07 March 2025
EMA/MB/580677/2024 - Adopted
Management Board

Minutes of the 126th meeting of the Management Board

Amsterdam 11-12 December 2024

The Chair of the Management Board opened the meeting, which was held as a face-to-face meeting. The Chair welcomed the new member for Denmark, Mr Nils Falk Bjerregaard (Director General, Danish Medicines Agency, DKMA), member for Norway, Mr Trygve Ottersen (Director General, Norwegian Medical Products Agency, NOMA), and alternate for Italy, Mr Armando Magrelli (Head of Independent Research Office, Italian Medicines Agency, AIFA). The Board was informed that posters would be on display for Board members to further familiarise themselves with selected EMA activities of interest regarding EMA Stakeholder Engagement with Patients, HCP, Academia, SMEs & Industry, during the lunch break on the second day. The Management Board was informed that the mandate of the current Chair would be ending at the end of March 2025 and thus an election would be organised at the next Board meeting in March 2025.

1. Draft agenda for the 11-12 December 2024 meeting

[EMA/MB/501393/2024] The agenda was adopted with no amendments.

2. Declaration of competing interests 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.3 Programming 2025-2028; B.4b. 2025 Audit Annual Plan and Audit Strategy 2025-2027; B.5 Revised Policy 0044 and Management Board members Policy 0058; and B.7 New Fee Regulation implementation a) Revision of the Fee Regulation Working Arrangements*. 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.

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3. Minutes from the 125th meeting, held on 03 October 2024

[EMA/MB/449773/2024] The Management Board noted the final draft minutes, which were being reviewed under written procedure with a deadline of 20 December.
Posting meeting note: The minutes were adopted on 20 December 2024.

4. 30 Churchill Place

- EMA Update

The Management Board noted an oral update by the EMA on the final renegotiated sub-lease agreement.

- IAS: audit on Management of the lease of 30CP 2024

The European Commission's Internal Audit Service (IAS) had conducted an audit on the management of the lease of the European Medicines Agency's former office premises in London, 30 Churchill Place, in July 2024, in accordance with the 2024-2026 strategic internal audit plan. The primary objective was to evaluate the effectiveness of lease management, focusing on EMA's efforts to mitigate potential financial liabilities linked to the lease in the framework of the Financial Regulation and the Agency's ability to reallocate resources to tasks on the lease management.

The IAS concluded that the risk management process put in place by EMA related to the lease of its former office premises in London was effective. The IAS noted that EMA sub-lets the premises to reduce the financial burden for the EU budget, has established a dedicated team to manage risks related to both lease and sub-lease contracts, actively monitors the UK commercial real estate market and media for emerging risks, engages external expertise as needed, and ensures that budget and resource oversight are addressed with the Management Board and the budgetary authority.

Given the overall positive results, no formal report will be issued. Instead, the IAS will issue a closing note which will summarise the audit's conclusions. The final IAS note will be shared with the Board once received by the Agency.

The Board thanked the IAS for the thorough review and was reassured by IAS's findings, in view of the importance of this topic for the Agency and its budget.

A. Points for automatic adoption/endorsement

A.1 Revision of budget remarks for budget 2025

[EMA/MB/539471/2024] The Management Board endorsed a revision of the line "Other expenditure in relation to meetings" in the budget 2025 to include a reference to the setting up and running of scientific and regulatory trainings for the EU network and for international partners under the African Medicines Agency project.

A.2 Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2025

[EMA/MB/148596/2024] The Management Board endorsed an adjustment of the budget 2025 to include the financial compensation and workload estimation of the NCA participation in the linguistic

checking of product-related information for 2025. The budget will be adjusted to reflect the endorsed workload estimation and the change in fixed hourly rate due to annual inflation.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board received an oral update on the continuing network resource shortfalls for the Centralised Procedure, despite multiple dedicated initiatives that have been taken in particular by the HMA/EMA Strategic Oversight Group. An in-depth review of the situation is scheduled for early 2025, with EMA continuing to implement activities aimed at further improving the quality and efficiency of assessments. The Board urged the Agency and the network to continue collaborating on solutions to address resourcing challenges and to ensure balanced contributions from the agencies across the network.

The Board was also informed that the EMA had recommended over 100 human medicines for marketing authorisation in 2024, including 46 new active substances, with ground-breaking new treatments for ALS, early Alzheimer's, and the first vaccine for Chikungunya. On the veterinary side, the first certification of a veterinary vaccine platform technology master file was highlighted. The Board congratulated the Agency on these achievements, and noted that increased application volumes, not seen since 2019, have exacerbated resource challenges. Training under EU-NTC and IncreaseNET was highlighted as essential to prepare experts for the increased challenges, particularly for ATMPs.

Regarding medicine shortages, the Board was informed that the first version of the European Shortages Monitoring Platform had been officially launched on 28 November 2024, ahead of its go-live in Q1 2025, with several training activities organised to prepare stakeholders for its implementation.

The Board also received feedback from key international meetings that had taken place between October and November, and on 8 pilots for reliance by non-EU regulatory authorities on CHMP post-approval opinions. Concerning the African Medicines Agency (AMA) Project, the AMA Governing Board will attend part of the June 2025 EMA Management Board meeting to gain a better understanding of how EMA MB meetings are conducted and of the type of discussions that take place.

