# 124rd meeting of the Management Board of the European Medicines Agency

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**124th meeting of the Management Board of the European Medicines Agency**

On 12-13 June 2024, the 124th meeting of the Management Board of the European Medicines Agency (EMA) was held in Amsterdam. Poland was represented by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Dr Grzegorz Cessak.

The Management Board assessed and adopted the Executive Director’s annual activity report for 2023. The report describes the implementation of the Agency’s work programme and the management and control systems in place. The Board highlighted the achievements of the Agency and the European medicines regulatory network in the implementation of the European Medicines Agencies Network strategy and the Regulatory Science Strategy to 2025. It also welcomed the finalisation of implementation of the Agency’s extended mandate, including the establishment of a governance structure for the management of shortages of medical devices in the EU. The Board also noted that in 2023 EMA continued to support the implementation of the European One Health Action Plan against Antimicrobial Resistance with a wide range of activities, and welcomed EMA’s continued commitment to involving patient experts and healthcare professionals in the work of its scientific committees.

The report will be published on the EMA website shortly, together with the assessment by the Board.

Several documents were adopted by the Board in preparation for the coming into application of the new fee regulation (Regulation 2024/568) on fees payable to the Agency as of January 2025. These include the working arrangements that will clarify the requirements and terminology of the regulation, outline conditions for fee reductions for certain types of applications and provide further details on payment modalities. The working arrangements will be published on the Agency’s website.

The new fee regulation aims to ensure the sustainability of the European medicines regulatory network, providing a sound financial basis to support its operations as well as the objectives outlined in the European medicines agencies network strategy.

The Board was updated on recent progress in the areas of shortages, which remains a priority for EMA and the network. The voluntary solidarity mechanism for EU Member States, which was set up at the end of 2023, has already been used successfully to address shortages of three critical anti-cancer medicines. Through the solidarity mechanism, EU Member States facing a critical shortage can request help from other Member States. The interaction is coordinated by EMA’s Medicine Shortages Steering Group, or MSSG.

The Board was also informed about a multistakeholder workshop on the ongoing shortages of glucagon-like peptide-1 (GLP-1) receptor agonists which is planned to take place on 1 July 2024. The workshop will be hosted by the MSSG and will bring together relevant parties to discuss and identify possible solutions to the shortage.

Violeta Stoyanova, chair of EMA’s orphan medicines committee, or COMP, presented an overview of recent trends and challenges in the development of medicines for rare and very rare diseases. There are currently 257 medicines authorised for rare diseases, of which 159 still hold an orphan status in the EU.

“Rare diseases and ultra rare diseases pose additional challenges for patients, clinicians, medicine developers and regulators,” said Dr Stoyanova. “We are receiving increasingly complex

submissions of applications which require expertise that combines scientific and clinical knowledge with regulatory understanding and experience in the assessment of orphan medicines."

Dr Stoyanova also highlighted the key role that patients with rare diseases play in capturing 'patient experience data', which is becoming increasingly important for regulatory decision making across the globe.

Board members discussed principles for the revision of the Agency's policies on handling of competing interests of its Board members, scientific committee members and external experts. The revision is intended to ensure the compliance of the Agency's policies with the appellate judgments of the Court of Justice in Joined Cases C-6/21 and C-16/21 P and Case C-291/22 P. The revision aims to strike the right balance between safeguarding impartiality and independence, and access to the best scientific expertise to support EMA's assessments. The Agency will progress with the drafting of the revised policies and discussions will continue at the next meeting of the Board in October.

The Board was updated on the implementation of the Clinical Trials Regulation including the Clinical Trials Information System (CTIS). Revised transparency rules will become applicable on 18 June 2024 with the launch of a new version of the CTIS public portal. One of the key changes under the updated transparency rules is the removal of the 'deferral mechanism', which previously allowed clinical trial sponsors to delay the publication of certain data and documents for up to seven years after the end of the trial to protect commercially confidential information. The removal of this mechanism will give stakeholders, including patients and healthcare professionals, quicker access to clinical trial information while commercially confidential information continues to be protected through redaction of documents.

Clinical trials approved under the Clinical Trials Directive must be transitioned to CTIS by 30 January 2025. Sponsors of clinical trials that were approved under the Clinical Trials Directive and are expected to continue after 30 January 2025 must consider in their transition planning the time required for Member States to complete the evaluation procedure, which can take up to three months.

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

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