How is EMA preparing for an extended mandate

PCWP/HCPWP Joint meeting
Background

On 11 November 2020, the European Commission (EC) published a legal proposal to expand EMA's mandate to act in preparation for and during public-health emergencies.

The current draft text is proposing to give the Agency the legal mandate to:

- **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. Steering Group on shortages, EU SPOC 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' for **clinical evaluation of certain high-risk medical devices and in vitro diagnostics** that are being set up according to the new Medical Devices regulations.
Objectives 1/2

The proposed new legal mandate, if unchanged, would formalise and strengthen the Agency's crisis-coordination role through the following measures:

• **Formalising the role of the current** EU Executive Steering Group on Shortages Caused by Major Events, as well as providing a legal basis for involving ECDC to obtain epidemiological data to help forecast medicines needs and to request specific data from Member States and supply-chain stakeholders. In this context, the steering group would be asked to provide opinions to the European Commission, Member States and marketing-authorisation holders on how to mitigate shortages.

• **Establishing a Medical Devices Executive Steering Group**, which would have the same legal basis as the Medicines Executive Steering Group, with powers to coordinate the monitoring of shortages for critical medical devices, request information from Member States, notified bodies and industry, and provide recommendations on measures to prevent or mitigate shortages.

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Objectives 2/2

- **Establishing an Emergency Task Force**, to be chaired by EMA. This task force would be responsible for leading the scientific response to a declared public-health emergency. It would provide accelerated scientific advice to be submitted in clinical trial applications, provide advice on clinical trials, undertake reviews of medicines to be used in the public-health emergency and provide recommendations on compassionate use of medicines and on use and distribution of unauthorised medicines.

Providing a legal basis for the establishment of the vaccines monitoring platform and for DARWIN (Data Analysis Real World Interrogation Network). The legal proposal would enable the Agency to further support innovative approaches to the development, approval and post-authorisation monitoring of vaccines, and deliver a sustainable platform to access and analyse healthcare data from across the EU.
EMA follow-up

Following the publication of the EC legal proposal, EMA has undertaken the following:

- Launch of an exercise to define the scope of the changes that will have to be introduced to implement the new legal mandate, to analyse the consequences of these changes, and to draft a high-level road map for the implementation.
- Establish a dedicated governance system, comprising a Task Force (EMTF), organised in 3 different workstreams each looking at specific aspects of the draft legal text:
  - WS1: Shortages of medicines
  - WS2: Public health emergencies
  - WS3: Shortages of medical devices, and the medical devices expert panels

These workstreams are supported by horizontal enablers who provide expertise on specific areas.
EMA preparedness activities

Through the Extended Mandate Task Force, the Agency, on the basis of the current draft legal text:

• has carried out an analysis of the scope of the changes that would be required to implement the legislation

• is currently in the process of developing an implementation roadmap detailing the activities and deliverables to be implemented by day 21
EMA’s preliminary view

Taking into account the current legal proposals and the identified challenges, EMA’s preliminary view is:

• A proposed strengthening of EMA’s role in crisis preparedness and management of public health threats should demonstrate added value for patients, HCPs and other stakeholders.

• If the final legal provisions for extending the current EMA mandate cannot include a more realistic deadline to allow for adequate implementation, then only minimum deliverables are possible at the implementation date, largely building on what EMA has put in place since the COVID-19 pandemic started. Even these minimum deliverables should allow for a future proofed operation in terms of objectives, processes and tools.

• Any activities which will not be covered in the final legislation could be undertaken in the context of strategic initiatives such as the EMANS to 2025 and the EC Pharmaceutical Strategy.
Thank you!

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