14 August 2025
EMA/MB/189883/2025 - Adopted
Management Board

Minutes of the 128th meeting of the Management Board

Held in Amsterdam on 11-12 June 2025

The Chair of the EMA Management Board (MB) opened the meeting, which was held as a face-to-face meeting, with a few Members joining via videoconference. The Chair welcomed the Governing Board and the delegation of the African Medicines Agency (AMA), who attended the first half-day of the meeting to observe the proceedings of the MB meeting.

The Chair also welcomed the new member for Sweden, Ms Ann Lindberg (Director General, Swedish Medicines Agency, MPA, DKMA), and alternate for Portugal, Ms Susana Pombo (Director General, Directorate General for Food and Veterinary, DGAV) who will be acting as Member following the Portuguese member's new role as Chair. The Chair further informed the Board that, due to this new role, he would need to step down as reporting officer for the annual appraisal of the Agency's Executive Director, and that a new reporting officer should be designated by the Board at its next meeting in October. Board members were invited to share their interest with the Chair in taking on this role.

The Chair thanked the current civil society representatives to the Board whose mandates are set to expire at the end of 14 June 2025, for their valuable contributions and support to the Board, in particular Marco Greco, the representative of patients' organisations. Additionally, the Chair was pleased to confirm that three of the current representatives, Virginie Hivert representative of patients' organisations, Denis Lacombe representative of doctors' organisations and Christophe Buhot representative of veterinarians' organisations, had been appointed by the Council for a second 3-year mandate. A new patient representative, Marko Korenjak, has been appointed and will attend the next MB meeting in October. With regards to the new European Parliament representatives for EMA's Management Board, the Chair informed the Board that the EP process concluded on 11 June but that the formal nomination letter was still awaited. Therefore, the two new EP representatives would attend the June MB meeting as observers only.

The Chair noted that the election of the new MB vice-Chair would take place on 12 June and that, according to the Rules of Procedure, applications for vice-Chair could be submitted in writing to the EMA secretariat "no later than the start of the Management Board meeting at which the election is to take place". The call for nominations had been launched in mid-May and [redacted] had been received ahead of the June MB meeting.

1. Draft agenda for the 11-12 June 2025 meeting

[EMA/MB/116543/2025] The agenda was adopted with no amendments.

2. Welcome African Medicines Agency Governing Board and delegation

The Chair warmly welcomed members of the Governing Board of the AMA and heads of African national regulatory agencies as observers to the MB meeting, as part of a historic first meeting between the European and African regulatory networks. The delegation was led by Dr. Yossounon Chabi, Chair of the AMA Governing Board and Director-General of the Benin Agency for Medicines and Health Products, and included Dr. Delese Mimi Darko, the newly elected AMA Director-General Designate, and currently Chief Executive of the Ghana Food and Drugs Authority. The delegation also included members of the AMA Interim Secretariat, representatives of the African Union Commission, colleagues from the African Medicines Regulatory Harmonization initiative, regulatory authorities with WHO Maturity Level 3 status, and the West African Health Organisation. To mark the occasion, the Chair briefly addressed the delegation in French before inviting AMA representatives to introduce their team. Observers from the European Commission's Directorate-General for International Partnerships (DG INTPA) and the World Health Organization were also warmly welcomed. The meeting offered the AMA delegation valuable insights into the governance and supervisory role of the EMA Management Board. The visit was acknowledged as a crucial step toward strengthening dialogue and fostering long-term cooperation between the European and African regulatory networks.

3. Declaration of competing interest related to the current agenda

The Secretariat informed members of the Management Board that it had reviewed members declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning topics B.9 on New Fee Regulation documents. The Secretariat informed the Board that all concerned members had been informed before the meeting. Should the need for a vote on the above topics arise, the chair would take up the matter again.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

4. Minutes from the 127th meeting, held on 13 March 2025 adopted via written procedure on 06 May 2025

[EMA/MB/87893/2025] The Management Board noted the final minutes, adopted by written procedure on 06 May 2025. The EMA note on the outcome of the extraordinary MB meeting on 28 April, as communicated publicly, will be circulated to the Board.

Further to the extraordinary MB meeting, the Chair recalled that the Board is awaiting the outcome of the Executive Director's renewal proposal, currently under consideration in the Commission, with a decision expected in the coming weeks. The final Commission proposal to renew Ms Cooke's mandate until her pension age (1 May 2027) will require formal approval by the Management Board. In view of the recommendation reached unanimously at the 28 April meeting, the Chair proposed that the formal

MB approval could be obtained via written procedure. If no concerns would be raised by MB members on the written procedure, it is expected that it will be launched in mid/end July.

The Chair also reminded the Board that the review of the draft vacancy notice for the recruitment of the next Executive Director is planned for the October MB meeting. He invited expressions of interest from Board members wishing to act as observer to the pre-selection panel with the appointment of the observers to be confirmed in October.

5. Election of the Vice-Chair of the Management Board *(in camera)*

The election of the Vice-Chair was held *in camera* and was attended only by members or in their absence, their alternates, the observers from the EEA countries and a limited number of EMA staff.

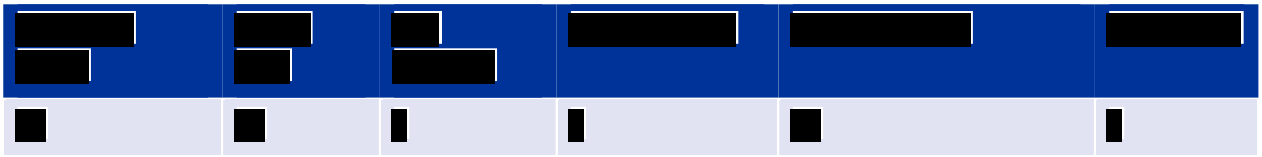
In accordance with the election procedure, the Chair announced votes by proxy as follows:

- Momir Radulović (Slovenia) proxy to Maria Lamas Dias (Spain) for part of the meeting;
- Katrin Kiisk (Estonia) proxy to Eija Pelkonen (Finland);
- Bogdan Kirilov (Bulgaria) proxy to Grzegorz Cessak (Poland).