The Executive Director highlighted the recent adoption of the revised 'HMA/EMA guidance document on identifying commercially confidential information (CCI) and personal data in marketing authorisation applications for human medicines', aiming to enhance transparency and establish clearer processes for management of sensitive data in line with evolving practices and data protection laws. The Board commended the excellent work of the joint HMA-EMA Working Group on Transparency.

On the European Medicines Agencies Network Strategy to 2028, the Board was informed that 77 contributions were received during the public consultation, with 78% of stakeholders expressing a positive view. An HMA/EMA drafting group is analysing the feedback, and the team leading each thematic area will consider any necessary updates to the strategy in January 2025. Following a multi-stakeholder workshop under the Polish Presidency on 13 February 2025, the final Strategy document will be presented for adoption at the March 2025 Management Board meeting.

The Board was also informed of several planned events in 2025 to celebrate EMA's 30th anniversary.

Lastly, the Executive Director informed the Board of the appointment of Ms Monika Benstetter as Head of Communication from 1 November 2024 further to the upcoming retirement of Ms Marie-Agnes Heine, and of the appointment of Ms Corinne De Vries as EMA Liaison Official to the FDA, replacing Ms Anabela Marcal, as of July 2025.

B.2 Report from the European Commission

The Management Board noted an oral update from the representatives of DG SANTE and DG RTD.

The representative of DG SANTE provided updates on a variety of topics, including the revision of the pharmaceutical legislation, the developments of the upcoming EU Joint Action on regulatory flexibilities using magistral preparations, the medical devices legislation, implementation of the Veterinary Medicinal Products Regulation, the Windsor Framework, and the upcoming European Commission study on hospital exemption under the ATMP regulation. As regards the new pharmaceutical legislation, discussions at Council are still addressing sensitive themes related to incentives and security of supply, while the work on more technical topics is progressing more rapidly. As regards the implementation of the veterinary legislation, the legal framework for implementing Article 118 on the ban of antimicrobials for growth promotion purposes is in place, and input is being sought for two other Implementing Acts, i.e. on GMP for veterinary medicinal products, active substances and autogenous inactivated immunologicals, and on the EU list of substances essential for equine species. Work on implementing the medical device/IVD regulations is continuing and short to medium-term actions including a pilot on orphan devices and extending the scope of scientific advice are being developed with involvement from EMA. Next steps in the targeted evaluation of the medical device legislation include an open public consultation and call for evidence, as well as targeted surveys to Competent Authorities, EMA, and Notified Bodies. As regards the Windsor Framework, the Commission has assessed UK's written guarantees on certain medicinal products marketed in Northern Ireland and will publish a notice in the EU Official Journal regarding the application of new rules from 1 January 2025. A study on hospital exemption under the ATMP regulation is underway, and a stakeholder event related to this took place in Brussels on 21 November 2024.

During the meeting, several members expressed an interest in receiving more information from the Commission on cross-sectoral legislation affecting the medicines sector, including recent legislation on urban wastewater treatment and packaging materials. As regards the revision of the medical device legislation, Board members emphasised the importance of a thorough impact assessment. Some members suggested that there should be reconsideration of the Implementing Act related to veterinary GMP to ensure continued alignment with human medicines and international standards. In the context of to the new pharma legislation, a member highlighted for a diverse geographical representation of experts in future EMA governance. This would help ensure that all EU Member States, including smaller ones, can participate and share knowledge.

Some members also enquired about the possibility to pilot certain proposed changes to EMA's governance already under the current legal framework to help improve sustainability of the network. Members also asked about the Critical Medicines Act, the study on hospital exemption and the Notice on the application of the Windsor Framework.

The representative of DG RTD provided an update on EU funded projects on environmental sustainability in the pharmaceutical and healthcare sectors. The current EU political context places a strong focus on research and sustainable competitiveness, building on the European Green Deal. The Commission has invested heavily in research and innovation for various environmental and health aspects, with over 700 projects and €3 billion spent in this area over the last 20 years. The emerging area of climate and health is being given special attention. Several specific project clusters were presented, such as on endocrine disruptors and green pharmaceuticals, and a new IHI call on PFAS was highlighted.

The representative of DG RTD also noted that the new EU Commissioner for research and innovation will lead the development of a Life Science Strategy in collaboration with colleagues across various EC departments. A call for evidence will be launched for this strategy, and input from various stakeholders

is welcome. The European Partnership for personalised medicine will launch in 2025 a call for projects on pharmacogenomics. With an indicative budget of €35 million, this call is aimed at identifying new pharmacogenomic markers to tailor personalised treatment. Board members were encouraged to engage in an advisory role capacity in EU funded projects under this call to ensure that the results can be swiftly considered for regulatory use.

Board members underscored the importance of a regulatory environment that fosters and supports innovation in the green sector. Some members highlighted the necessity of early regulatory involvement to ensure the efficient approval and supervision of sustainable biobased products. Suggestions included exploring the use of a regulatory sandbox and developing trainings programs on new green technologies for regulators, potentially through the EU Network Training Centre. EMA emphasized the vital role of regulators in bridging the gap between academia and industry on green manufacturing. EMA also noted early engagement between academia and regulators on advanced technologies is crucial and that green manufacturing can boost EU competitiveness.

