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Press release

EMA and heads of national competent authorities discuss consequences of Brexit

Key principles and working methodology established

The European Medicines Agency (EMA) organised an information meeting yesterday with members of its Management Board and heads of the National Competent Authorities (NCAs) of the EU/EEA Member States. The goal was to start discussing how the work related to the evaluation and monitoring of medicines will be shared between Member States in view of the United Kingdom's (UK) withdrawal from the European Union.

Although negotiations on the terms of the UK's departure have not yet officially commenced and one cannot prejudge their outcome, work will now start on the basis of the scenario that foresees that the UK will no longer participate in the work of EMA and the European medicines regulatory system as of 30 March 2019.

"I am reassured to see the overall commitment of the Member States to step up their efforts and to explore the options to take on a bigger share of the workload," said EMA's Executive Director Guido Rasi at the closing of the meeting. "The expertise available across the network is impressive and this is an opportunity to streamline the way we work, increase our capacity and work even more efficiently."

General principles for workload distribution will include:

- ensuring business continuity;
- maintaining the quality and robustness of the scientific assessment;
- continuing to comply with legal timelines;
- ensuring knowledge retention, either by building on existing knowledge, or through knowledge transfer;
- assuring an easy implementation and medium- and long-term sustainability.

It is expected that all NCAs will contribute to EMA activities as per the capacity and capability of each authority, to ensure an optimised and robust allocation of the workload across the network.

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The envisaged working methodology will include a mapping of current and future capacity and expertise in the network and the identification of potential gaps. This could help the network to increase its capacity in selected areas, and would be supported with enhanced training opportunities.

Based on the general principles, EMA, its scientific committees and working parties, together with the NCAs, will now assess the different options for workload distribution. A follow-up meeting will take place on 5 July 2017.

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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