[redacted]

The Board appointed the observers from Iceland, Norway and Liechtenstein, Runa Hauksdottir Hvannberg, Trygve Otterson, and Vlasta Zavadova to act as tellers. The vote took place by secret paper ballot.

The Board requires 22 votes in favour to reach a decision. [redacted]



The Management Board elected Aimad Torqui, representing the Netherlands, as its Vice-Chair for the next three years. He will take up his new role as of 1 September 2025. The newly elected Vice-Chair thanked the Management Board.

6. 30 Churchill Place update *(in camera)*

EMA provided a detailed update about 30 Churchill Place following the information provided in March 2025. [redacted]

The Board expressed their appreciation for EMA's clear and proactive management of 30 Churchill Place, noting encouraging signs of stability despite broader market challenges within Canary Wharf. The DG SANTE representative echoed the appreciation and welcomed the arrival of new tenants and modest improvements in revenue, while stressing the importance of achieving financial sustainability. [redacted]

A. Points for automatic adoption/endorsement

A.1 Management Board meeting dates 2026-2027

[EMA/MB/164895/2025] The Management Board adopted the meeting dates for 2026 and noted the meeting dates for 2027.

A.2 Inflationary adjustment for rates payable to EDQM for testing and sampling activities in 2026

[EMA/MB/116543/2025] The Management Board endorsed the inflationary adjustment for rates payable to the European Directorate for the Quality of Medicines & HealthCare (EDQM) for testing and sampling activities in 2026. Pursuant to Article 5.4 of the Cooperation Agreement between EMA and EDQM, EMA annually adjusts the rates in Annex II of this Cooperation Agreement based on inflation, as measured by the Harmonised Index of Consumer Prices (HICP) published by Eurostat under Regulation (EU) No 2016/792. Following a 2.7% inflation rate in December 2024, the rates have been revised accordingly for application in the 2026 annual programme.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update from EMA's Executive Director, beginning with highlights of EMA's 30th anniversary celebration in Q2-2025. This included the first "Open Day" at the Agency held on 9 May on the occasion of Europe Day, welcoming 110 visitors for guided tours and providing insights into EMA's three-decade journey. On 25 June, a 30th anniversary scientific conference will be organised under the theme 'Medicines, regulation and the future', which will be opened by His Majesty Willem-Alexander, the King of the Netherlands. Over 185 participants are expected for a full day of sessions on regulatory achievements, scientific innovation, and future challenges, featuring expert contributions across scientific, policy and regulatory areas, with online participation also possible.

As regards European activities, the Board was informed of EMA's participation in the informal meeting of EU Health Ministers in Warsaw on 24–25 March, in particular on the efforts to address supply disruptions. The Board was also updated on the visit of a delegation from the European Parliament's SANT Committee to EMA on 27 March, the Executive Director's annual exchange with the SANT committee and that the European Parliament had granted discharge for EMA's 2023 budget implementation on 7 May 2025.

For international activities, the Board was informed about the meeting of the ICH Assembly and Management Committee in Madrid on 11–14 May, which resulted in the adoption of a draft guideline (ICH E21) on the inclusion of pregnant and breastfeeding individuals in clinical trials, for public consultation. The Board expressed strong support for this guideline and emphasised the importance of communicating this guideline effectively, in a coordinated manner also at national level, given its potential sensitivity regarding the inclusion of pregnancy and breastfeeding individuals within clinical trials.

The Board was also updated on the persistent Network resource issues, particularly the continued shortfall in Rapporteur bids. Following a recent brainstorming session of HMA/EMA Strategic Oversight Group (SROG), a number of priority actions had been identified with an HMA or EMA main lead. These include establishing a cross-NCA HR and recruitment forum, developing so-called centres of excellence, organising an 'Assessors' Day at EMA, expanding EU-NTC training and exploring AI-driven solutions to alleviate workload.

The Executive Director also highlighted a significant number of Access to Documents (AtD) requests that had been received since February 2025 for COVID-19 vaccines, prompted by a campaign by the North Group. Due to volume and complexity, EMA plans to proactively publish the requested documents as an exceptional additional COVID-19 transparency measure. Publication is expected by early July 2025. The European Ombudsman has also been informed.

The Board was also informed of the first European Agencies Network (EUAN) HR Strategy meeting hosted by EMA on 12 May. Over 110 participants from 45 EU Agencies and Joint Undertakings attended discussions on talent acquisition, leadership development, digital tools, AI in HR, and modern workplace culture with a keynote by the Commission (DG HR) on future HR strategy and public sector reform. The event will be held annually, with the next meeting hosted by ENISA in 2026.

Regarding implementation of the HTA Regulation, the Board was updated on the operations that began on 12 January 2025 with close coordination between EMA and EC secretariat. Six Marketing Authorization Applications (MAAs) for Joint Clinical Assessment (JCA) have been received thus far with up to 20 more expected by end of 2025. The first product for advice under the new parallel joint scientific consultation (JSC) framework will begin in July. EMA continues to support the successful

implementation of the HTA Regulation in line with the EMANS "Accessibility" theme and the HTA Agencies' strategy.