B.3 Programming 2025-2028

[EMA/348813/2024], [EMA/538371/2024], [EMA/MB/548847/2024], [EMA/MB/500033/2024], [EMA/486596/2024]. The Management Board adopted the Single Programming Document (SPD) for 2025-2028, the key planning document for the Agency. Spanning over a four-year period, it provides the financing decision that allows the Executive Director to implement the budget and deploy the resources made available to the Agency.

The document encompasses both the final work program, budget, and establishment plan for the period 2025-27, as well as the draft work program, budget, and establishment plan for the period 2026-28.

Topic Coordinators Eija Pelkonen, Franck Fourès, Grzegorz Cessak, and Rui Santos Ivo, along with the Chair, reviewed and presented these documents to the Board.

The 2025 work programme outlines the Agency's strategy for adapting to the rapidly evolving medicines landscape and facilitating the transition from the current European Medicines Agencies Network Strategy (EMANS) to its updated version through to 2028. In this context, during 2025 the EMA will pay particular attention to three focus areas: accelerating and optimising the assessment of medicines, improving their accessibility and availability, and future-proofing medicines regulation in the EU.

The Agency’s commitment to providing technical and scientific advice to the European Commission on implementing the Veterinary Regulation is reiterated, focusing on adopting new processes and guidance while further developing the required IT systems.

The Agency’s 2025 draft budget is aligned with the strategic focus areas while also providing substantial funding for public health activities through scientific studies and real-world data. The budget aims to support efficiencies through investments in outsourcing document redaction, further developing EMA’s Scientific Explorer, and process reviews and improvements. Additionally, the budget reflects increased information security, IT maintenance, operating and administrative costs.

Topic coordinators underlined that the 2025 budget is balanced and robust, ensuring strong support for public health activities with a 26% revenue increase from the New Fee Regulation. The budget also includes a 40% increase in remuneration for Member States’ NCA scientific work, supports EMA and HMA efforts on the EMANS strategy, and funds the Network portfolio, change management, and IT security.

Significant investments are planned in IT infrastructure, including pan-European systems such as CTIS, UPD, SPOR, and the IRIS collaboration platform, alongside enhanced information security measures. The 2025 IT budget prioritises investments in new legislative requirements, data analytics, AI, and digitalisation to support the EMANS to 2028. The Agency is focusing on key strategic projects and actively seeking ways to reverse rising IT operations costs.

Regarding staffing, the budget reflects a reduction of COVID-19 posts and an increase in resources in preparation

for the revised pharmaceutical legislation. Despite the allocation of resources for the revised pharmaceutical legislation, the growing workload from the annually expanding product portfolio, new pieces of legislation with flat establishment plan levels are creating staffing challenges at the Agency, with various legislative areas like data protection, health technology assessment, interoperability across the Union and others competing for resources.

The Topic Coordinators stressed that the document includes 'negative priorities', noting that resource constraints have led EMA to deprioritise certain activities in areas such as IT technology, innovation, international cooperation, and transparency, impacting its ability to fully address its growing workload and legal obligations. As a result, and in preparation for the 2026 preliminary draft budget, the SPD includes a request to the European Commission for additional resources.

The Board acknowledged the efforts made in assessing and preparing the programming documents and thanked the topic coordinators. A Board member inquired about the impact of the New Fee Regulation and how it might influence applicants' approach to their product portfolios. EMA acknowledged that this aspect will be subject to close monitoring as the Agency gains experience under the new Regulation. Following the discussion, the Agency will reflect any final comments received in the final document, circulate it to the Board, and submit it to the European Commission and other institutions by 31 January 2025.

B.4 Audit topics

[EMA/337503/2024], [EMA/320999/2024], [EMA/MB/337502/2024]; [EMA/MB/530557/2024]. The Management Board noted an update on the activities of the Management Board Audit and Risks Group (MBARG) and adopted the Audit Plan for 2025, the Audit Strategy for 2025-2027 and the 6th biennial report on Pharmacovigilance audits at EMA.

a) MBARG update

The MBARG Chair presented on the activities of the Audit and Risks Group since June 2024. These included two bite-size training sessions presented by AF-AUD respectively on the financial / budgetary planning and reporting cycle and on the revised Global Internal Audit Standards issued by the Institute of Internal Auditors which enter into force on 9 January 2025. During two MBARG meetings, Board members in the group had the opportunity to review, provide feedback and endorse on the draft 6th biennial report on the pharmacovigilance audits 2022 to 2024, as well as the draft EMA's 2025 audit plan and strategy covering 2025-2027. The long-term resource allocation for the EMA's internal audit function continued to be a topic of discussion in 2024 and will be further developed in 2025, together with a review of the operating model.

The Management Board acknowledged the challenges related to resourcing of the internal audit function and requested to receive updates on any future developments in this regard.

b) 2025 Audit Annual Plan and Audit Strategy 2025-2027

EMA's Head of Internal Audit *ad interim* presented the three strategic objectives of the internal audit function, the Agency's 2025 Audit Annual Plan and the EMA Audit Strategy 2025-2027. Both documents have been developed following a risk assessment based on consultation with EMA Senior Management as well as the Agency's Quality and Risk management function, consultation with other assurance providers (Internal Audit Service of the European Commission), and desk research and analysis. Taking account of the availability of auditing capacity, the EMA Audit Plan 2025 will cover a number of internal activities, including variations for human medicines and management of Periodic Safety Update Reports following the migration of these activities to IRIS (postponed from 2024). It will also include audits on environmental management, exchange of data and information with international partners and talent management (through the implementation of the EMA HR strategy). The proposed audit to assess the effectiveness of the Agency's IT enterprise architecture, will depend on available resources. The planned audits for 2026 and 2027 were also presented in detail.

c) 6th biennial report on Pharmacovigilance audits

EMA presented the 6th biennial report on pharmacovigilance audits carried out from 1 July 2022 to 30 June 2024, which was prepared in accordance with Article 28f of Regulation (EC) 726/2004. These audits focused on safety communications (GVP Module XV), and on the management of PRAC secretariat and related working groups. The report identified a few areas for improvement and action plans to address these are being implemented.

