



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication and Stakeholders' Engagement Plan on extended mandate

PCWP/HCPWP – 2 March 2022
Inga Abed

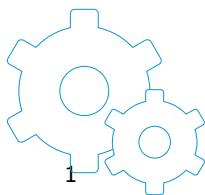




Background

Regulation extending EMA's mandate

- ✓ Monitor and mitigate shortages of both medicinal products and medical devices during public-health emergencies, building on structures and processes already set up by EMA (i.e. Executive Steering Group on Shortages and Safety of Medicinal Products, Medicines Shortage SPOC Working Party and i-SPOC networks)
- ✓ Anchor in legislation the **ETF activities** covering scientific advice, reviewing clinical-trial protocols and rolling reviews during public-health emergencies
- ✓ Transfer to EMA the tasks currently assigned to the EC of managing the '**EU Expert Panels**' of certain high-risk medical devices and in vitro diagnostics medical devices as well as scientific advice.
 - Mandate will **strengthen coordinated EU level action** during crisis
 - Mandate **formalises structures** established during the pandemic



Strategic communication & engagement on extended mandate

- **Objective:** To outline how EMA will communicate and engage with its external stakeholders and partners:



mapping key stakeholders, audiences, as well as anticipation of communication and engagement needs



overarching key messages, communication risks and mitigation measures



Activities specific to key milestones



planning communication and engagement actions with different stakeholders, including timelines and responsibilities

Phases - Communication and engagement plan

- **Preparatory phase**

background work started prior to the new regulations being finalised

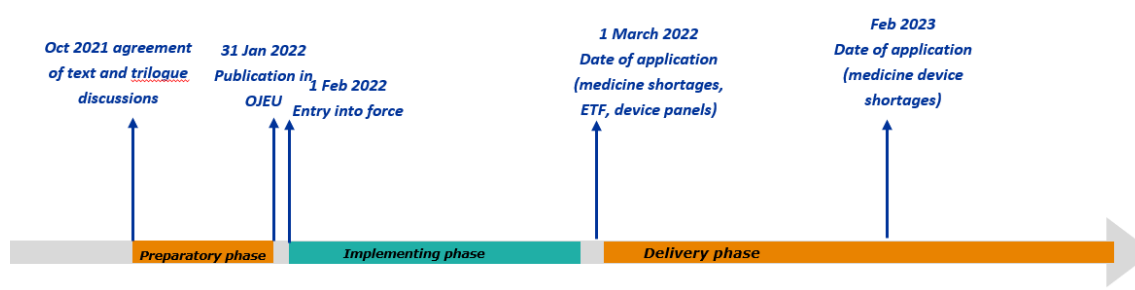
- **Implementing phase**

in parallel to the development of the new processes, after publication in OJEU

- **Delivery phase**

output of individual procedures & activities

- Dedicated **crisis action plan** in the event of future crisis





Mapping key audiences, engagement needs and channels

- Patients and Consumers
 - Healthcare professionals
 - Academia
 - Industry
 - Medical device industry
 - EMRN and HMA
 - European Commission
 - ECDC and other health authorities
 - European Parliament/ENVI
 - Media
- ✓ Overall background, scoping and implementation planning
 - ✓ EMA new procedures, processes and timelines
 - ✓ IT tools
 - ✓ Lists of critical medicines and devices
 - ✓ Outcome of procedures and processes

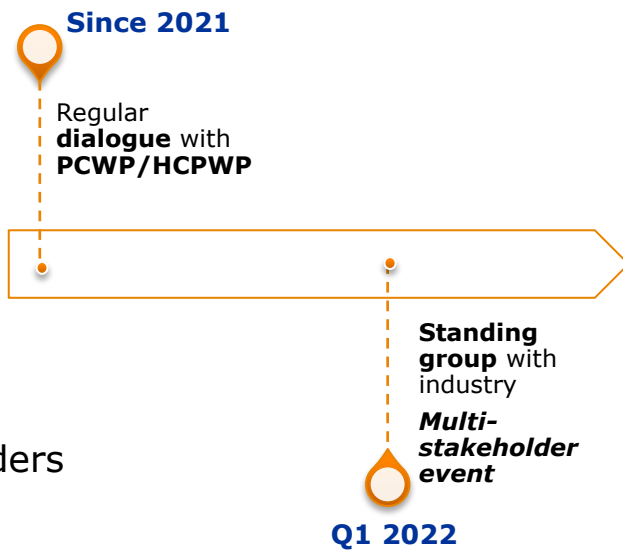
Main communication and engagement tools and channels

Audience specific messages & activities:

- Regular dialogue with PCWP/HCPWP
- Regular meetings with industry
- Multi-stakeholder workshop planned for Q1 2022
- Activities specific to key milestones
- Use of existing tools and channels but new tools may also be needed

Communication risks and mitigation measures

- Highlights expectations and potential concerns from stakeholders to be addressed





