123rd meeting of the Management Board of the European Medicines Agency

Wysłane przez m.koszewski w Wto, 26/03/2024 - 14:45

123rd meeting of the Management Board of the European Medicines Agency

The 123rd meeting of the Management Board of the European Medicines Agency was held on 21 March 2024. Poland was represented by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Dr Grzegorz Cessak, and the meeting was held virtually.

The Board heard that preparations are ongoing by the European Commission, together with EU Member States, for the implementation of the new Health Technology Assessment Regulation (HTAR). EMA is contributing to these preparatory activities and is working closely with the European Commission, the Member State Coordination Group on HTA (HTACG) and its subgroups, as well as its stakeholders, including industry, healthcare professionals, patients and academia. The Regulation, which entered into force in January 2022, will govern European cooperation on health technology assessment for medicinal products and medical devices. Under the new framework, EMA and the HTA secretariat will collaborate in the context of joint clinical assessments, joint scientific consultations and the identification of emerging health technologies by the HTACG. The Regulation will apply as of January 2025.

EMA updated the Board on upcoming milestones for clinical trials in the EU. The Commission acknowledged the important modernisation and simplification work of EMA on CTIS to allow an efficient use of the platform by Member States and sponsors. The revised transparency rules for the Clinical Trials Information System (CTIS) will apply after their technical implementation in CTIS. The three-year transition period that began when the Clinical Trials Regulation (CTR) became applicable ends on 30 January 2025. 20% of the transitioning trials have been moved to CTIS. Sponsors are strongly advised to submit the applications as soon as possible considering the time necessary for completing the authorisation procedure, which can take up to three months.

The Board noted that work on preparation for the implementation of the new fee regulation has begun. This includes the redrafting and updating of various documentation including the cooperation agreement with national competent authorities (NCAs) and the working arrangements that will replace the current implementing rules. The working arrangements will further clarify the terminology and requirements of the new regulation, outline conditions for fee incentives and provide a description of payment modalities including remuneration to NCAs. From 1 January 2025, the new fee regulation will be implemented across the EU. It aims to provide harmonisation between the fee regulation and pharmacovigilance fee regulation, align fees with underlying costs and reduce the current complexity of the fee system. The Board will continue discussions at its June meeting.

The Board adopted EMA’s annual report for 2023. In 2023, EMA recommended 77 medicines for marketing authorisation for human use, 39 of which had a new active substance. The Agency also recommended 14 veterinary medicines for marketing authorisation. In addition, the report gives an overview of key achievements in EMA’s three strategic areas in 2023: cancer medicines, better data to translate innovation into medicines, and transparency and communication.

Delegates were also informed about the planned publication, in May 2024, of the Agency's 2023 summary report on the EMA website.

The Board was informed about EMA’s report on its stakeholder engagement activities in 2022 and 2023. The report presents all activities involving the Agency’s key stakeholder groups: patient and

consumer organisations, healthcare professional organisations, academia, and EU industry trade organisations together in one report for the first time. It includes a section on multi-stakeholder engagement topics, such as the EU clinical trial initiative ACT-EU, as well as targeted engagement activities with each stakeholder group. The Board agreed that contributions from stakeholders continue to be key in making the most of opportunities and addressing future challenges in medicines regulation. The report will be published in Q2.

More information available on the website: https://www.ema.europa.eu/en/news/ema-management-board-highlights-march-2024-meeting [1]

Źródłowy URL: https://archiwum.urpl.gov.pl/pl/node/8105

Odnośniki
[1] https://www.ema.europa.eu/en/news/ema-management-board-highlights-march-2024-meeting