119th meeting of the Management Board of the European Medicines Agency

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On 16 March 2023, the 119th meeting of the Management Board of the European Medicines Agency was held. 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 in a virtual format.

First of all, the Management Board was updated on the ongoing efforts of EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to closely monitor several critical shortages of medicines in the EU/EEA, in particular medicines containing the antibiotic amoxicillin.

Since the last Board meeting, the MSSG has been encouraging EU Member States to consider national regulatory flexibilities to allow the distribution of medicines that may not be authorised in their Member States. In addition, EU regulators have met with the main parties involved in the supply chain of amoxicillin to provide regulatory support to increase production capacity.

At their latest meeting on 15 March, the MSSG discussed plans to mitigate shortages of antibiotics for the next autumn/winter season. EMA, in cooperation with the European Commission's Health Emergencies and Preparedness Response Authority (DG HERA), will liaise with key manufacturers to discuss manufacturing capacity and forecasts of demand for a selected group of critical antibiotics.

At the meeting, the Management Board was informed, as of 2 February, EMA has additional responsibilities regarding the monitoring and mitigation of shortages of critical medical devices during public health emergencies. The new provisions are the last remaining chapter to be implemented of Regulation (EU) 2022/123, EMA's extended mandate, that reinforces the Agency's role in the management of critical medicines and medical devices during public health emergencies.

Moreover, a new executive body, the Medical Devices Shortages Steering Group (MDSSG) met for the first time on 15 March. The group's role is to coordinate urgent actions in the EU related to the management of supply-and-demand issues of critical medical devices during public health emergencies. Karl Broich, the head of Germany's Federal Institute for Drugs and Medical Devices (BfArM), was elected to co-chair the group together with EMA's Executive Director, Emer Cooke.

An additional issue raised at the Management Board meeting was the multi-stakeholder workshop on medicine shortages, held on 1-2 March. During the workshop, approximately 300 participants exchanged perspectives on the work of the HMA/EMA Task Force on medicines shortages and availability, provided updates on ongoing initiatives in the area and expressed strong commitment to work together to prevent shortages in the future. A report on the workshop will be published in the coming weeks.

The Management Board adopted EMA's annual report for 2022. EMA recommended 89 medicines for marketing authorisation for human use, 41 of which contained new active substances, including the first gene therapy for the treatment of severe and moderately severe haemophilia B and the first medicine for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants. EMA also recommended ten veterinary medicines for marketing authorisation in 2022, including the first DNA vaccine for dogs. Publication of the 2022 report, including an interactive digital version, is planned for May 2023.

The meeting was followed by a presentation of recent developments and ongoing challenges in the field of animal health by the chairman of the EMA's Committee for Veterinary Medicinal Products (CVMP), Mr Johan Schefferlie, who particularly highlighted the achievements in the implementation of the Veterinary Medicines Regulation during the COVID-19 pandemic, with a significant amount of new or updated guidance issued during this time. Scientific advice was also given to the European Commission in support of developing follow-on legislation on several high impact topics. Mr Schefferlie highlighted the creation of a dedicated CVMP working party on novel therapies, a new category of veterinary medicines under Regulation (EU) 2019/6, with operational expert groups on cell-based therapies, phage therapies and nanomedicine. In addition, a new working group, ESUAvet, has been set up to guide both the CVMP and EMA in implementing the requirements for collecting, analysing and reporting sales and data on antimicrobials used in animals.

Futhermore, the Management Board endorsed EMA’s annual report on the implementation of the Agency’s policies related to the independence of members and experts of EMA’s scientific committees, Management Board members and Agency staff. The report provides facts and figures on controls carried out in 2022. It also gives information on initiatives taken during the year, notably the revision of the policy on the handling of competing interests for scientific committee members and experts and the separate policy for Board members related to the Agency’s new responsibilities in the area of medical devices and its reinforced role in crisis preparedness and management. Medical device interests must be declared and restrictions are applied as required. In line with the Agency's commitment to continually review its operations, the report also identifies recommendations for further improvement in 2023. The report will be published shortly.

Since 31 January 2023, the use of the Clinical Trials Information System (CTIS) is mandatory for initial clinical trial applications and serves as the single-entry point for submission by sponsors and for regulatory assessment in the EU/EEA.

In the first meeting after this milestone, the Board received an update on recent operational experience with CTIS and on the latest improvements implemented in the system. Over 320 clinical trials authorised under the Clinical Trials Regulation are available in CTIS. EMA reported on the next steps, including upcoming system releases planned for the first quarter of 2023. Enhancements are planned throughout 2023 aimed at further improving the CTIS user experience.

The Management Board was updated on the communication campaign supporting implementation of the Clinical Trials Regulation and welcomed EMA’s ongoing efforts to support sponsor and Member State CTIS users via trainings, information events and the publication of related materials.

In addition, the Management Board was presented with an update on the implementation of the new operational model of EMA’s working parties was presented to the Board. The process started in early 2022, focusing on the reorganisation of the working parties for the nonclinical, methodology and clinical domains. A pilot phase for the oncology European Specialised Expert Community (ESEC) was initiated later in the year. The Board has now agreed on the expertise-based model that will be applied to the operations and future structures of the Biologics Working Party (BWP) and Quality Working Party (QWP), including a proposed structure for their membership. A call for experts will start at the end of 2023.

More information available on the website: https://www.ema.europa.eu/en/news/ema-management-board-highlights-march-2023-meeting [1]

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