5 October 2018
EMA/678495/2018
Media and Public Relations

Press release

EMA Management Board: highlights of October 2018 meeting

EMA mid-year report 2018

At its 4 October 2018 meeting in London, the Management Board of the European Medicines Agency (EMA) heard an update on the Agency's activities in the first half of 2018.

In human medicine, EMA recommended the first two CAR-T cell medicines for approval in the European Union (EU). These innovative medicines present a new approach in the treatment of cancer and were also the first medicines supported through EMA's PRIority MEdicines (PRIME) scheme to receive positive opinions from EMA's Committee for Medicinal Products for Human Use (CHMP).

The number of new initial evaluation applications for human medicines received in the first half of 2018 was 30% higher than that received during the same period in 2017 (47 in the first half 2018 versus 36 in the first half of 2017).

In veterinary medicine, initial evaluation applications remained at the same level as in the first half of 2017, with seven applications received. The number of requests for scientific advice for veterinary medicines increased to 16 in the first half of 2018 compared to 14 during the same period in 2017.

The number of transfers of marketing authorisation applications has seen a six-fold increase compared to 2017, primarily due to Brexit-related transfers (232 in the first half of 2018, compared to 36 in the same period in 2017).

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

Report from the Scientific Advice Working Party

The Chair of the Scientific Advice Working Party (SAWP), Rob Hemmings, briefed the Board on the activities of the working party, highlighting the constant increase in scientific advice procedures over the past ten years. He also underlined the continuing interest of applicants for the qualification of novel methodologies procedure and the parallel scientific advice with health technology assessment (HTA) bodies. The SAWP's role in informing EMA committee decisions on eligibility to the PRIME scheme was also highlighted.

"Scientific advice is an important tool for EMA and the network to clarify regulatory requirements for the development of new medicines for the benefit of patients," said Mr Hemmings. "We are helping to

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

ensure that companies generate robust evidence on their medicines development and a key challenge in the future will be to have the right expertise on the working party to keep pace with rapidly evolving innovation in pharmaceutical development."

The SAWP is an EMA working party which upon request advises medicine developers on the use of the best methods to develop their medicine and collect the most robust data. Its members are appointed according to the areas of expertise needed. Assessing whether the generated data support a positive benefit/risk for the product concerned is always done independently by the CHMP at time of marketing authorisation application.

Ten-year study on procedures for authorisation and monitoring of human medicines

As part of the EU's ongoing drive to make sure that its laws are fit for purpose, the European Commission has commissioned a study to examine the procedures for authorisation and monitoring of medicines for human use.

The focus of the study, which will be conducted by Ernst & Young, is on the operation of the regulatory procedures, and in particular their effectiveness, efficiency, relevance to the objectives laid down in the current EU legislative framework, as well as to check that they are delivering for patients. The Board heard that a report to the European Parliament and the Council of the EU will be published by the European Commission in 2020. Member States, the pharmaceutical industry and representatives of patient and healthcare professional organisations will be asked to contribute to the preparation of the study.

EMA's founding regulation requires that the Agency is evaluated at least every ten years; such an evaluation was last carried out in January 2010.

Revision to policy on access to documents

Providing access to documents is an important element in EMA's continued commitment to transparency.

The Board was updated on revisions to EMA's access to documents policy following a public consultation in 2017. The policy describes the rules EMA applies, in accordance with Regulation (EC) No 1049/2001, which gives EU citizens the right to access EU documents.

The new version extends the scope of the policy to include documents held by the Agency that are not related to medicinal products. It includes a new table outlining the access rules for these documents and a revised table on access rules for documents related to medicines for human and veterinary use. The policy reiterates that EMA is no longer in a position to process access to documents requests issued from outside the EU.

EU Clinical Trial Regulation and development of the EU portal and database

The Board was updated on the quality and status of the ongoing development of the EU clinical trial portal and database, both of which are being carefully monitored. The Board heard that the development of the auditable release of the portal and database (release 0.7) is complete. The release is now in an intensive phase of pre-testing before formal user acceptance testing (UAT7) can start in early 2019. Taking into account the rate of progress with testing and bug fixing, and the relocation of the Agency, the audit field work will take place once the Agency has settled in Amsterdam, after March 2019. Dependent on successful completion of the audit and review by the Management Board around the end of 2019, the system could be ready to go live later in 2020.

Brexit preparations

The Board was also updated on the Agency's ongoing preparations for the withdrawal of the United Kingdom (UK) from the EU. Board members heard that the cooperation with the Netherlands is running smoothly and preparations for both the interim and the permanent buildings are on track. The Board congratulated EMA on the quality and professionalism of its preparatory work so far and acknowledged the heavy workload that the Agency has to deal with.

EMA will communicate further on the operational preparations for Brexit shortly.

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

Contact our press officers

Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News