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Press release

EMA Management Board: highlights of June 2017 meeting

Focus on Brexit preparations and the development of the EU clinical trial portal and database

Brexit preparations

The Management Board of the European Medicines Agency (EMA) was updated on the Agency's preparation for the withdrawal of the United Kingdom (UK) from the European Union (EU). Further to the UK's invocation of Article 50 on 29 March 2017, EMA needs to prepare and is working on the assumption that the UK will become a third country as of 30 March 2019. This is without prejudice to the outcome of the withdrawal negotiations. The UK fully participates in the activities of EMA; it continues to participate in all formal meetings and retains its speaking and voting rights.

EMA is essential to the functioning of the single market for medicines in the EU. The Agency's work is vital to provide EU citizens with effective, safe and high-quality medicines and to maintain a regulatory environment which fosters innovation and the development of new medicines. Timely preparations are necessary to ensure that EMA can continue to deliver on its mission and protect public and animal health beyond March 2019.

Preparatory work is carried out along several work streams, including:

- physical relocation of the Agency from London to one of the remaining 27 Member States: the Agency is carrying out impact assessments that will help prepare for the move while retaining as many staff as possible, once the European Council has taken its decision on EMA's new location, expected in October 2017.
- re-distribution of the workload: the Management Board endorsed principles and a working methodology to successfully undertake a (re)distribution of the workload relating to the evaluation and monitoring of medicines to ensure the high quality of EMA's scientific assessments and compliance with legal timelines. The Board endorsed the mandates of two working groups, one focusing on human medicines and one on veterinary medicines, which will explore options for a robust allocation of the workload across the network as well as ways to streamline work and further increase capacity in the network.
- provision of guidance and information to pharmaceutical companies: the EU regulatory network wants to ensure that companies are ready to take the necessary steps to enable undisrupted

supply of their medicines for the benefit of patients. Guidance was published to help them review and adapt their processes and consider changes to the terms of marketing authorisations to ensure their continuous validity.

A business continuity plan on EMA Brexit preparedness was presented to the Board. The Board endorsed the principles and the methodology that will help EMA prioritise its activities to make available the necessary resources to prepare for Brexit and cope with a potentially significant staff loss.

Positive assessment of EMA 2016 operations

In its assessment of the Executive Director's annual activity report for 2016, the Board expressed its appreciation for the taskforce promptly set up by the Agency to prepare for the upcoming change resulting from the UK's decision to leave the EU and ensure continuous and undisturbed operations.

Other areas of work highlighted by the Board included the launch of PRIME (PRiority MEDicines), an initiative to enhance support to medicines that target unmet medical needs; the launch of a website for the proactive publication of clinical data for new medicines; the conclusion of a pilot on parallel scientific advice with health technology assessment (HTA) bodies; and the vital role of the Agency in the global response to the threat of antimicrobial resistance.

The annual activity report describes the management and control systems in place at the Agency. Every year it is submitted to the Management Board that assesses whether the Agency has carried out its activities in accordance with the principles of good governance.

Entry into application of EU Clinical Trial Regulation postponed to 2019

The Board discussed the progress made regarding the development of the EU clinical trial portal and database. Due to technical difficulties with the development of the IT systems, the portal's go-live date has to be postponed. EMA is working closely with its IT service provider to ensure that corrective measures are implemented and will closely monitor progress. The Board was informed about the mitigation measures taken and the revised plan from the developer. The Agency will provide an update at the next meeting of the Management Board in October 2017 where a new delivery time frame will be discussed once progress with development has been confirmed. Due to these delays, the EU Clinical Trial Regulation will now come into application in 2019 instead of October 2018, as previously scheduled.

EMA's priority is to ensure that a high quality and functional system is delivered to the EU regulatory network and its stakeholders.

The EU clinical trial portal and database supports the ambitious modernisation of the processes for authorisation and oversight of clinical trials in the EU laid down in the EU Clinical Trial Regulation. The system will provide a single portal for submission and maintenance of clinical trial applications and authorisations, and support coordinated assessment and supervision. The portal and database will also serve as the source of public information on the full lifecycle of all clinical trials conducted in the EU, from their initial review up to the publication of their results.

This is the most ambitious IT system required by the EU legislation in the last decade, involving a complete EU-wide system to be used for clinical trial applications, urgent safety measures and other notifications to regulators before, during and after the conduct of clinical trials.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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