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Press release

EMA Management Board: highlights of December 2017 meeting

Brexit update and adoption of work programme and budget for 2018

Update on Brexit preparations

The Management Board of the European Medicines Agency (EMA) heard from Executive Director Guido Rasi and Deputy Executive Director Noël Wathion how the Agency is preparing for relocation to Amsterdam in the Netherlands, and operationally for the United Kingdom's (UK) withdrawal from the European Union (EU). This is the first meeting of the Board since the General Affairs Council (Art.50) of 20 November and the decision of the EU 27 Member States to relocate the Agency to Amsterdam. EMA now has just over 15 months to prepare for the move and take up its new seat in Amsterdam by 30 March 2019 at the latest.

EMA's collaboration with the Netherlands commenced promptly and agreement has been reached on the joint governance structure with plans to progress activities within five work streams relating to the temporary and permanent premises, staff relocation, financial and legal aspects, and external communication.

A delegation from the Dutch government attended part of the Management Board meeting. The delegates presented the next steps regarding the relocation process and explained how the Dutch authorities plan to meet EMA's requirements. The Board was pleased to hear that the Netherlands are committed to ensure a seamless transition of the Agency's operations in the course of the relocation to Amsterdam. As the tailor-made Vivaldi building, which will become EMA's new permanent headquarters, is planned for completion in November 2019, the Dutch government will offer temporary premises to EMA from 1 January 2019, or earlier if requested by EMA, for an interim period until the new building is ready.

EMA and the Dutch authorities are currently working on a Memorandum of Understanding (MoU). The Board also heard that a permanent Netherlands helpdesk has been set up within EMA to offer guidance to staff on practical aspects to facilitate their relocation to the Netherlands.

The Board was also informed that EMA's Brexit preparedness business continuity plan will enter Phase 2 in January 2018, in order to free up further resources needed to prepare for the withdrawal of

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the UK from the EU. The Agency committed to providing transparent information on the details of the plan which will be published as part of the 2018 work programme.

The EU27 Member States and EMA have developed a methodology for the redistribution of the work currently carried out by the UK's Medicines & Healthcare products Regulatory Agency (MHRA) and Veterinary Medicines Directorate (VMD). The joint redistribution plan reflects the strengthened capacity of the European medicines regulatory network. The risk-based methodology takes into account the diverse expertise in the network and the workload associated with the medicines. EMA will communicate details of the methodology and next steps in early 2018.

2018 work programme and budget

EMA's preparations for the UK's withdrawal from the EU will impact on the activities of the Agency. This became clear in the discussion on the Agency's work programme and the budget for 2018-2019.

The Board adopted the work programme for 2018 and the preliminary work programme for 2019. For 2018, some growth in the level of applications for marketing authorisation applications for human and veterinary medicines and requests for scientific advice is foreseen, as reflected in a 6.8% increase in fee-related revenues. This suggests that EMA will be able to maintain its core activities, but also signals that in other areas the Agency will have to temporarily reduce or suspend activities. The work programme will be published in the first quarter of 2018. The Management Board supported EMA's job mapping exercise, which among other things will support the recruitment and training priorities in 2018 in the context of Brexit, and will lay the foundation for the development of a competency framework.

The Board adopted a budget of 337 million euros for 2018, a 2% increase over the previous year, driven primarily by an increase in fee-generating activities. The budget for 2018 includes provisions for Brexit-related costs such as IT-related relocation expenses and costs of the physical relocation of the Agency staff and assets. As the relocation process evolves, the budget will need to be monitored carefully and any additional costs that cannot be absorbed should be discussed with the European Commission.

Update on the development of the EU clinical trial portal and database for the EU Clinical Trial Regulation

The development of the EU Portal and Database is making important progress. A partially-completed version of the system has been subjected to user acceptance testing by representatives of the European Commission, Member States, academia, pharmaceutical industry and contract research organisation (CRO) associations throughout November, while technical testing and further development continue in parallel.

The extensive feedback from the user acceptance testing is being consolidated and analysed. Bugs which have been identified are being fixed and requests for improvement of the system are being prioritised in close cooperation with Member States and sponsors. The development of the auditable version, which will deliver the end-to-end processes required, is moving forward and this version will be presented for a next round of comprehensive user acceptance and technical testing before submitting the system to audit.

Subsequently, further improvements of the system will be made after the audit and before, as well as after, the system goes live. The audit will be carried out in 2018. Further information on timelines will be communicated after the audit.

This is the most ambitious IT development project so far required by the EU pharmaceutical legislation. The Agency is working hard in collaboration with Member States, stakeholders and the developers to deliver a good, functional system to support the needs of EU clinical research, and to have the Clinical

Trial Regulation enter in operation as soon as practicable. However, to be able to fully support the clinical trial authorisation procedures of all Member States from day one when the legislation applies, EMA's first priority is to ensure that a good quality and functional system is delivered to the EU regulatory network and stakeholders.

Notes

1. All relevant documents adopted at the Management Board meeting will be available on the Agency's website in due course. This press release is available on the Agency's website.
2. EMA's Brexit Preparedness Business Continuity Plan is available here.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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