118th meeting of the Management Board of the European Medicines Agency

Wysłane przez m.koszewski w Wto, 20/12/2022 - 14:48

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At its meeting of 14-15 December 2022 in Amsterdam, the European Medicines Agency (EMA) Management Board heard an update on the recent activities related to the response to COVID-19. Since the start of the pandemic, a total of seven vaccines, four adapted booster vaccines and eight treatments have been authorised for use in the European Union (EU).

The President of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products, as a member of the European Medicines Agency's Budget and Work Programme Coordination Group (Topic Coordinator for Single Programming Documents), provided the Management Board with a work programme for 2023-2026.

Presented multi-annual programming has been developed by clustering the activities around 3 main pillars: product related activities concerning medicines lifecycle, working parties and guidelines, strategies (European medicines agencies network strategy and Regulatory Science Strategy), Public health activities and programmes and projects covering development activities aiming at enhancing efficiency and effectiveness of the current operations. Continuously implementing the COVID-19 lessons learned will be one of the major focus for the Agency’s Work Programme 2023. EMA’s Work Programme 2023 also includes other pivotal activities: e.g. improvements to the Clinical Trials Information Systems, implementation of monitoring and mitigation activities for medical devices and pilot for scientific advice to medical devices developers.

Negative priorities were also presented. EMA is managing to absorb some of the growing activities through efficiency gains and effective staff reallocation, but also through increased reliance on short-term staffing contracts to reduce impact on the EMA activities.

The Board adopted EMA’s multiannual programming document for 2023-2025, including the Agency’s work programme and budget for 2023. The document will be published on EMA’s website in the first quarter of 2023. The 2023 budget increased by 8.6% compared to 2022, to a total of 458 million euros. The Board also adopted a preliminary programming document for 2024-2026.

EMA’s work programme for 2023 foresees the gradual lifting of business continuity measures that were implemented in the course of the Agency’s relocation and had to be maintained since 2020 to cope with the COVID-19 pandemic and the initial waves of infection. By monitoring the evolution of the workload related to COVID-19 and based on resource availability, the Agency will seek opportunities to gradually reinitiate previously suspended or reduced activities, notably implementing a phased restart of clinical data publication (CDP) for centrally authorised medicines beyond the scope of COVID-19. The Board noted that, in case of significant changes to the business continuity status, the programming document will be amended accordingly.

On 31 January 2023, the Clinical Trials Information System (CTIS) will become the single-entry point for sponsors and regulators for the submission and assessment of all new clinical trials.

The system was launched on 31 January 2022, starting the clock for the one-year transition time for all sponsors of clinical trials. During the transition period clinical trial sponsors can still choose whether to submit an initial clinical trial application in line with the Clinical Trials Directive or under the Clinical Trials Regulation, via CTIS. On 31 January 2023, the use of CTIS will become mandatory for new clinical trial applications.

The Agency informed the Board that the system delivers the functionality required for new clinical trial applications which will continue to be developed and enhanced. The Board noted the progress

towards further stabilisation of the system in preparation of compulsory use. This stabilisation will improve user experience. The Agency informed the Board about its delivery plan to ensure no blocking technical issues in the core processes by the legal deadline and its commitment to this plan.

The Board welcomed the 2023 CTIS workplan which focusses on enhancing the user experience by implementing improvements in the most impactful functional areas of the system, future proofing and minimising risks to the technical core of CTIS. The Board also agreed to review the current rules on disclosure of certain clinical trial documents and a review of CTIS transparency measures for 2023. As the initiation of this workplan is subject to the stabilisation of the system, the Agency committed to update the Board on a weekly basis on the progress towards stabilisation and full functionality of the system. This update will start on Friday 16 December and stakeholders will be kept regularly informed.

The Agency informed the Board of the various potential risk scenarios and of the development of a business contingency plan.

The Board noted the last regular report on the implementation of the Veterinary Medicinal Products Regulation since its coming into application in January 2022. The programme delivered the Union Product Database (UPD), an upgraded system for pharmacovigilance reporting and management of safety signals, as well as changes to a total of nine IT systems over the course of the last four years. The Board noted the efforts and collaboration between Member States and EMA to complete the data upload into the UPD and plans to focus on enriching these data over the next year. The Board welcomed the commitment to improve the systems in 2023 following the Agency’s agile governance model, as well as the plan of the Veterinary Division to work on the implementation of the PDF icon EU Veterinary Big Data strategy over the next five years.

The Chair of EMA’s Committee for Advanced Therapies (CAT) presented key highlights and achievements of the Committee from 2017-2022 to the Board. The CAT is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs). The Committee prepares a draft opinion on each ATMP application submitted to the Agency before the Committee for Medicinal Products for Human Use (CHMP) adopts a final opinion on the marketing authorisation of the medicine concerned.

More information available on the website: https://www.ema.europa.eu/en/news/ema-management-board-highlights-december-2022-meeting [1]

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