - Companion diagnostics (‘*in vitro* medical diagnostics’)
- The support for expert panels on medical devices is a **new activity for the Agency** that builds upon this prior experience, taking into consideration the specificities of the medical devices' regulatory framework.

Any questions?

Further information

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