A member of the Board queried the process for scheduling of audits. It was clarified that this is largely dependent on available resources. However, in order to continue complying with Article 28f of Regulation (EC) 726/2004, the EMA's internal audit function aims to conduct at least one audit on pharmacovigilance per year using a risk-based approach, given the importance of this topic for patients and the network.

B.5 Revision of EMA independence policies

[EMA/54457/2024], [EMA/MB/89817/2024], [EMA/MB/543764/2024], [EMA/543492/2024]. The Management Board adopted the revised Policy 0044 on handling of competing interests for Committee members and experts and the revised Policy 0058 on handling of competing interests for Management Board members.

- Outcome of public consultation

EMA's senior policy specialist informed the Board about the outcome of the public consultation on the draft revised policy 0044 that was held between 10 October and 10 November 2024. A total of 35 Responses had been received from a wide range of stakeholders Several respondents acknowledged EMA's efforts to revise the policy in a balanced and proportionate way in the light of recent Court judgements. However, some stakeholders also expressed concern on the impact that the revised rules may have on the Agency's ability to involve relevant and necessary expertise, whilst others called for applying stricter rules or definitions. The Board was informed about the main recurring comments from the public consultation on the themes: cooling-off period, financial interests and reimbursement of expenses, restrictions to 'products in the same declared condition', an expert witness, definition and interests in research organisations, conflicts of opinion, participation in community advisory boards, and transparency.

A summary report of the public consultation was circulated to the Management Board ahead of the December meeting and will be published on the Agency's website together with the final revised policy.

- Revised Policy 0044 (Committee members and experts) and revised Policy 0058 (Management Board members)

EMA explained that, after review of all comments received from the public consultation, no major changes to the main principles or scope of restrictions are proposed. Where needed, some clarifications have been made, in particular to definitions as well as editorial changes to improve the overall readability of the policy.

Policy 0058 on the handling of competing interests of Management Board members is also revised to align as needed with Policy 0044, including the introduction of rules to handle interests from Management Board members related to involvement or affiliation in a research organisation. The two policies are proposed to be effective on 1 May 2025, to allow sufficient time to update the Expert Management Tool and related guidance. The Management Board Decision on rules concerning the handling of declared interests of EMA staff members will be aligned with the revision of Policy 0044 and shared with the Management Board for adoption at its March 2025 meeting.

During the discussion, the patients' organisations representative asked for clarification about considering the role of patients in Community Advisory Boards as consultancy, and expressed support for the concept of an 'expert witness' which will allow patients with some conflicts, to still provide some form of valuable input in EMA's activities. One member highlighted the importance to carefully consider the handling of conflict of interests in the new EU pharmaceutical legislation to ensure access to best expertise and suggested including the concept of an expert witness. The healthcare professionals' representative asked for examples of situations where an independent research organisation is also a marketing authorisation holder. While several members commented that the revised policy 0044 may impact on the availability of external scientific experts for the EU medicines regulatory network, they acknowledged that a balanced risk-based approach has been achieved by EMA given the constraints of the recent Court judgements. It was suggested that EMA monitors the impact of the revised policy and reports back on specific areas/cases where involvement of relevant experts proves to be difficult.

EMA confirmed that it will report on the first experiences with the revised policies, when presenting the 2025 annual report on independence. National competent authorities were also invited to provide feedback to the Agency on their experience with applying the policy to their assessment teams. Regarding the community advisory boards, EMA clarified that for the purpose of the policy they fall under the definition of consultancy, however other individuals from the same patient organisation could still be allowed to participate in EMA activities. EMA also confirmed that there has been one example in recent years of a non-profit research organisation becoming a marketing authorisation holder, although this is quite rare. In response to a question about the timeline for developing implementing guidance on the new policy, EMA explained that this is planned for early 2025. EMA indicated that it had also presented the updated policy to the HMA Working Group of Quality Managers who will adapt the HMA guidance on conflicts of interests so that it may become effective at the same time as Policy 0044.

B.6 Clinical Data Publication (CDP) Relaunch Strategy – Step 2

[EMA/MB/557989] The Management Board endorsed step two of the relaunch of EMA's clinical data publication.

In September 2023, the first step of the relaunch of clinical data publication activities was implemented with a focus on initial marketing authorisation applications for medicines containing a new active substance and in January 2024 the first set of documents related to this relaunch was published. The Board was informed that, for the medicines in scope of the second step of the relaunch,

clinical data underpinning initial marketing authorisation applications, extensions of therapeutic indications and line extensions will be published on the Agency's clinical data website - with the exclusion of generics, biosimilars and hybrids - starting with opinions adopted by the Agency's Committee for Human Medicines (CHMP) from May 2025. Clinical data for medicines that were approved while EMA's policy was suspended can be requested via the standard access to documents webform to EMA. Those clinical data packages will then also be published on EMA's clinical data website.

