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Press release

EMA Management Board: highlights of March 2018 meeting

Board adopts 2017 report on veterinary medicines for minor use minor species and hears update on clinical trial portal and database

Increasing availability of veterinary medicines for minor use and minor species

At its 15 March meeting in London, the European Medicines Agency's (EMA) Management Board endorsed the 2017 report on the implementation of the policy on veterinary medicines for minor use minor species (MUMS) / limited markets. The policy aims to stimulate the development of new veterinary medicines for minor species and for rare diseases in major species that would otherwise not be developed under current market conditions.

Stakeholders continue to be highly interested in the scheme. A total of 207 requests for classification as a MUMS medicine were received since the policy entered into force in 2009. 31% of the 29 requests received last year were submitted by small and medium-sized enterprises (SMEs).

The MUMS scheme foresees two types of incentives for developers: reduced data requirements and financial incentives for applications. It has proved successful in facilitating the authorisation of new treatments for animals, especially for food-producing species. In 2017, two MUMS medicines were recommended for marketing authorisation, including a product intended for the treatment of honey bees in hives infested with Varroa destructor and a bait vaccine for the immunisation of foxes and raccoon dogs against rabies.

Review of clinical trial portal and database

The Board received an update on progress with the development of the EU portal and database. Based on the experience with this complex development so far, the developer has submitted a revised project plan with improved project management, development and testing processes and resources. It also contains increased contingency.

The Board heard that the first item (release 0.6) due under that plan has been received and has met the acceptance criteria. Further experience will enable greater confidence in the plan to be gained and an external party will also be asked to review this and report to the Board. The plan shows that release

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0.7 should be available for audit, as required by Article 82 of the Clinical Trial Regulation, early in 2019. More precise information on timelines will be communicated after the audit.

Advanced therapies: achievements and challenges

Dr Martina Schüssler-Lenz, chair of EMA's Committee for Advanced Therapies (CAT), also deputy head of advanced therapy medicinal products at the Paul-Ehrlich Institute (PEI) in Germany, presented the achievements and ongoing challenges in the area of advanced therapies, i.e. medicines that are based either on cells, genes or tissues. These medicines offer new treatment options for rare diseases and patients with high unmet medical need.

Ten advanced therapies have been granted an EU-wide marketing authorisation since the creation of the CAT in 2009. Four advanced therapies are currently under evaluation, including one cell-based and three gene-based therapies. In 2018, the CAT expects to start evaluating four additional medicines.

"We are observing rapidly evolving scientific and technical innovation entering the field of advanced therapies," explained Dr Schüssler-Lenz, "but the Committee is well set up to cope with the scientific and regulatory challenges ahead due to its expertise and the way members interact and learn from each other."

Dr Schüssler-Lenz also noted that requests for scientific advice for advanced therapies have increased significantly between 2012 and 2017 and that the CAT is now routinely involved in all scientific advice procedures for these medicines.

Monitoring of EMA independence policies

The Board reviewed the progress made during 2016 and 2017 with the implementation of the various Agency policies related to the independence of members and experts of EMA's scientific committees, Management Board members and Agency staff. A report on independence covering 2016 and 2017 includes controls carried out during that time period. In line with the Agency's commitment to continually review its operations, the report also identifies recommendations for further improvement and an action plan for 2018. The report will be made available on EMA's website in due course.

Update on Brexit

The Board was informed that the dossier on EMA's intention to move to its new permanent building in the Zuidas district of Amsterdam has been sent to the EU's budgetary authority. The notification to the budgetary authority of EMA's intention to move to new headquarters is required by the Agency's financial regulation and is a key step in the building approval process.

The Board was also updated on the survey to marketing authorisation holders that EMA launched in January. The survey was sent to marketing authorisation holders of centrally authorised products (CAPs) who are located in the United Kingdom (UK) or who have quality control, batch release and/or import/manufacturing sites or a qualified person for pharmacovigilance (QPPV) or pharmacovigilance system master files in the UK. The aim of the survey is to identify CAPs potentially at risk of supply shortages and to obtain information on the timelines for submission of the necessary regulatory changes. Responses received provided information on 90% of the medicines that were subject to the survey. The data are currently being analysed and a high-level summary of the results will be published.

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. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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