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Press release

EMA Management Board: highlights of October 2017 meeting

Board hears update on preparations for Brexit and adopts Agency's mid-year report

Brexit preparations

At its 5 October 2017 meeting in London, the Management Board of the European Medicines Agency (EMA) was updated on the Agency's ongoing preparations for the withdrawal of the United Kingdom (UK) from the European Union (EU).

The European Commission's assessment of the 19 Member States' bids to host the Agency, which EMA contributed to, was published on 30 September 2017. EMA released its comments on the offers of the Member States on 3 October. The General Affairs Council of the European Union is scheduled to decide on the Agency's new location on 20 November 2017.

Reflecting on EMA's comments on the Member States' bids, Noël Wathion, EMA's Deputy Executive Director, stressed that the accessibility of the new premises for delegates and experts, and staff retention, are key to ensuring the Agency remains operational and able to deliver on its mission after its relocation. This needs to be supported by adequate premises and facilities. By explaining the methodology used, he was able to address concerns regarding EMA's assessment raised by a few Member States.

Yann Le Cam, patient representative on the Board and Chief Executive Officer of Eurordis commented, "EMA is a key asset of the European Union to make it an attractive place for medical innovation and job creation. The decision where to locate EMA as of March 2019 should not be based on what EMA would bring to the new host country, but on whether the new host country has what it takes to preserve the value EMA brings to patients in the European Union. The capacity of the new host city to retain current staff and attract new people at the same level of quality is key for this."

In view of the challenges EMA will face over the next few years, the Board initiated an early discussion on the implications for the draft budget for 2018 and the preliminary draft budget for 2019.

While no firm predictions can be made until the new location of the Agency is known, EMA is anticipating staff losses which will not only challenge the Agency's operability but could also result in a major deficit in

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its budget. If operations are delayed or have to stop because of massive staff losses, the Agency could experience a dramatic drop in fee income which would in turn result in reduced payments to the national competent authorities. The financial consequences would be further exacerbated by the cost of replacing staff. Such shortfall would need to be made up from the Union budget.

The final budget will be proposed to the Board in December, after the new location of the Agency is announced in November.

The Board also heard an update on progress made by the EMA working groups on Committee preparedness for human and veterinary medicines. The groups discussed how the workload that is currently carried out by the UK in relation to the assessment of medicines will be distributed among the EU27 after the UK has left the EU. Further meetings will be held in November with a view to finalising recommendations for the Management Board at their next meeting in December.

The Management Board was informed about the next phase of EMA's Brexit preparedness business continuity plan to be launched as of 1 January 2018. The Management Board agreed to continuously analyse the impact of this plan, which will be released next week.

Mid-year report

Despite the impact on EMA of the UK's decision to leave the EU, the Agency continues to deliver on its main public health objectives as set out in its work programe for 2017.

The mid-year report shows that PRIME, the Agency's scheme to support the development of promising medicines addressing unmet medical needs, continues to generate high interest from medicine developers. In the first half of 2017, EMA received 46 applications for PRIME. By the end of June, 42 applications had been assessed and ten had been accepted into the scheme. Underlining the important role EMA plays in facilitating the research and development of new medicines and reducing time to patients, EMA also recorded a 20% increase in the number of requests for scientific advice in the first half of 2017 (345 requests compared to 287 in the first half of 2016).

The Agency continued to provide high-quality, efficient and consistent support to the evaluation process for human and veterinary medicines. For human medicines, the number of new applications for marketing authorisation received in the first half of 2017 was slightly lower than that received during the same period in 2016 (36 in the first half 2017 versus 42 in the first half of 2016). However, the overall forecast for 2017 is in line with 2016 figures.

EMA continued to support early access to medicines for patients through the accelerated assessment framework. 57% of requests for accelerated assessment were granted and 75% of the marketing authorisation applications initiated under this mechanism were completed under the accelerated timetable during the first half of 2017.

For veterinary medicines, seven requests for marketing authorisation were received in the first half of 2017. This follows a spike in the number of applications for marketing authorisation received in the same time period in 2016 (12), demonstrating the fluctuations in submission patterns between years. The number of requests for scientific advice for veterinary medicines received in the first half of 2017 was higher than that received during the same period in recent years (14 versus a range of 8-11 in recent years).

EMA's mid-year report will be published on the EMA website shortly.

Report from the Committee for Orphan Medicinal Products (COMP)

COMP Chair, Bruno Sepodes, briefed the Board on the ongoing efforts of the Committee for more, better, and faster approved treatments for rare diseases. Over the years the COMP has seen an increasing number of applications for orphan designations of medicines under development. The Chair stressed that

the work of the Committee has changed significantly over the years requiring more direct engagement with stakeholders and more expert input. To address this, the COMP created several ad-hoc working groups (including a more efficient response to protocol assistance requests) and stepped up its dialogue with other stakeholders concerning the clarification of 'significant benefit' and other aspects of the orphan regulation.

Given the increasing number of medicines with orphan designation that are coming to the market and acknowledging that access to these products is often challenging, Bruno Sepodes also highlighted the need to fully exploit the legal possibilities in the Regulation to reduce protection periods for orphan medicines that do not meet the criteria over time. This also entails the need to generate relevant data for these products after authorisation.

Update on the EU Clinical Trial Regulation and development of the clinical trial EU Portal and Database

The Board heard an update on the EU Portal and Database project. The development is progressing, though still requires close monitoring. More precision of the delivery timeframe will be possible after a planned cycle of extensive testing by Member States and sponsor representatives and when further progress with the auditable version of the system has been made. The development remains aligned to the schedule that enables the EU Clinical Trial Regulation to come into application in the second half of 2019.

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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