EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press release

Highlights of Management Board: June 2020 meeting

At its virtual meeting on 11 June, the Management Board was updated on how EMA is prioritising the response to the COVID-19 pandemic and what measures the Agency has put in place to tackle the crisis. The Agency and the European medicines regulatory network are currently operating under a network COVID-19 business continuity plan to ensure that core public and animal health regulatory activities, such as the authorisation, maintenance and supervision of medicines continue to be carried out during the pandemic and do not incur any possible delays. In particular, the network is mobilised to support the development and evaluation of medicines for COVID-19.

The Board noted that EMA is working on providing an increased level of transparency for medicines and vaccines targeting COVID-19, including the publication of clinical data for these products. More information will be communicated shortly.

In order to speed up the assessment of promising investigational medicines during the pandemic, EMA's human medicines committee (CHMP) reviews data as they become available on a rolling basis, while development is still ongoing. The Board agreed to the introduction of a new fee for the 'rolling review' assessment for potential marketing authorisations. This fee would be deducted from the fee that would become due with the submission of an actual marketing authorisation application. Small and medium-sized enterprises (SMEs) are eligible for a 90% reduction. Revised implementing rules to the Fee Regulation will be published shorty.

Positive assessment of EMA operations in 2019

The Board has assessed and adopted the Executive Director's annual activity report for 2019. The Board noted that although business continuity planning for Brexit and the Agency's relocation to the Netherlands had taken up considerable resources last year, EMA managed to maintain its core operations and delivered its 2019 work programme. The UK portfolio of medicines had been reallocated to other EU Member States and the Board was confident that all steps have now been taken to ensure that the network is prepared for any scenario at the end of the transition period of the UK's withdrawal from the EU.

Other achievements highlighted by the Board include the Agency's activities in the global fight against antimicrobial resistance and the implementation by the EU and the USA of the mutual recognition agreement for inspections of manufacturing sites for certain human medicines in their respective territories.

The Board acknowledged the progress made in developing the Regulatory Science Strategy to 2025. This strategy will be an important element of the next joint EMA/HMA European Medicines Agencies Network Strategy to 2025 due to be released for public consultation next month. It also received an update on the work to 'future proof' EMA, which has strengthened the Agency's ability to perform new activities with the EU network and tackle new challenges such as big data, digitalisation, new scientific methods and technologies.

The annual activity report describes the implementation of the Agency's work programme and the management and control systems in place. 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. The report, as well as the assessment by the Board, will be published on the EMA website shortly.

EMA 2018-2019 annual reports on independence

The Board adopted a plan for implementing the recommendations set out in the 2018-2019 annual reports on independence, which were endorsed by the Board at its March 2020 meeting. The recommendations will be implemented in steps, with several actions to be carried out in 2020, including changes to EMA's policy relating to the handling of competing interests of scientific committees' members and experts.

The revision takes into account the requirement for members and alternates of EMA's Committee for Advanced Therapies (CAT) to declare interests in the biotechnology and medical device sectors which could affect their impartiality, as well as the requirement for experts to declare interests in relation to their personal or organisation's involvement in the repurposing of a medicine. The changes introduced also include a minor update to the definition of financial interest, the definition of partner, additional restrictions for inspectors declaring close family interests and grants/funding, as well as reference to the new EU General Data Protection Regulation (GDPR).

The revised policy will come into effect in January 2021. EMA's policies for Management Board members and staff have been aligned and the declaration of interests form for experts will be updated accordingly.

The revisions demonstrate the Agency's commitment to a policy that effectively addresses the Agency's specific needs regarding independence. The 2018-2019 annual reports on independence, together with the revised policies, will be published shortly.

Development of the Clinical Trials Information System (CTIS) for the EU Clinical Trials Regulation

The Board endorsed the methodology and next steps to further develop the Clinical Trials Information System (CTIS) 'go-live' plan. A group will be responsible for prioritising all outstanding issues to the CTIS governance and matching the items remaining after the audit to the capacity available before go-live and thereafter. This group will include representatives of the Member States product owners, sponsors product owners, as well as representatives from EMA and the European Commission. For the purpose of the prioritisation exercise, as a working assumption, it is proposed to fix the go-live date of CTIS to December 2021.

The Board noted that further operational assessments of various elements of CTIS were carried out in May, including the public portal and the publication of documents. This allows finalisation of the scope of the audit version of the system.

The Board also noted the progress in the development of CTIS made by the supplier. In view of the upcoming start of the audit in December 2020, a key milestone for CTIS, the Board decided to extend the monitoring of agreed key performance indicators until after the CTIS audit and to monitor the delivery of the items selected for audit and go-live.

Date for election of new EMA Executive Director

The Management Board will elect a new Executive Director in a virtual meeting on Thursday, 25 June 2020.

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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