B. Points for discussion

B.2 Report from the European Commission

The DG RTD representative informed the Board of a newly selected Innovative Health Initiative (IHI) collaborative project on regulatory sandboxes, which will assess existing sandbox models, develop a horizon scanning methodology for emerging technologies, and provide recommendations for sandbox implementation in health innovation. She then also informed the Board about the Research & Innovation aspects of One Health. The European Commission promotes an integrated One Health approach through a scientific advice mechanism, which in 2024 issued recommendations to strengthen One Health governance at all levels at the EU and national level. Addressing antimicrobial resistance (AMR) is a key focus, with the One Health AMR Network and the Joint Programming Initiative on AMR - now evolving into a €250 million European Partnership on One Health AMR - facilitating coordinated research and policy. DG HERA contributes by monitoring threats from animal and environmental sources, supporting control of vector-borne diseases, and funding innovation in medical countermeasures. It also leads initiatives like the DURABLE network bringing together public and animal health laboratories and academic research institutes and funds a global wastewater surveillance consortium to detect emerging health threats. Internationally, the Team Europe Initiative with Africa promotes sustainable health security by addressing zoonotic diseases, AMR, food safety, and climate-related health risks, while enhancing vaccine and medicine manufacturing capacity via the EU Africa Global Gateway Prosperity Package Health. The Horizon Europe programme funds numerous projects at the intersection of health, environment, and climate, especially via the 'Planetary Health Cluster' and 'Climate and Health Cluster'. A Strategic Research Agenda on Health and Climate Change was published in early June 2025. Despite its importance, implementing One Health remains challenging due to important sectoral differences and requires clearer guidelines and sustainable, coordinated solutions. Lastly, the DG RTD representative, Irene Norstedt, informed the Board that this would be her last meeting as she would be retiring in September 2025. The Board thanked Irene Norstedt for her contribution and dedication throughout her mandate as a Board member.

The DG SANTE representative updated the Board on recent developments with regard to the revision of the pharmaceutical legislation and the implementation of the medical devices legislation, of the Health Technology Assessment (HTA) regulation and of the European Health Data Space (EHDS) regulation. A key milestone was reached on 4 June when the Council agreed on a negotiation mandate with the European Parliament for the pharmaceutical package, maintaining core objectives such as availability, access, affordability, and regulatory simplification. While the Commission welcomed the progress, it noted areas for improvement, including assessment timelines, transition periods, voting rights of civil society representatives in the EMA committees, and contingency stock mechanisms. In the medical devices domain, efforts are underway to balance patient safety with support to innovation, with two short-term measures expected before the summer break: an implementing act on electronic instructions for use and the establishment of an expert panel on orphan and paediatric medical devices. Other short-term actions will be delivered before the end of the year. A targeted evaluation and review of the Medical Devices Regulations is also expected by year-end. Regarding HTA, the integration with the marketing authorisation process is progressing, with joint clinical assessments to follow within 30 days of authorisation decisions. The EHDS regulation will apply from March 2027 with most provisions effective in 2029. Its implementation is advancing through the drafting of several implementing acts by March 2027 and via preparatory projects like XT-HER (primary use of health

data) and TEHDAS 2 (secondary use of health data) and EMA and Board members were encouraged to continue to contribute to upcoming milestone activities. A new EHDS committee, including Member State representatives, will begin work in June 2025.

Several Board members expressed support for the adoption of Council's position on the pharmaceutical package, with patient organisations' representatives in the Board emphasising the importance of maintaining their voting rights to ensure continuity of their voice in EMA's work. Regarding the IHI project on regulatory sandboxes, the DG RTD representative confirmed that the project will develop methodologies tailored to different health interventions and that regular feedback to Board members can be provided once the project is operational. On the implementation of urban wastewater treatment directive, members requested more information about the upcoming EC impact assessment due to its potential effects on the availability of generics; DG SANTE noted that the matter is under close political scrutiny and further details will be shared once decisions are finalised. A suggestion was made to use the EC inter-service group on One Health to harmonise terminology for integrated scientific risk assessments, which DG RTD agreed to take forward for further consideration. On medical devices, one member supported current initiatives but highlighted the need to address limitations in EUDAMED's functionalities early on, suggesting further collaboration between the Commission and the Member States competent authorities to implement workarounds and improve coordination and process efficiency as a whole. The DG SANTE representative welcomed the proposal on EUDAMED and promised that more precise timelines for the revision of the medical devices framework will be shared at future Board meetings.

B.3 Assessment of the Executive Director's Annual Activity Report (AAR) 2024 and Annual accounts 2024 and launch of written procedure

[EMA/175888/2025], [EMA/MB/175856/2025], [EMA/69085/2025], The Management Board noted the Executive Director's Annual Activity Report (AAR) 2024 and adopted the Board's Assessment of the Executive Director's AAR 2024 which had been prepared by the MB topic coordinators Nils Falk Bjerregaard, Franck Foures, Virginie Hivert and Momir Radulović.

The AAR 2024 details the EMA's management and control systems and the implementation of its work programme. Prepared in accordance with Article 48 of the EU Financial Regulation, it is part of the discharge process. The AAR is submitted to the Management Board for assessment, and, by 1 July, the assessed AAR is to be sent to the Court of Auditors, the Commission, the European Parliament, and the Council.

The topic coordinators presented a summary of the main elements of the proposed Management Board's assessment of AAR 2024. The Board noted the achievements under the European Medicines Agencies Network Strategy (EMANS) to 2025 and the launch of EMANS 2028. It highlighted the Agency's timely implementation of new EU legislation and ongoing leadership in regulatory science. EMA's contribution to EU health priorities was recognised, including the European Health Union, the Beating Cancer Plan, antimicrobial resistance, One Health, pharmaceutical sustainability, and the EU Chemicals Strategy. Key outcomes in human and veterinary medicines were noted, with EMA recommending 114 new human and 25 veterinary medicines in 2024, including numerous new active substances, PRIME approvals, orphan designations, and certification of an innovative veterinary vaccine platform. The conclusion of the veterinary pharmacovigilance pilot and strengthened communication with animal health professionals were also welcomed. The Board acknowledged the growth of the DARWIN EU® real-world data network, now with 30 data partners, and EMA's active role in tackling medicines shortages. This included the Union list of critical medicines, development of the

