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**Press release**

# EMA Management Board – highlights of March 2020 meeting

EMA's first Management Board meeting of 2020 was held virtually in view of the rapidly changing situation in the context of the COVID-19 pandemic. The Board was shortened to one and a half hours to allow EMA and Member States to continue to focus resources on the response to the pandemic.

EMA has now invoked its Business Continuity Plan (BCP) to allow the Agency to manage the pandemic. The plan aims to safeguard the Agency's core activities and to ring-fence resources that are needed to deal with COVID-19.

Most EMA staff are now working remotely. Despite the reduction in the physical presence of staff at the Agency's premises, EMA's core activities in relation to the authorisation and supervision of medicines continue in phase 1 of the EMA COVID-19 BCP. In addition, EMA's scientific committees, working parties and certain stakeholder events will, for the time being, take place virtually until the end of April 2020.

**Annual report 2019**

The Board adopted EMA's annual report for 2019, a year which saw many advances related to new medicines. Altogether, EMA recommended 66 medicines for marketing authorisation in 2019. Of these, 30 had a new active substance: seven were orphan medicines, and one (Zynteglo) was an advanced-therapy medicine for the treatment of a rare inherited blood condition that causes severe anaemia. A conditional marketing authorisation was granted for the first vaccine against the Ebola virus.

In veterinary medicine, EMA recommended 15 medicines for marketing authorisation, an increase of 50% compared to 2018. Of these, five had a new active substance. Four were vaccines, including one new biotechnological vaccine.

EMA continued to monitor closely the safety of medicines on the market and took action when needed, e.g., in 2019, the product information for 405 centrally authorised medicines was updated on the basis of new safety data.

Publication of the 2019 report, as well as a new digital version, is planned towards the end of April 2020.

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**Update on the presence of nitrosamine impurities in medicines**

The Board was updated on the exercise undertaken by EU authorities to determine what lessons can be learned from the presence of nitrosamines in sartans, which came to light in mid-2018. A draft report was presented to the Board. An external targeted consultation with stakeholders is planned, after which the final recommendations will be submitted for endorsement by the Board and by Heads of Medicines Agencies (HMA) and published later in the year.

**Update on the development of the Clinical Trials Information System (CTIS) for the EU Clinical Trials Regulation**

The Management Board endorsed the Clinical Trials Information System (CTIS) audit methodology enabling the process for the selection of the supplier for the audit of the system to commence. The audit is planned to begin in December 2020.

Further to the endorsement in December 2019 of the 'audit readiness assessment' the Board noted that a second assessment is being carried out in the first months of 2020 to further identify critical items that must be addressed prior to the audit. So far, the Union Control and Inspection modules of CTIS have been assessed by specialised users in those areas, in collaboration with the product owners. This assessment will be completed in April 2020 and will be followed by a further operational assessment including of the public portal to allow determining the full scope of the auditable version of the system.

The Board also noted the progress in the development of CTIS by the supplier, with reassurance being provided by the results of the last sprints. The supplier performance and quality will continue to be closely monitored to ensure timely delivery of a reliable audit version of CTIS.

**Other meeting highlights**

**Regulatory Science Strategy to 2025**

The Board endorsed the Regulatory Science Strategy to 2025, the plan for advancing engagement with regulatory science over the next few years. This process involved several rounds of consultation and two major workshops with academia, scientific organisations, patients, healthcare professionals, industry and partners. The final strategy and the public consultation analysis will be published at the end of March. The strategy will be a key pillar of the work of the Agency and the network in the coming years and will feed into the development of the European medicines network strategy to 2025.

**Tenth Annual Report: MUMS/limited market scheme for veterinary medicines**

The Board adopted the ten-year report on the MUMS/limited market scheme for veterinary medicines. The report will be published shortly.

## Notes

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

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