During the meeting, members asked for clarification on why biosimilars were excluded from this step of the relaunch and asked about the collaboration with Health Canada. EMA explained that biosimilars products contain limited clinical data in the dossiers submitted to the Agency and are less frequently requested in the clinical data publication portal and that therefore they are excluded for this step of the relaunch, together with generics. EMA also clarified that the Agency has been working together with the Canadian regulator for several years in the area of clinical data publication, since Health Canada has adopted a similar publication policy as EMA. EMA and Health Canada have aligned their methodology for redacting personal and commercially confidential data in the clinical dossiers and have a common template for anonymisation reports. EMA and Health Canada are also piloting a project to mutually recognise each other's work in anonymising clinical data for medicines when marketing authorisation applications are being assessed at the same time in the two jurisdictions.

B.7 New EMA Fee Regulation implementation

[EMA/539474/2024], [EMA/557929/2024], [EMA/MB/5394742024], [Ares (2024)8652210], [EMA/MB/557930/2024]. The Management Board adopted the revised Fee Regulation Working Arrangements and adopted the MB Decision on the common format for reporting performance information.

a) Revision of the Fee Regulation Working Arrangements

EMA presented a proposal for revisions to the Working Arrangements since its adoption at the June Management Board meeting, as new provisions needed to be introduced to provide for a reduced fee and remuneration for consultations on companion diagnostics under Section 7.3 of Annex IV to Regulation (EU) 2024/568 (the 'new Fee Regulation'), in relation to the second and subsequent medicinal products covered in the same consultation. In addition, minor corrections were introduced to align the Working Arrangements with the second Corrigendum to the new Fee Regulation. A positive opinion had been received by the European Commission on 4 December. The revised document was adopted by the Management Board.

b) MB Decision on the common format for reporting performance information

EMA presented a draft Management Board Decision which specified the types of procedures and the format to provide information about time spent by national competent authorities and medical device experts, as required by Annex VI of Regulation (EU) 2024/568. The Decision complements the Working Arrangements and Cooperation Agreements and was developed by a Management Board subgroup which was set up following discussion at the June Management Board meeting. The sub-group recognised the need for National Competent Authorities (NCAs) to establish time recording systems and the following procedures were proposed: Type II variations for new indications or modification of approved indications of human medicinal products, consultation on the suitability of companion diagnostics, variations requiring assessment for veterinary medicinal products, and certain medical device assessments by the Expert Panels. As outlined in the legislation, the performance information including information on time spent per type of procedure will be made publicly available on the Agency's website and will also be used to prepare the special report for the European Commission

pursuant to Article 10 of the new Fee Regulation. EMA also sought the Board's opinion to set up sub-group to reflect on the common format to report significant changes in costs. The Board welcomed the proposal to establish a group but agreed that gaining sufficient experience in operating the new fee regulation is essential first, and thus will revisit this suggestion at a later stage. The MB Decision on the common format was adopted.

B.8 Update on the preparations for implementation of the Health Technology Assessment (HTA) Regulation:

The Management Board noted an update from the European Commission and EMA on the preparations for implementation of the Health Technology Assessment (HTA) Regulation.

• EC activities

The Board was reminded that the HTA Regulation will apply from 12 January 2025. The Commission representative highlighted that four implementing acts have been adopted by the HTA Committee so far. In addition, several guidance documents have been developed and adopted by the HTA Coordination Group (HTACG). The HTA CG work plan 2025 foresees 17 joint clinical assessments (JCA) for medicinal products for the treatment of cancer and 8 for ATMPs. Also 5 to 7 joint scientific consultations for medicinal products are foreseen, with gradual increases over the next years. Collaboration between DG SANTE and EMA involves the following: biweekly bilateral; monthly meetings on MAAs in the scope of the JCA; trilaterals with HTA CG subgroup chairs; EMA participation in the HTA committee and its working groups. Reference was also made to the work of the HTA Stakeholder Network and on the development of an IT platform that provides a secure working space for Member States, the EC, EMA, and developers to exchange information.

• EMA activities

EMA presented highlights of its implementation activities at the intersection of regulatory processes and HTA assessment. Collaboration with HTA CG under the HTA Regulation includes information exchange in the context of joint scientific consultation, joint clinical assessment and identification of emerging technologies.

The Board noted the Agency's first experiences with the new parallel notification by companies which intend to submit a marketing authorisation application for regulatory assessment by EMA and for joint clinical assessment by EU-HTA bodies under the new HTA Regulation. The Implementing Act on Cooperation with the EMA, adopted in October 2024, provides a robust framework for protection of confidential information exchanged between EMA and HTA secretariat/network. The Board was informed of several EMA stakeholder webinars and workshops in 2024 to prepare for the HTA Regulation implementation. Procedural guidance as well as joint templates for Joint Scientific Consultation have been agreed.

Members of the Board complemented the extensive preparation for implementation of the HTA Regulation. Questions were asked about the process for identifying emerging technologies for joint clinical assessments, the consequence of a negative opinion by CHMP on HTA work, and the right level of interaction between HTA bodies and regulatory agencies in each member State given that some countries have integrated systems and others have separate agencies. One member commented that there is a need to consider financial incentives for HTA cooperation as it is challenging, especially for small Member States to join the JCA process due to insufficient resources.