European Shortages Monitoring Platform, guidance on prevention plans, and preventative actions by the MSSG to strengthen supply chains. Support for the transition to the Clinical Trials Regulation via CTIS, the ACT EU multi-stakeholder platform, and enhanced transparency in clinical trials were also recognised. Progress on the Agency's Artificial Intelligence workplan and preparations for implementation of the HTA Regulation were noted. The designation of the EU medicines regulatory network as a WHO Listed Authority was welcomed as a key milestone. Ongoing engagement with stakeholders was acknowledged, as well as the revision of Policies 0044 and 0058 to ensure scientific independence and transparency, while addressing recent legal rulings. The Agency's full cloud migration and agile IT governance approach were seen as important for future readiness. Advances in data-driven systems such as PMS, IRIS, eCTD4, and the Union Product Database were noted. The new Fee Regulation's successful implementation helped strengthen financial sustainability. EMA's final budget for 2024 stood at €491.9 million, with nearly 90% funded by fee-based activities. Budget implementation reaching 99,7%**,** with both current and carried-over funds nearing full implementation. The Board also noted staff-related developments, including measures supporting wellbeing, mobility and training. Furthermore, the positive audit outcomes confirmed the reliability of EMA's accounts and internal controls, while encouraging further progress on outstanding recommendations.

The Board took note of the Executive Director's declaration of assurance and acknowledged that no reservations were made. It reiterated its deep concern that the Agency remains obliged to manage its former premises in the United Kingdom, diverting resources toward an activity beyond its legal mandate. The Board called on EU institutions to resolve this unsustainable situation at a political level and to ensure continued EU funding so that EMA and national competent authorities can fulfil their public and animal health responsibilities without disruption.

[EMA/MB/131692/2025] The Management Board noted the draft annual accounts 2024.

During the assessment by the Topic Coordinators, the Board reviewed the Agency's accounts with input from the Agency's Accounting Officer noting full compliance with budgetary KPIs and the Agency's strong financial position at year-end. The Board took note of the accounting provision linked to the ongoing obligation under the lease for the Agency's former premises in London, following the subtenant's bankruptcy in 2023. It was acknowledged this did not impact the 2024 budget or work programme. As per Article 102.3 of the Agency's Financial Regulation, the Accounting Officer will finalise the Agency's accounts, which will undergo a written procedure for adoption by the Management Board after the June meeting. Subsequently, the Executive Director will transmit the finalised accounts, along with the Management Board's opinion, to the Commission's Accounting Officer, the Court of Auditors, the European Parliament, and the Council by 1 July 2025.

B.4 Annual report 2024 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use

[EMA/MB/143612/2025], [EMA/MB/146952/2025] The Management Board endorsed the Annual Report 2024 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use.

The EMA explained that the cooperation agreement between the EMA and national competent authorities (NCAs) outlines key performance indicators (KPIs) for scientific work, such as meeting deadlines for drafting assessment reports. The annual report on KPIs includes detailed performance data per NCA and a summary of trends. Scientific advice for human medicinal products has consistently been an area under pressure. Although timelines for scientific advice assessment reports

have shown some progress, delays in appointing coordinators continue. In contrast, veterinary scientific advice has reached full compliance. The KPIs for GMP inspections are gradually improving, though pharmacovigilance inspections remain constrained by limited staffing in the NCAs. Overall, while there are no new major concerns compared to previous years, previous issues capacity in scientific advice and inspections remain. Additional metrics, introduced in the annual report upon proposal by the HMA-EMA strategic oversight group on resourcing, are used monitor the timeliness of rapporteur appointments. Although around 90% of rapporteur appointments for initial marketing applications met the expected timeframe, delays — when they occur — are significant, difficult to manage and will continue to require close monitoring and mitigation.

A Board member highlighted that a reflection on the operation of the scientific advice procedure and on the quality of its outputs is timely, especially as the new pharmaceutical legislation is expected to increase the importance of such advice for applicants. In discussing the challenges around rapporteur appointments, members emphasised that the unpredictability in industry submissions plays a significant role, and that the negative trends should be considered in the broader context of rising volumes of marketing authorisation applications. EMA acknowledged that submission predictability is a key issue and agreed with the need to reassess and improve the scientific advice process by making it more agile in line with future legislative changes and the broader political goal of enhancing competitiveness.

B.5 Report from the CHMP Chair

The Management Board noted an oral update from Bruno Sepodes, Chair of the Committee for Human Medicinal Products (CHMP) on ongoing activities and strategic priorities.

The CHMP Chair paid tribute to Harald Enzmann, who led the Committee from 2018 to 2024, guiding it through challenging periods such as Brexit and the COVID-19 pandemic. Under his leadership, the CHMP maintained strong performance, with 114 positive opinions in 2024, marking a return to pre-pandemic output levels. This success was attributed not only to CHMP but also to the collaborative efforts of other EMA committees like COMP, PDCO and CAT. In 2025, the CHMP has already achieved significant milestones, including approvals of key vaccines, such as for chikungunya under the PRIME scheme, and numerous positive opinions on other new medicines and extensions of indications. Biosimilars have seen a notable rise and progress continues also in orphan medicines, with new options emerging for conditions like epidermolysis bullosa and Duchenne muscular dystrophy. The CHMP also successfully concluded several referrals, such as for refining and harmonising indications for azithromycin, and supported global access to medicines through the 'EU-M4all' programme, including a positive opinion for an antiparasitic and the ongoing assessment of lecapanavir for HIV prophylaxis.

