EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on EC legal proposal for extending the mandate of the EMA

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EC legal proposal as part of the "EU Health Union Package"

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 EC proposes 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 performing 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

EMA mandate extension legal proposal - State of Play

- Commission legal proposal adopted on 11 Nov 2020 Link
- Council agreed on a General approach on 15 June 2021 Link
- Parliament adopted its negotiating mandate on 8 July 2021 Link
- Trialogues between EP, Council and EC started on 13 July 2021
- Legal proposals for ECDC and Cross-Border Health Threats (Council position agreed in July and EP position agreed on 15 September): aiming to start Trilogues in Q4 2021
- Ratification of final text by co-legislators: dates *tbd*
- Entry into force and date of application: 20 days after publication in the OJ

EMA preparedness activities

Following the publication of the EC legal proposal, EMA set-up a temporary 'Extended Mandate Task Force':

- has **carried out an analysis of the scope of the changes** that would be required to implement the legislation – based on the draft published legal text;
- has **developed an implementation roadmap** detailing the activities and deliverables to be implemented by "day 21";
- has **planned for the necessary recruitment for 2021**, in accordance with the proposed 'fiche financière' in the EC legal proposal.

EMA preparation for implementation - 1/2

- The roadmap has highlighted the **need for the Agency to urgently start with the implementation** in order to deliver the minimum requirements within the twenty days implementation period set in the current draft proposal.

- Therefore, and with due consideration to the current state of the legislative process, the Agency has taken the decision to prepare for start of implementation on the basis of the draft legal text.

EMA preparation for implementation - 2/2

- In view of the different remits described in the current legal proposal, the Agency has split the **implementation phase into three different areas**, each led by a different accountable executive:
  - Shortages of medicines and medical devices;
  - Public Health Emergencies (ETF);
  - Medical devices expert panels.
- Once the legislative process will be concluded the Agency will carry out a further analysis to identify **possible changes between the final version of the legal text and the current draft version** that could impact on the tasks and activities identified in the implementation roadmap.

Main implementation constraints

The roadmap has highlight a **number of constraints** that could affect the implementation of the legal text. The main are summarised below:

- Tight 'entry-into-force' deadline of 20 days to be ready for implementation Uncertainty of final agreed text due to ongoing inter-institutional negotiations;
- Possible dependency of implementation activities on other legislations
  (e.g. cross-borders health threats legal proposal);
- Need of delivering IT tools to properly run the new activities
  (e.g. to manage the volume of submissions of shortages)

EMA's Management Board is being kept informed about the progress of EMA's preparation for implementation.

Thank you for your attention

Further information

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