The representative of the European Commission replied that if there is a negative CHMP opinion, the joint clinical assessment will be discontinued, and JCAs will be published only if there is a positive marketing authorisation decision. The relevant subgroup of the HTA CG is examining various sources to

create a report on emerging health technologies for upcoming JCAs. It is welcomed that several Member States have used the EU Technical Support instrument to adapt their healthcare systems to fit the EU framework, including on HTA capacity building. EMA highlighted that for horizon scanning they currently provide only information about upcoming submissions for marketing authorisation but acknowledged that there is an opportunity for wider collaboration looking at different sources of information. The Agency also recognises the value of collaboration with HTA bodies in evidence planning and have found it to be extremely valuable in their experience of parallel scientific advice.

B.9 Update on the implementation of the Veterinary Medicinal Products Regulation

The Management Board noted an update from EMA on the activities for the implementation of the Veterinary Medicinal Products Regulation.

The Agency has provided scientific and technical recommendations to the European Commission for an Implementing Act on the list of substances which are essential for the treatment of equine species and is currently providing input for an Implementing Act on a list for substances used in food-producing aquatic species. The Agency has also made progress in regulatory innovation, with milestones such as the first marketing authorisation for a veterinary Vaccine Antigen Master File and first certification of a veterinary Vaccine Platform Technology Master File. On pharmacovigilance, it was agreed to establish a new expert group and a new process for veterinary signal management. The Union Pharmacovigilance Database (UPhV) and the Antimicrobial Sales and Use data collection (ASU) IT system will be further optimised and finalised in Q12025. As EMA will be disbanding agile governance for these IT systems and transitioning them to a maintenance phase, the Agency expressed gratitude to the NCA Product Owner and NCA Subject Matter Experts for their collaboration over the past years. Another important area that EMA has been involved in is One Health, through the Cross-Agency Task Force (TF) and its Framework for action. This initiative aims to strengthen the EU's ability to respond to health crises by enabling EU agencies to contribute to the implementation of the One Health approach in Europe.

Members of the Board congratulated the Agency on the approval of the first vaccine platform technology master file. In addition, one member inquired about the possibility of having a search engine for the Union Product Database that would allow searching for the Summary of Product Characteristics for all veterinary medicines authorised in the EU. The DG SANTE representative suggested linking the work of One Health Cross-Agency TF to the inter-agency WG which was mentioned in the Council Recommendation on AMR of 2023. EMA confirmed it is working on a search engine for the UPD as this could be helpful for veterinarians to look up all available medicines in the EU for a specific indication. As regards the One Health TF, EMA will consider making the link to the Council Recommendation and underlined the role of the TF in facilitating better collaboration between agencies, which could also help alleviate some of the pressure coming from cross-sectoral legislation and prepare for upcoming policy initiatives.

B.10 Update of HMA/EMA Task Force on Availability (TF-AAM), including Union list of critical medicines

The Management Board noted the second phase (‘version 2’) of the Union List of Critical Medicines (ULCM) in the EU, which will be adopted by written procedure and subsequent publishing on 16 December 2024. The first version of the Union List, adopted in December 2023, was based on medicines from six national critical medicine lists. The second version expands to 270 active substances by incorporating additional medicines reviewed by the European Medicines Regulatory Network (EMRN) according to the published criteria, sourced from crisis preparedness lists such as the

EMA MSSG's Main Therapeutic Groups and active substance groups flagged by EMA Stakeholder Groups. This updated list will guide EU actions to ensure continuity of medicine supply, including regulatory recommendations from the EMA and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). The HMA/EMA TF-AAM has engaged with stakeholders throughout the process. The list will be periodically reviewed and updated to add or remove medicines based on criticality. The Board commended the work undertaken and highlighted the importance of ensuring availability of these critical medicines. The representative of DG SANTE reminded the Board that the Critical Medicines Alliance (CMA) will use the Union List to identify supply chain vulnerabilities, prioritise actions, and propose solutions to strengthen the availability and resilience of critical medicines in the EU.

The Board also noted an updated version of 'Good Practice Guidance for Communication on Medicines' Availability Issues,' which was first published in 2019 by Task Force. The guidance offers recommendations for regulators on communicating shortages to the public. Based on feedback from Member States and EMA workshops in 2023, the updated version addresses the role of media and social media in influencing public behaviour and medicines use. The implementation of the guidance will be monitored, and the guidance will be reviewed as necessary.

The HMA co-chair of the HMA/EMA Taskforce) presented to the Board a summary of the Taskforce's key achievements from its work programmes between 2016 and 2024. The Board expressed its gratitude to the Taskforce for its pioneering work, which has laid the foundation for EU cooperation on medicines shortages. Established voluntarily by Member States and EMA in 2016, when the Agency had no formal responsibilities regarding shortages, the Taskforce will now be dissolved. Its activities will be transferred to the MSSG and the Medicines Shortages Single Point of Contact (SPOC) Working Party. A comprehensive report is being prepared to summarize the TF-AAM's activities over the past eight years and will be delivered in early 2025.