The Committee is preparing for new responsibilities under the new EU pharmaceutical legislation, aiming to preserve expertise from other committees and streamline operations. The Chair emphasized the vital role of working parties, scientific advisory groups, and ad hoc expert groups in supporting assessments and guideline development. CHMP remains aligned with HMA/EMA strategy of incorporating real-world evidence in regulatory decision-making alongside clinical trial data. Patient engagement continues to be a priority, particularly in scientific advice and oral explanations. Internationally, CHMP contributes to ICH initiatives by co-sponsoring new guidelines with Health Canada on comparative efficacy in biosimilar development and the use of real-world evidence to inform regulatory decision making. The PRIME programme continues to support innovation, with submission readiness meetings proving valuable for applicants. However, submission predictability remains a challenge, as unpredictable and delayed submissions disrupt the work of rapporteurs and the broader network. The CHMP is closely monitoring extended clock-stop requests and exploring ways to enforce existing rules to ensure more efficient assessments.

In parallel, the CHMP together with HMA/EMA Strategic Resource Oversight Group (SROG), is undertaking a broad internal effort to improve efficiency and quality. This includes streamlining processes, simplifying templates, and enhancing dialogue with applicants to improve the marketing authorisation process. Enhanced use of digital tools like SharePoint, improved pre-submission interactions and better coordination of work plans across committees and working parties are also being implemented. The Committee and the SROG is committed to improving communication, better highlighting the scientific basis of its decisions and further reinforcing the human side of the regulatory decision making at CHMP. In addition, a structured onboarding and mentoring programme for new members and alternates is in place to ensure continuity and engagement. The Chair reaffirmed the Committee's dedication to maintaining the highest standards of quality, safety, and efficacy in its work for patients.

The Management Board fully supported the path forward delineated by Bruno Sepodes in his presentation and reiterated the importance of a solid, motivated, efficient, and cohesive CHMP to the vitality of the European Medicines Regulatory Network. Additionally, the Management Board voiced appreciation for the exceptional work of the CHMP, extending this not only to the Chair and to the members, but also by the assessors of the network that continuously support the work of the Committee

B.6 Update on Audit topics

[EMA/MB/50992/2025], [EMA/MB/51003/2025], [EMA/MB/181090/2025] The Management Board noted an oral update by the MB Audits and Risks Group (MBARG) and adopted the Internal Audit Function's 2024 audit activity report, half-year 2025 report and revised 2025 Audit Plan.

Since the March MB meeting and the adoption of its revised Terms of Reference, the MBARG has elected Anna Chioti as vice-chair following a call for expression of interest and the Management Board agreed to the nomination. The Group's composition remains unchanged, but a new position may open soon, and members were encouraged to consider joining. Since September 2024, MBARG has participated in several EMA-organised training sessions on audits and risk management, which were found to be valuable. MBARG recommended the MB endorses the 2024 Audit Activity Report, which now also includes a foreword from the MBARG Chair. The MBARG continues to monitor the sustainable resourcing of the Agency's Internal Audit function, with a dedicated meeting with the EMA management scheduled in late June to discuss a new approach to resourcing.

The Agency's Head of Internal Audit confirmed that the function operated independently throughout 2024, with no interference, full access to necessary data, and in alignment with the Internal Audit Charter adopted by the Management Board.

In 2024, the internal audit function conducted four internal audits (veterinary pharmacovigilance system, effective management of conflict of interest, PRAC secretariat, environmental management) and one targeted independent review on anti-fraud activities, while initiating at the end of 2024 a co-sourced internal audit on metadata management at EMA. The internal audit function also coordinated two external audits carried out by the European Court of Auditors on COVID-19 response and medicine shortages, as well as two engagements conducted by IAS audit on EMA's former London office lease and the 2025 risk assessment. The 2024 Audit Activity Report also outlined a wider range of activities, including the organisation of the BEMA assessors training, several EMA-wide lunchtime talks (e.g. on cybersecurity or anti-fraud) and the ongoing digitalisation of several auditing processes.

The 2025 Audit Plan includes four internal audits (on data exchange with international partners, environmental management, variations for human medicines and PSURs), two co-sourced audits (on talent management and enterprise architecture (reserve audit)), and an IAS audit on the Clinical Trials

Information System. Preparations are underway for the biennial audit on EudraVigilance focusing on personal data protection in 2026 and to support the EMA's Data Protection Officer coordinating an external audit on IRIS focusing on data protection planned later in 2025. The MB was requested to approve the rescheduling of the audit on talent management to 2026 due to ongoing implementation of key HR activities, and that the audit on enterprise architecture is performed at the end of 2025.

MB Board adopted the 2024 activity report and proposed changes to the 2025 audit plan, while one MB member expressed some reservation and raised concerns about the audit function's current resourcing and sustainability. EMA acknowledged the issue and confirmed several measures were being taken (e.g. ongoing external recruitment of a contract agent to reduce reliance on interim staff). Regular updates on the resourcing plan will continue to be provided to the MB through the MBARG.

B.7 2024 EMA Annual Report on the implementation of the EMA's Anti-Fraud Strategy and EMA Anti-Fraud Strategy and related Action Plan for 2025-2028

[EMA/165696/2025], [EMA/MB/182991/2025] The Management Board noted an oral report from the EMA's Head of Legal Department on the implementation of the EMA's Anti-Fraud Strategy in 2024 and endorsed the Agency's Anti-Fraud Strategy for the period June 2025 to June 2028.

During 2024 and the first half of 2025, anti-fraud activities were aligned with three strategic priorities. The first was to maintain an anti-fraud culture in the Agency with high awareness, integrity, impartiality, and transparency. This included updating Anti-Fraud information on the intranet, launching an online Ethics training module, and ensuring mandatory Anti-Fraud training for all (including new) staff. The second priority was to strengthen measures for detecting suspicious behaviours, including updating the intranet with information on reporting wrongdoing. The third priority focused on mitigating fraud risks identified through audits. This involved an independent review of Anti-Fraud activities and updating the Risk Register with fraud-related risks. Assistance was provided to implement closed and ongoing OLAF investigations. Additionally, EMA chaired the Inter-Agencies Legal Network (IALN) working group on transparency and ethics.

