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Press release

EMA Management Board: highlights of December 2018 meeting

EMA's Management Board heard an update from Deputy Executive Director Noël Wathion on the Agency's preparations for 2019, a year of transition for EMA. The Agency's temporary premises in Amsterdam are on track to be fully operational on 1 January 2019 to allow for final preparations for EMA's move to Amsterdam in March next year. Work on the permanent premises is also progressing as planned and should be completed by mid-November 2019.

A delegation of the Board, led by Board chair Christa Wirthumer-Hoche, visited both sites on 7 November and was reassured by the progress made by the Dutch authorities to deliver both premises on time and to a high quality standard. A report on the visit is available.

Since the last Management Board meeting in October, the Agency has continued to closely monitor staff's intention to relocate to Amsterdam and shared a more robust forecast with the Board. Overall the Agency expects to lose approximately 25 per cent of its overall workforce. These projections should allow EMA to gradually resume temporarily suspended and reduced activities as of July 2019. However, the first half of the year will see a further temporary reduction of activities also because the Agency moves into the final phase of its physical relocation. All core activities related to the evaluation and supervision of medicines are expected to continue without any interruption or delays foreseen and to the same quality.

EMA will communicate further on phase 4 of its Brexit preparedness business continuity plan, to be introduced as of 1 January 2019, and on its activities during the critical period around the Agency's physical relocation to Amsterdam shortly.

Annual work programme for 2019 and budget

The Board adopted EMA's work programme and budget for 2019 and a preliminary draft programme and budget for 2020.

Both the work programme and the budget for 2019 reflect the challenges of the Agency's physical relocation to Amsterdam. Overall, there is a slight decrease of 1.4 per cent in the Agency's draft budget for 2019 compared to 2018 (€332,959,000 in 2019 compared to €337,761,000 in 2018). This decrease is caused by the general uncertainty around Brexit, but is expected to stabilise as EMA resumes its normal activity in 2020. EMA will review its work programme once it has settled in

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Amsterdam to analyse how to best return to a full level of activity in line with the priorities identified in the network strategy to 2020.

Overall, EMA expects a stable level of pre-authorisation activities for human medicines in 2019, with the exception of scientific advice on medicine development where EMA expects an increase of 3.8%, compared to 2018 (708 in 2019 vs 682 in 2018).

For initial marketing authorisation applications, according to current forecasts, EMA expects to receive a slightly lower number with 102 applications in 2019 versus 109 in 2018.

The number of applications for medicines containing a new active substance should remain stable.

In the area of veterinary medicines, EMA expects to receive 14 applications for initial marketing authorisation in 2019 compared to 18 in 2018.

EMA's budget and work programme for 2019 will be published on the EMA website in Q1 2019.

Potential impact of Brexit on the supply of centrally authorised products

The Board was updated on the steps undertaken by EMA and its scientific committees to manage the risk of supply shortages of centrally authorised products (CAPs) as a result of Brexit. At its October 2018 meeting, the Board heard that the number of CAPs at risk of supply shortages had decreased to 31 (19 human medicines and 12 veterinary medicines). For each of these medicines, EMA, together with its scientific committees, has assessed how critical they are for the treatment of the disease they target. National competent authorities will now be checking whether there are possible therapeutic alternatives available in their country. It was noted that the medicines deemed to be at risk of supply shortages are subject to change based on updated information coming from marketing authorisation holders. EMA will continue to closely monitor all CAPs at risk of Brexit-related supply shortages.

Update on the development of the Clinical Trials Information System for the EU Clinical Trial Regulation

The Board was updated on the status of the ongoing development of the Clinical Trials Information System (formerly the EU clinical trial portal and database). The system remains in a phase of pre-testing of the auditable release (release 0.7) by the Agency together with stakeholders before user acceptance testing (UAT7) can start.

The Agency continues its work to fix the remaining bugs with the contractor and will implement improvements in the system prior to user acceptance testing. At the same time the work to develop the safety reporting part of the system is progressing.

The project plan is under revision to improve delivery and to ensure that stakeholders can give feedback more regularly during the process so that their expectations can be taken into account as early as possible. Further announcements will be made before user acceptance testing of release 0.7 commences. The Agency and the Member States are fully committed to ensuring the success of this project and its delivery.

Notes

1. All relevant documents adopted at the Management Board meeting will be available on the Agency's website in due course.
2. This press release is available on the Agency's website.

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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