B.11 Clinical Trials in the EU

- ACT EU (EMA)

The Board received an update on the ACT EU initiative, highlighting key achievements in 2024, including the establishment of the Multi-Stakeholder Platform (MSP) and MSP Advisory Group (MSP AG) in March, the introduction of regulatory support for non-commercial sponsors to navigate Clinical Trial Regulation (CTR) requirements and CTIS usage, and the launch of pilots in June for integrated scientific and regulatory advice on clinical trials. The MSP AG Regulatory Co-Chair, Maria Lamas, presented feedback from the first annual MSP meeting on 22 October and outlined plans to incorporate key MSP priorities into the ACT EU workplan. EMA also provided an update on efforts to implement the CTR and enhance the EU clinical trials landscape, with stakeholder feedback from various initiatives being integrated into the revised ACT EU workplan for 2025-2026, which aims to better address stakeholder and network needs. The updated workplan will be adopted at a subsequent ACT EU Steering Group meeting in mid-December. A Board member inquired about the use of risk proportionality in clinical trials. EMA clarified that the revised ACT EU workplan will include a workshop on risk-based approaches and low-interventional clinical trials, scheduled for 2025.

- Report to the Management Board on operation of CTIS (EMA)

[EMA/MB/551429/2024], [EMA/MB/580677/2024]. The Management Board noted the report and was informed that the Clinical Trials Information System (CTIS) had received 10,000 clinical trial applications to date. The new CTIS public portal, launched on 18 June 2024, has published over 7,600 trials and 110,000 documents, with enhancements introduced in September 2024 to improve search

functionality and enable easier document downloads. Key milestones for CTIS in 2024 were outlined, including significant system and user experience improvements, the transition to the SAFe Agile methodology, and CTIS becoming a data provider for WHO. EMA also updated the Board on the ongoing transition to a new service provider, which is expected to be completed by early Q2 2025, with the aim of delivering a more efficient and modern CTIS. Additionally, the Board noted the CTIS high-level Roadmap for the coming years, with the first key CTIS forum scheduled for 30 January 2025. The Board acknowledged the excellent efforts to ensure system stabilisation and improvements, with overall system performance strengthening.

- Transition to Clinical Trial Regulation (European Commission)

The Board recognised the efforts underway to ensure that all ongoing clinical trials transition to CTIS by 30 January 2025, marking the conclusion of a three-year transition period that began with the implementation of the Clinical Trials Regulation (CTR). The representative of DG SANTE highlighted that, based on EMA CTIS/EudraCT data, some ongoing clinical trials approved under the Clinical Trials Directive 2001/20/EC may not have transitioned to the CTR at the end of the transition period. Consequently, Member States will be required to apply corrective measures as per Article 77(1) of Regulation (EU) 536/2014. In December, the Commission, through CTAG, is conducting a survey to gather information on the measures Member States plan to implement to ensure compliance. The representative of DG SANTE stressed the importance of mobilising sufficient resources at the national level to facilitate sponsor outreach and the continued processing of transitioning clinical trial applications. A Board member suggested that the next steps following the transition period should be included in the 2025 plans, while another member raised a question about the approach for transitioned clinical trials submitted on 29 January but not evaluated by the 30 January deadline. The representative of DG SANTE clarified that a harmonised approach, informed by the CTAG survey results and aligned with national laws, may need to be explored.

B.12 Big Data Steering Group progress report

The Management Board noted an oral report by the EMA co-chair about the progress of the Big Data Steering Group in carrying out its work programme.

EMA presented the highlights of an interim study report on the EMA/HMA pilot on using individual patient level data from clinical studies in medicines evaluation, which was published in October 2024. The report provides preliminary insights from the analysis of voluntarily submitted clinical study data across five regulatory procedures between September 2022 and December 2023, drawing on feedback from pilot participants. Key findings from the initial pilot may suggest that access to clinical study data could assist in improving understanding of product dossiers, potentially aid decision-making and thereby reduces queries. The pilot also underscores the need for increased network expertise in statistical analysis, biostatistics, and clinical trial data standards, along with recommendations for refining regulatory processes and upgrading technical infrastructure. The Board welcomed the results of the interim pilot report. Nevertheless, a few Board members expressed concerns on the possible impact on NCA resources as the initial pilot was based on a small sample size, the need for more specialised expertise and the importance of further analysis to demonstrate the benefits of clinical study data assessment. EMA acknowledged these concerns and agreed that further analysis would be needed in future phases of the pilot, but also noted that the pilot showed benefits in particular for innovative products and complex dossiers.

EMA also provided a high-level overview of the Big Data Steering Group's key achievements since its inception in 2020, emphasizing 2024 as a milestone year for data-driven regulation. Notable successes

included the growth of the DARWIN EU® network, the launch of HMA-EMA catalogues for RWD sources and studies, the introduction of Data Science curriculum training modules and advancements in AI capabilities through workshops and experimentation. The Veterinary Big Data strategy 2025-2027 was also developed, alongside 2022-2025 workplan which were significant milestones. The Board was reminded that the BDSG was now being superseded by the Network Data Steering Group (NDSG), whose mandate, was endorsed in October 2024, and that the NDSG workplan will be presented to the EMA Management Board in March 2025. The Board commended the BDSG for its outstanding work over the past five years.

B.13 Report on the data protection activities by EMA in accordance with the EU Data Protection Regulation

The Management Board noted an oral report on the data protection activities by EMA in accordance with the EU Data Protection Regulation.

