EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication and Stakeholders' Engagement Plan on extended mandate

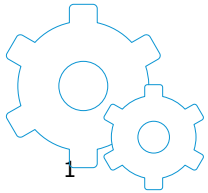
PCWP/HCPWP – 2 March 2022
Inga Abed

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

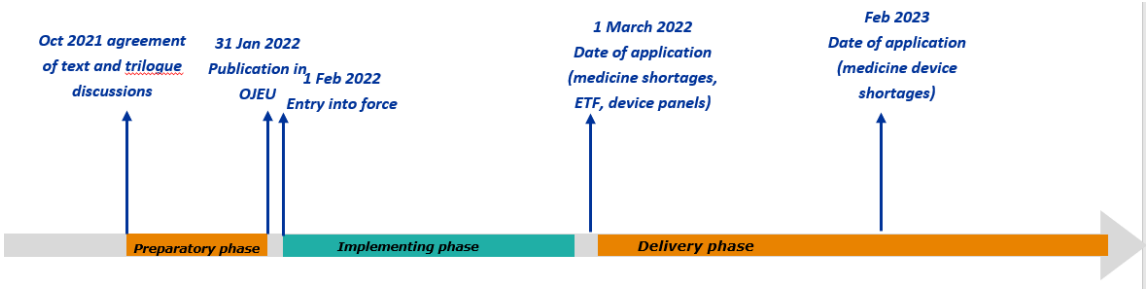
- **Implementing phase**

  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

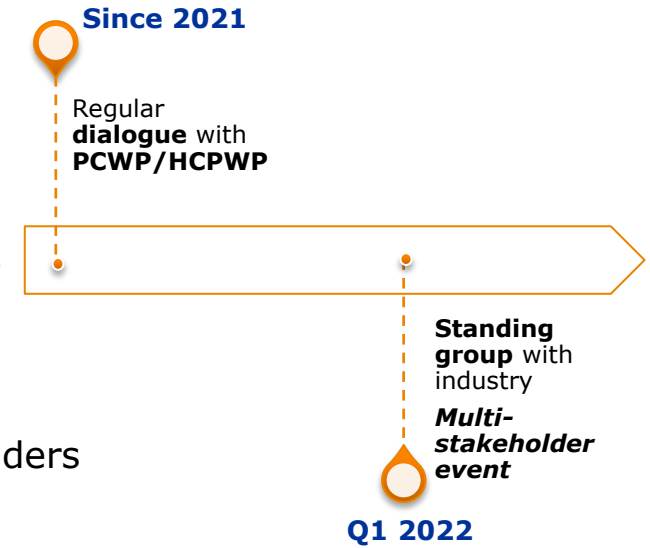
- ✓ Overall background, scoping and implementation planning
- ✓ EMA new procedures, processes and timelines
- ✓ IT tools
- ✓ Lists of critical medicines and devices
- ✓ Outcome of procedures and processes

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

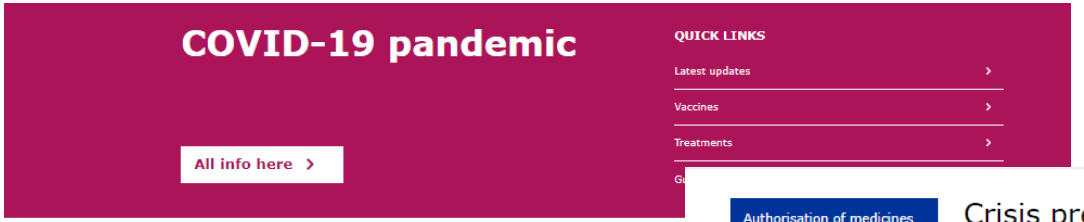
Medical devices' shortages

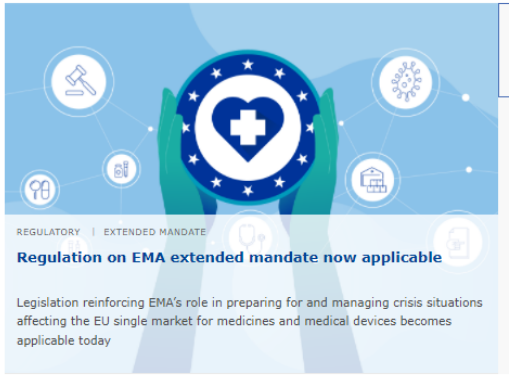
- Establishment of MDSSG
- Establish iSPOCs
- Publication of list of critical devices and outcome documents

Medical devices panels

- Set up of permanent secretariat to support expert panels

EMA Communication





Any questions?

Further information

Inga.abed@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**