The new Strategy to 2028 aims to include new activities to enhance fraud prevention and to take into account recently adopted legislation, the 2024 OLAF's methodology for the drafting of Anti-Fraud Strategies in decentralised agencies, along with other EU-level initiatives such as the revised Commission's Anti-Fraud Strategy Action Plan of 2023. The new strategic objectives are to reinforce anti-fraud awareness, increase fraud detection capabilities, and improve information exchange with OLAF and cooperation within the IALN. The Action Plan implementing the Strategy includes a description of planned activities, fraud risks addressed, responsible services, performance indicators, and timelines. Monitoring and reporting will be conducted, with results presented to the Executive Director and Management Board annually. The Strategy will be published on EMA's website, communicated to OLAF, and shared with the Agency's staff for awareness and compliance.

B.8 Revision of EMA Code of Conduct

[EMA/171864/2025], [EMA/MB/171906/2025], [EMA/385894/2012] The Management Board endorsed the Revision of EMA's Code of Conduct.

The EMA Code of Conduct was last revised in 2016 and it has been updated to take into account the new responsibilities for EMA following the adoption of the EMA's extended mandate in 2022, the latest updates to the EMA policies and staff rules regarding competing interests, the European Parliament's discharge observations and aligning with code of conducts in other EU institutions and bodies. The new

Code of Conduct consolidates existing legal provisions, enhancing clarity, transparency, and accountability of the Agency's staff members. It distinguishes the rules between different staff categories and provides relevant examples.

B.9 New Fee Regulation

[EMA/MB/183645/2024], [EMA/135783/2025], [EMA/MB/165209/2025] The Management Board adopted the second revision of the Fee Regulation Working Arrangements and a revised Decision on the financial arrangements on remuneration for (co-)rapporteur services provided by committee members appointed by the Commission in COMP and PDCO, repealing the previous Management Board Decision of 4 July 2024 (EMA/MB/183670/2024).

A summary of the changes to the Working Arrangements was presented to the Board, providing clarifications on topics such as re-examination fees, SME incentives, MRL fees, new scientific service fees for certain veterinary assessments.

Arrangements on remuneration for (co-)rapporteur services provided by committee members appointed by the Commission on EMA recommendation in COMP have been introduced to remunerate them for assessments performed as (co-)rapporteur.

B.10 Update on proposals to expand the involvement of external experts, including re-opening of MNAT-expert pilot

[EMA/144751/2025], [EMA/MB/154423/2025], [EMA/160519/2025] The Management Board noted the ongoing efforts to expand the use of external experts in support of the Network, as part of broader discussions on resourcing at the level of the HMA/EMA Strategic Oversight Group (SROG). The current model enables National Competent Authorities (NCAs) to select, contract, and remunerate experts for both assessment and inspection activities using fees received under the New Fee Regulation. The Board also noted complementary EMA-led initiatives to engage external experts through open calls for tasks such as training delivery, mentoring, peer review, inspection support, and ad hoc advice. These calls operate independently of NCA remuneration frameworks and are subject to EMA budget availability. In parallel, the MNAT-expert pilot, running from April 2023 to May 2025, allows EMA to remunerate experts directly by allocating a portion of the NCA's fee for specific MNAT procedures. Participation in the pilot has been limited to date, and a proposal to extend its scope will be presented to the Board in October, informed by feedback from NCAs.

A survey has been circulated to HMA to collect further information on NCAs' interest in engaging external experts, suitable mechanisms, supportive activities, and potential approaches to attract expertise. In addition, a webinar will be held on 9 July to raise awareness among potential experts, present opportunities for engagement, and explain relevant EU procedures and requirements, including rules on conflicts of interest.

Board members broadly welcomed the aim of strengthening expert resourcing across the Network. Nevertheless, concerns were raised regarding the practical implementation and possible unintended consequences of involving renumerated external experts. A phased approach was suggested as a means to test the proposed mechanisms in lower-risk areas such as training. It was agreed that the matter should be further explored within the HMA/EMA SROG, with findings from the survey and the phased approach, before returning to the Management Board for further consideration in October.

B.11 Update on remuneration of NCA staff for EU-NTC training development and delivery

[EMA/MB/183903/2025] The Management Board noted the proposed changes to Addendum to the EMA-NCA cooperation agreements to increase the remuneration for the development and delivery of priority training services under the EU Network Training Centre (EU NTC). This proposal builds on the Board's June 2023 decision to include training services in the scope of the agreements and the subsequent pilot to test the remuneration scheme. Following the pilot, data has been gathered in order to propose adjustments to the number of reimbursable days depending on the type of training activity. The Agency is also preparing an external call for expression of interest to engage and remunerate external experts for training, under the same rates as those applied to NCA staff. These changes aim to support the capacity and capability building of the EU Medicines Regulatory Network and will be reflected in Addendum 6 to be adopted via written procedure after the June 2025 meeting.

Post-meeting note: Taking into account the outcome of the discussion under point B. 10, it was decided not to launch a written procedure at this stage but to bring all the proposed changes to the EMA-NCA cooperation agreements to the October 2025 Management Board meeting.

B.12 Network Data Steering Group

- Update on activities

[EMA/MB/171350/2025] The Management Board noted the recent developments under the Artificial Intelligence (AI) workstream of the Network Data Steering Group (NDSG), particularly in view of the EU AI Act. NDSG is coordinating a phased implementation approach, starting with the cataloguing of AI tools and use cases and the promotion of AI literacy across the Network. As part of the work on AI, a Temporary Drafting Group has been established to collaborate with the US FDA on developing common principles and terminology for responsible AI, with stakeholder consultation planned by the end of the year. In parallel, a dedicated AI industry focus group is being established to facilitate open dialogue with industry stakeholders on the development and use of AI in the regulatory context. Key deliverables for 2025 include the publication of the annual AI Observatory report, guidance on AI use, endorsement of an AI tools framework, and preparation of an EMA AI inventory to be submitted to the European Data Protection Supervisor. A workshop with Network assessors and experts on AI use cases is planned for Q3, alongside a series of training initiatives and multi-stakeholder events throughout the year.