The Agency provided an overview of its activities in 2024 to comply with the EU personal data protection legislation (EUDPR), highlighting efforts to protect data entrusted to EMA while ensuring access to this data, as required. The Agency has been actively engaging with its supervisory authority, notably the European Data Protection Supervisor (EDPS) and has followed-up on several EDPS audit recommendations particularly on EMA's EudraVigilance system and on EMA's corporate website. EMA undertook several data protection impact assessments (DPIAs) and developed new internal guidance on data protection in 2024, including on data retention, international transfers of personal data, and considerations for implementing and using artificial intelligence. The Agency has continued providing training to its staff and focused on developing new training materials. It has implemented robust measures to manage data breaches in full compliance with the EUDPR. Collaborating with other EU institutions on data protection topics of common interest has proven helpful, and the Agency plans to continue this in 2025. In 2025, EMA's Data Protection Office will continue focusing on addressing EDPS recommendations, advising on AI risks, implementing new European Data Protection Board (EDPB) guidelines, and providing data protection advice and training to staff.

List of written procedures during the period from 26 September to 04 December 2024:

- Consultation no. 05/2024 on the appointment of Urška Peunik as CVMP alternate as proposed by Slovenia ended on 02 October 2024. The mandate of the nominee commenced on 03 October 2024.
- Consultation no. 06/2024 on the appointment of Boje Kvorning Pires Ehmsen as CHMP alternate as proposed by Denmark ended on 11 October 2024. The mandate of the nominee commenced on 12 October 2024.
- Consultation no. 07/2024 on the appointment of Despoina Iatridou as CVMP alternate as proposed by Luxembourg ended on 25 October 2024. The mandate of the nominee commenced on 26 October 2024.
- Consultation no. 08/2024 on the appointment of Aris Angelis as CHMP member as proposed by Greece ended on 27 November 2024. The mandate of the nominee commenced on 28 November 2024.
- Consultation procedure for the adoption of Amending Budget ended on 04 December 2024. The Amending Budget was adopted.

- Consultation procedure for the adoption of the final draft of 'HMA/EMA guidance document on the identification of personal data and commercially confidential information within the structure of the marketing authorisation application (MAA)' will end on 09 December 2024.

Documents for information

- [EMA/MB/454481/2024] Outcome of written procedures finalised during the period from 26 September to 4 December 2024
- [EMA/MB/559501/2024] Summary of transfers in budget 2024
- [EMA/MB/559904/2024] Summary of implementation of assigned revenue
- [EMA/MB/544528/2024] [EMA/MB/544497/2024], Network portfolio report

List of participants at the 126th meeting of the Management Board, held in Amsterdam, 11-12 December 2024

Chair: *Lorraine Nolan*

	Participants
Belgium	Hugues Malone *(member)* Charles Denonne *(alternate)*
Bulgaria	*Apologies received from Bulgaria*
Czech Republic	Boráň Tomáš *(member)*
Croatia	Siniša Tomić *(member)*
Denmark	Nils Falk Bjerregaard (*member)* Mette Aaboe Hansen (*alternate*) Birgitte Faber (*support observer*)
Germany	Karl Broich (*member*) Wiebke Löbker (*support observer)*
Estonia	Katrin Kiisk *(member)*
Ireland	Rita Purcell *(alternate)*
Greece	Evangelos Manolopoulos *(member)* Spyridon Th. Sapounas (*alternate)*
Spain	María-Jesús Lamas Díaz *(member)*
France	Alexandre de la Volpilière *(member)* Franck Fourès (*alternate)* Miguel Bley *(support observer)* Catherine Paugam-Burtz (*support observer)*
Italy	Robert Nisticò *(member)* Armando Magrelli (*alternate)* Marta Giovanna Toma *(support observer)*
Cyprus	Helena Panayiotopoulou (*member)* Irini Chrysafi Fanidou *(alternate)*
Latvia	Indra Dreika (*member*) Sergejs Akuličs (*alternate*)
Lithuania	Dovilė Marcinkė[1] *(member)*
Luxembourg	Anna Chioti *(member)*
Hungary	Beatrix Horváth (*alternate)*
Malta	Anthony Serracino Inglott (*member)* John Joseph Borg (*alternate)* Valentina Sammut (*support observer)*
Netherlands	Paula Loekemeijer (*member)* Aimad Torqui[1] *(alternate)* Roelie Marinus *(support observer)*
Austria	Günter Waxenecker *(member)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)* Magdalena Pajewska-Lewandowska (support *observer*)
Portugal	Rui Santos Ivo (*member*) Maria João Morais *(support observer)*

[1] Restrictions applied for agenda item B.3, B.4, B.5 and B.7

	Participants
Romania	Razvan Prisada *(member)*
Slovakia	Katarína Massányiová (*alternate)*
Slovenia	Momir Radulovic *(member)*
Finland	Eija Pelkonen (*member*) Anna Siira[1] (*alternate*)
Sweden	Åsa Kumlin Howell[1] *(alternate)* Erik Malmström *(support observer)*
European Parliament	Karin Kadenbach *(member)* Giovanni La Via *(member)*
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)* Trygve Ottersen (Norway) *(member)* Audun Hågå (Norway) (*alternate*) Katrine Heier (Norway) (*support observer*)

Guest Speaker	Volker Rokos (IAS) Maya Matthews (DG SANTE)

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 Rebecca Harding Zahra Hanaizi Anne-Sophie Henry-Eude Eftychia-Eirini Psarelli Michael Lenihan Sabine Brosch Riccardo Mezzasalma

	Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin