EMA Management Board: highlights of December 2020 meeting

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The December 2020 meeting of the Management Board was Emer Cooke's first Board meeting as EMA's Executive Director since she took up leadership of EMA in November.

Update on COVID-19

The Management Board was updated that evaluation of applications for conditional marketing authorisations for COVID-19 vaccines from BioNTech/Pfizer and Moderna is ongoing and, depending on the outcome of the assessments, may conclude at the exceptional meetings of EMA's human medicines committee (CHMP) to be convened virtually on 21 December 2020 and 6 January 2021 respectively. In addition, rolling reviews of two additional vaccines are currently ongoing, one for the vaccine being developed by AstraZeneca with the University of Oxford and one for the vaccine from Janssen Cilag.

The Board was also provided with feedback from the public stakeholder meeting on COVID-19 vaccines held on 11 December and noted that a further public meeting will be organised in January 2021.

The Board heard that EMA is collaborating with a number of international authorities and the World Health Organization (WHO) on the evaluation of COVID-19 medicines and vaccines to enrich its scientific discussion. This pilot 'OPEN' initiative will allow the regulators Health Canada, Swissmedic, Japan MHLW/PMDA, and WHO, to participate in the evaluation of applications for COVID-19 medicines and vaccines. These non-EU regulators will join under existing confidentiality arrangements but will not participate in the finalisation of the opinion on benefit/risk, nor in the decision on marketing authorisation. They will maintain their independence when it comes to taking decisions on whether or not to approve a medicine in their own territories. This initiative is limited to COVID-19 medicines and vaccines and a report on the initiative will be prepared after the pandemic. More information will be published on the EMA website shortly.

EMA budget for 2021

The Board adopted EMA's budget for 2021 and the programming document for 2021-2023, which will be published on EMA's website in Q1 2021. The 2021 budget increased by about 4% compared to the budget of 2020, to overall 386 million euros. The budget includes 27.8 million euros earmarked for the preparation of the implementation of the extension of the Agency's mandate proposed by the European Commission. A preliminary draft programming document for 2022-2024 was also presented during the meeting.

Update on the EU IT systems required by the Clinical Trial Regulation

The Board noted the progress in the development of the Clinical Trial Information System (CTIS). The independent audit began as scheduled and the first phase has been completed. Nominated Member State and Commission product owners were able to participate in all meetings and interviews were conducted including with representative Member State and sponsor product owners and other future users.

User testing has revealed important issues on the system quality, that need to be addressed. CTIS is a system with extensive functionality that has been under continuous development for a long period. With one year remaining to the planned go-live, a period of stabilisation and focus on improving usability, performance and reliability is essential. Therefore, the development is now focused on improving the quality and stability of the CTIS system, rectifying findings from user testing and then also findings from the first audit fieldwork.

The group responsible for prioritising all outstanding issues has made good progress. This group includes representatives of the Member States, the European Commission and sponsor product owners, as well as from EMA. Taking into account these priorities, the test findings and those of the independent audit, the CTIS programme governance will work to finalise an agreed Minimum Viable Product in light of the development capacity available.

The go-live date of CTIS is planned for December 2021 and activities are foreseen throughout the year to ensure knowledge transfer and to facilitate preparation for adoption of CTIS into daily business processes and activities.

Update on DARWIN EU (Data Analysis and Real World Interrogation Network)

The Board was presented with planning to start the project phase of DARWIN EU in January 2021. By working closely with the Member States, European Commission and stakeholders, DARWIN EU will deliver strengthened regulatory decisions for public health and act as a pathfinder initiative for the European Health Data Space.