Board members commended all the work undertaken but noted that issues around data sovereignty and clarity on process ownership might contribute to current assessors' perspective on using AI tools. EMA shared that Copilot is being piloted at the EMA in a secure environment, with positive early feedback, and proposed to share experiences through a future workshop.

- Recommendations for human Product Master Data implementation and data management.

[EMA/135628/2025] The Management Board endorsed the recommendations from the NDSG on the implementation of human Product Master Data and related data management principles. The Product Management System (PMS) is recognised as the central source of product master data for all EU medicinal products, aiming to provide a unified, EU-level repository supporting the full product data lifecycle. To support this, NDSG developed high-level guiding recommendations, incorporating input from the Regulatory Optimisation Group (ROG), which will form the basis for defining EMRN working arrangements for PMS data use and qualification aiming for a draft by the end of 2025. The recommendations were adopted by NDSG on 30 April 2025, presented to the HMA plenary in May, and subsequently endorsed by HMA via written procedure. Following endorsement by the EMA Management Board, the document will be published on the NDSG webpage. A few members of the

Board emphasised the importance of ensuring that data qualification does not place an undue burden on NCAs with regards to the upcoming feasibility study. EMA confirmed that the study would explore a range of implementation models and would take variations in national capacity into account.

B.13 Clinical Trials in the EU

- Report on operation of CTIS

[EMA/MB/177235/2025] The Management Board noted the report and was informed of continued positive progress with clinical trials in the EU. Since its launch in 2022 and as of 30 April 2025, the Clinical Trials Information System (CTIS) has received over 11,300 initial clinical trial applications, including initial, transitional, and resubmitted trials, with almost 9,300 decisions issued by EU Member States. CTIS was officially designated as a primary registry by the World Health Organization (WHO) within the International Clinical Trials Registry Platform (ICTRP) on 3 April 2025. Simplification of CTIS business rules remains a key priority, with good progress made under the Simplification Task Force. The analysis of several high-priority topics, such as the revised roles matrix and user management, safety, timetable, quality dossier (IMPD Q), and ad hoc assessment, has been finalised, and significant advancement has been made on key CTA submission and workflow subtopics. The Board was also informed that knowledge transfer to the new CTIS supplier was completed on 30 April 2025, and that a roadmap for modernising the system, focusing on further improvements, simplification, and technology upgrades starting with the safety module, is currently being drafted and will be presented at the next Management Board meeting.

- Policy and regulatory update including ACT EU (European Commission & EMA)

[EMA/175638/2025] The Management Board noted an update from the chair of the ACT EU Steering Group and the DG SANTE representative, who highlighted the critical role of clinical research in Europe and concerns over declining clinical trial applications as well as longer authorisation timelines compared to other regions. Despite progress with CTIS, further improvements and possible targeted amendments to the Clinical Trials Regulation (CTR) were considered, with the upcoming Biotech Act seen as a legislative opportunity. Other key initiatives such as ACT EU, COMBINE and MedEthicsEU were also mentioned to support a stronger clinical trials environment in Europe. The DG SANTE representative further noted that the ACT EU Steering Group had endorsed KPIs and metrics aimed at increasing clinical trial attractiveness, accelerating patient access and monitoring impact, with quarterly reporting and publication on such metrics planned for Q3 2025 alongside a communication plan. Additional ACT EU initiatives were also presented, including work on clinical trials in public health emergencies (PHE), such as the establishment of a PHE ethics advisory group and ethics experts joining EMA's Emergency Task Force from Q3 2025. Work is also ongoing to improve CTR and CTIS implementation through simplified training materials, while the 'CTR Collaborate' initiative continues to address practical challenges with Member States.

The stakeholder co-chair of the Multi-stakeholder Platform Advisory Group (MSP AG) provided an update on MSP AG central role in ACT EU governance through regular consultations, contributing to the revision of recommendation papers on Auxiliary Medicinal Products and risk proportionate approaches in clinical trials. In addition, the stakeholder co-chair underlined that there is broad agreement on the need to work on streamling Requests for Information (RFIs) and strengthening the role of the Reference Member State (RMS) and that stakeholders are calling for quicker progress on the priorities agreed last year. Furthermore, the chair of the Clinical Trials Coordination Group (CTCG) also reported on 'CTR Collaborate', highlighting that the May 2025 workshop focused on improving alignment under

the CTR through pragmatic application in daily practice, clarifying critical considerations, and ensuring consistent levels of detail in assessment reports across Member States, with next steps to finalise outcome documents and plan further joint meetings. An update was also provided on the COMBINE programme, noting the launch of Project 1 (all-in-one coordination) in June 2025, with Projects 2 (safety reporting) and 4 (use of devices in clinical trials) underway, and Projects 5 (advice and assessors' fora) and Task 7 (information on national requirements) on track.

The Board commended the work of the ACT EU Steering Group and CTCG and noted improvements resulting from the implementation of the CTR and CTIS, while several Members highlighted the need to further optimise processes and coordination across Member States.

List of written procedures during the period from 04 March 2025 to 28 May 2025:

- Consultation no. 03/2025 on the appointment of Marcin Glanda as CVMP alternate as proposed by Poland ended on 21.04.2025. The mandate of the nominee commenced on 22.04.2025.
- Consultation no. 04/2025 on the appointment of Tsvetanka Valova as CVMP alternate as proposed by Bulgaria ended on 30.04.2025. The mandate of the nominee commenced on 01.05.2025.
- Consultation procedure for the adoption of the 127th EMA Management Board meeting minutes. The minutes were adopted.
- Consultation procedure for the endorsement of the HMA-EMA Network Data Steering Group (NDSG) workplan 2025 to 2028. The workplan was endorsed.

