17 June 2019
EMA/309156/2019
Media and Public Relations

Press release

Highlights of Management Board meeting: June 2019

At its 12-13 June meeting, the Board heard an update on EMA's first three months in its temporary building in Amsterdam Sloterdijk and the preparations for the Agency's move to its final premises in the Zuidas area of Amsterdam. Construction of the new building is expected to be completed by November 2019 and EMA staff are expected to move in as of 6 January 2020.

The Board was also informed about the uncertainty regarding the final number of staff who will eventually relocate to Amsterdam. EMA is still anticipating a staff loss of between 20-25%. At the end of 2018, the Agency's headcount was 901. As of early June 2019, the Agency's available workforce was 776. Of those 776, 464 have relocated to the Netherlands and 312 are currently teleworking mainly from London due to their personal circumstances. A recruitment exercise is currently ongoing to make sure that staff who decide not to relocate can be replaced. However, the Agency does not anticipate reaching its previous headcount, which included a large number of colleagues on short-term local contracts.

Due to resource constraints, most activities that were temporarily suspended at the end of 2018 as part of the Agency's business continuity planning remain on hold. A further review by the Board will take place in October 2019. Suspended activities include for example guideline development and most working party meetings, engagement in international activities and also the Agency's initiative on proactive publication of clinical data.

Some activities will start to be reinstated now. The focus will be on activities and projects that aim to increase the efficiency of EMA's operations to ensure that the Agency is fit-for-purpose in the longer term, e.g. IT systems supporting the medicines evaluation process and the digitalisation of administrative processes. In addition, some of the EU network working groups directly contributing to EMA's core activities will restart. More detail on activities to be reprioritised are outlined in this updated table.

On top of compensating for staff losses and resources diverted to Brexit preparations, EMA also faces a substantial workload stemming from various new pieces of legislation for which no additional resources have been made available. This includes the regulations on medical devices and *in vitro* diagnostic medical devices, the EU data protection regulation (EU DPR) and the veterinary legislation, which foresees the development of major IT infrastructure and re-engineering of processes. Preparatory work on these pieces of legislation has been tentatively planned to start as of now, but any work undertaken will be subject to availability of the required human and financial resources.

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Update on industry preparedness for Brexit

The Board heard an update on industry preparations for Brexit in relation to centrally authorised products (CAPs). Of the 400 marketing authorisations that need to be transferred from the UK to an EU27 Member State, just three (for human medicines) are still pending. Good progress has also been made for products with qualified persons for pharmacovigilance (QPPVs) and pharmacovigilance system master files (PSMFs) based in the UK as shown below:

- Transfers of marketing authorisations — Changes made for 397 out of 400
- Qualified persons for pharmacovigilance — Changes made for 243 out of 335 medicines
- Pharmacovigilance system master files — Changes made for 313 out of 376 medicines
- Batch release sites — Changes made for 95 out of 119 medicines

Although companies have reassured EMA that their plans are in place, the Agency reminds them of their responsibility to make the necessary changes required by EU law as soon as possible.

Positive assessment of EMA operations in 2018

The Board has assessed and adopted the Executive Director's annual activity report for 2018. Achievements highlighted by the Board include the launch of IRIS, the secure online portal for orphan designation applications, which is expected to significantly reduce submission time and provide efficiency gains, and the joint EMA/European Commission action plan to increase the efficiency of paediatric regulatory processes. The Board also noted that the first two medicines supported through EMA's PRIME (PRIority MEdicines) scheme had received positive opinions from the Agency, demonstrating the valuable support that the scheme provides to generate robust evidence for promising medicines that target unmet needs.

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

Implementation of the EU IT systems required by the Clinical Trial Regulation

The Board was updated on the status of the development of the Clinical Trials Information System (CTIS). Since the last update to the Board in March 2019, the project methodology and plan have been revised to improve delivery. Member States and stakeholders are now directly engaged in the development of CTIS through nominated 'product owners' to ensure that their expectations are taken into account. This means that business expert representatives have an enhanced and continuous opportunity to review, select and verify functionalities.

The codes of the EU Clinical Trial Portal and Database and the safety reporting module have been merged. The system has undergone testing and key bug fixing was carried out in spring 2019. The safety reporting functionalities have also been developed. This month, CTIS is entering a phase of agile, iterative delivery, initially to prepare the system for audit. It will then be further enhanced for 'go-live' and beyond in close cooperation with the user community.

New representative of the European Parliament on the Board

The Chair of the Board gave a warm welcome to the new representative of the European Parliament, Matthias Groote, to the Management Board. Mr Groote, who is the former chair of the Committee on the Environment, Public Health and Food Safety (ENVI) will serve a three-year term, that can be

renewed once. The mandate of Mr Tonio Borg, the second European Parliament representative to the Board, has been renewed for another term.

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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