Key deliverables

Medicine shortages



- Establish Executive Steering Group on Shortages and Safety of Medicinal Products
- Establish Medicines Shortage SPOC Working Party for monitoring and reporting of events that may lead to a crisis situation
- Provide guidance to marketing authorisation holders on the industry SPOC (i-SPOC) network
- Establishment of list of therapeutic groups and critical medicines
- Single reporting channel and European Shortages Monitoring Platform

Emergency Task Force



- Set up ETF
- Start of operation
- Update EMA's health threats plan to take account of changes introduced by Regulation (EU) 2022/123
- Publication and dissemination of outcome documents



Medical devices' shortages

- Establishment of MDSSG
- Establish iSPOCs
- Publication of list of critical devices and outcome documents

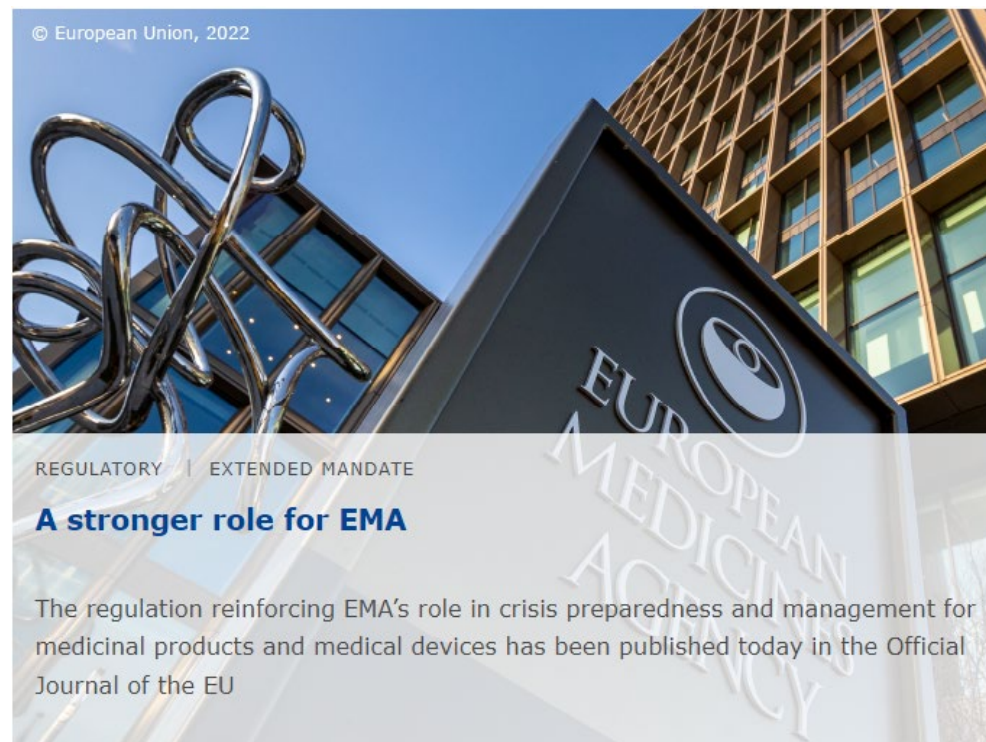


Medical devices panels

- Set up of permanent secretariat to support expert panels



EMA Communication





COVID-19 pandemic

[All info here >](#)

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REGULATORY | EXTENDED MANDATE

Regulation on EMA extended mandate now applicable

Legislation reinforcing EMA's role in preparing for and managing crisis situations affecting the EU single market for medicines and medical devices becomes applicable today

Authorisation of medicines

[Crisis preparedness and management](#)[Legal framework](#)[Regulatory science research](#)

Crisis preparedness and management [Share](#)

Table of contents

- [Shortages of critical medicines and medical devices](#)
- [Medicine development, approval and monitoring during emergencies](#)
- [Expert advice on high-risk medical devices](#)

The European Medicines Agency (EMA) has a formal role in preparing for and managing crisis situations affecting the European Union (EU) single market for medicines and medical devices, based on legislation that took effect on 1 March 2022.

[Regulation \(EU\) 2022/123](#) aims to empower the EU to react to **health crises** quickly, efficiently, and in a coordinated manner. It formalises some of the structures and processes EMA set up in the **COVID-19 pandemic** and assigns new tasks to EMA in the following areas:

- Monitoring and mitigating potential or actual shortages of critical medicinal products and medical devices
- Providing scientific support to the timely development of high quality, safe and effective medicines during public health emergencies
- Ensuring the smooth functioning of expert panels to assess high-risk medical devices and advise on crisis preparation and management

The Regulation became applicable on 1 March 2022. However, the provisions on shortages of critical medical devices will only begin to apply as of 2 February 2023.

It is part of the [European Health Union package](#) proposed by the European Commission in November 2020 and is in line with the priorities of the [European medicines regulatory network](#).

EMA is working with the Commission and other EU partners to implement the Regulation.

[Shortages of critical medicines and medical devices](#)



Any questions?

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