Documents for information

- [EMA/MB/114131/2025] Outcome of written procedures finalised during the period from 04 March to 28 May 2025.
- [EMA/MB/58668/2025], [EMA/158661/2025] Network Portfolio Report
- [EMA/177327/2025] Summary report of implementation of assigned revenue June25
- [EMA/MB/95999/2025] [EMA/95990/2025] EMA working document on buildings
- [EMA/MB/177295/2025] Summary report transfers of appropriations in budget 2025

List of participants at the 128th meeting of the Management Board, held in Amsterdam, 11-12 June 2025

Chair: Rui Santos Ivo

	Participants
Belgium	Charles Denonne *(alternate)*
Bulgaria	*Apologies received from Bulgaria*
Czech Republic	Tomáš Boráň *(member)*
Croatia	Siniša Tomić *(member)*
Denmark	Nils Falk Bjerregaard (*member)* Mette Aaboe Hansen (*alternate*) Birgitte Faber (*support observer*)
Germany	Lars-Christoph Nickel (*alternate*) Wiebke Löbker (*support observer)*
Estonia	*Apologies received from Estonia*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	Evangelos Manolopoulos *(member)* Spyridon Th. Sapounas (*alternate)*
Spain	María-Jesús Lamas Díaz *(member)* Julia Caro *(support observer)*
France	Catherine Paugam-Burtz *(member)* Franck Fourès (*alternate)* Miguel Bley *(support observer)*
Italy	Robert Nisticò *(member)* Armando Magrelli (*alternate)* Marta Giovanna Toma *(support observer)*
Cyprus	Helena Panayiotopoulou (*member)*
Latvia	Sergejs Akuličs (*alternate*)
Lithuania	Dovilė Marcinkė[1] *(member)*
Luxembourg	Anna Chioti *(member)*
Hungary	Beatrix Horváth (*alternate)*
Malta	Anthony Serracino Inglott (*member)* Caroline Muscat (*support observer)*
Netherlands	Paula Loekemeijer (*alternate)* Aimad Torqui[1] *(member)* Roelie Marinus *(support observer)*
Austria	Günter Waxenecker *(member)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)* Magdalena Pajewska-Lewandowska (support *observer*)
Portugal	Susana Guedes Pombo *(alternate)* Maria João Morais *(support observer)*
Romania	Răzvan Prisada *(member)*
Slovakia	Roman Dorčik[1] *(member)*
Slovenia	Momir Radulović *(member)* Sabina Zalar *(alternate)*
Finland	Eija Pelkonen (*member*)

	Participants
	Anna Siira[1] (*alternate*)
Sweden	Åsa Kumlin Howell[1] *(alternate)*
European Parliament	Cristian Bușoi (*observer*) Kristina Garuolienė (*observer)*
European Commission	Rainer Becker (DG SANTE) (*alternate*) Matus Ferech (DG SANTE) (*support observer*) Irene Norstedt (DG RTD) (*alternate*) Tomasz Dylag (DG RTD) (*support observer*)
Representatives of patients' organisations	Marco Greco *(member)* Virginie Hivert *(member)*
Representative of doctors' organisations	Denis Lacombe *(member)*
Representative of veterinarians' organisations	Christophe Buhot *(member)*
EEA-EFTA states	Rúna Hauksdóttir Hvannberg (Iceland) *(member)* Vlasta Zavadova (Liechtenstein) *(member)* Martin Stricker (Lichtenstein) *(alternate)* T Trygve Ottersen[1] (Norway) *(member)* Audun Hågå (Norway) (*alternate*)

[1] Restrictions apply for agenda item B.9

Guest Speaker	Bruno Sepodes, CHMP Chair Marianne Lunzer, CTCG Chair

African Medicines Agency (AMA) delegation participants (*observers*)

AMA Governing Board	Yossounon Chabi, Chair of the AMA Governing Board, Benin Haoua Haroun, Vice-chair of the AMA Governing Board, Tchad Emile Bienvenu, Member of the AMA Governing Board, Rwanda
African Union Commission	Benjamin Djoudalbaye; Head of AMA Interim Secretariat Nkaleang Modutlwa; Technical Officer, AMA Operationalisation
African Medicines Regulatory Harmonization (AMRH)	Boitumelo Semete-Makokotlela; AMRH Steering Committee Chair, South African Health Products Regulatory Authority Adam Mitangu Fimbo; AMRH SC Vice Chair, Medicines and Medical Devices Authority, Tanzania Chimwemwe Chamdimba; Head, AMRH Programme and Technical Support to AMA
NRAs which have reached ML3 status	Ali ElGhamrawy Chairman; Egyptian Drug Authority, Egypt Delese Mimi Darko; Chief Executive Officer, FDA, Ghana Mojisola Christianah Adeyeye; Director General, National Agency for Food and Drug Administration and Control, Nigeria
West African Health Organisation	Issiaka Sombie; Acting Director of the Department of Public Health and Research at the West African Health Organisation
DG INTPA	Martin Seychell; Deputy Director General responsible for Directorate G, R (INTPA.DGA3) Bianca Baluta; Policy Officer; Health and Investments
World Health Organization	Hiiti Silo; Unit Head, Regulation and Safety, Department of Regulation and Prequalification Mohamed Ismail; WHO Regional Office for Africa Tariro Daphney Sithole; WHO Regional Office for Africa

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Zaïde Frias Hilmar Hamman Emmanuel Cormier Alexis Nolte

	Nerimantas Steikunas Melanie Carr Steffen Thirstrup Hilde Boone Georgia Gavriilidou Franck Diafouka Martin Harvey-Allchurch Paola Samassa Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin