13 September 2024
EMA/MB/312765/2024 - Adopted
Management Board

Minutes of the 124th meeting of the Management Board

Amsterdam, 12-13 June 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 Czechia, Mr Tomáš Boráň (Director General of State Institute for Drug Control of Czechia), member for Italy, Mr Robert Nistico (President of Italian Medicines Agency), Ms Rugilė Pilvinienė (Acting Head of Marketing Authorisation unit, State Medicines Control Agency of Lithuania) and alternate for Iceland, Mr Sindri Kristjansson (Senior Legal Adviser, Icelandic Medicines Agency). The Board were informed that posters would be on display for Board members to further familiarise themselves with selected EMA activities of interest such as Medical Device expert panels, Wellbeing, Transparency, EMA Development Day, Diversity and Inclusion, during the lunch break on the second day. The Management Board Vice-Chair informed the Board of their decision to step down, as they will no longer be a member of the Board due to taking up a new role. An election will be organized at the next Board meeting in October to fill this vacancy.

1. Draft agenda for 12-13 June 2024 meeting

[EMA/MB/145463/2024] The agenda was adopted with no amendments.

2. Declaration of competing interest related to the agenda

The Secretariat informed 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 agenda were identified concerning topics *B.7a 'New Fee Regulation, related documents: Working arrangements."* The Secretariat informed the board that all concerned members had been informed before the meeting.
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.

3. Minutes from the 123rd meeting, held on 21 March 2024

[EMA/MB/158744/2024] The Management Board noted the final minutes, that had been adopted by written procedure on 11 June 2024.

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A. Points for automatic adoption

A.1 Management Board meeting dates 2025-2026

[EMA/MB/248390/2024] The Management Board adopted the proposed meeting dates for 2025 and noted the meeting dates for 2026.

A.2 Management Board decision – Adoption by analogy of amendment to Commission decision on transfer of pension rights C(2024) 1038 final

[EMA/MB/153252/2024], [EMA/MB/169190/2024] The Management Board adopted an amendment to the Commission decision on transfer of pension rights, C(2024) 1038 final, which applies by analogy also to EU agencies. The amendment relates to changes in the conversion coefficient for the calculation of pension entitlements for EMA staff.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update on the Agency's latest actions in addressing shortages of medicines, including the handling of shortages of GLP-1 receptor agonists, feedback on the use of 3 Voluntary Solidarity Mechanism (VSM) procedures, and recent deliverables of the Joint HMA/EMA Task Force on Availability of authorised medicinal products (TF-AAM). The Agency's and MSSG's roles within the Critical Medicines Alliance (CMA) were also explained to the Board. The need for complementarity between the work of MSSG and CMA was recognised. A Board member noted that most of the shortage-related activities presented primarily address human medicines. EMA clarified that the TFAAM and Theme 1 of EMANS also discuss possible solutions to resolve shortages of veterinary medicines.

Regarding the EMA's preparedness for an avian flu pandemic, the Board was updated on various vaccines (two veterinary and three human) and treatments (five antivirals) that the Agency has authorised for use over the past years.

With regards to the network sustainability, the Board was informed about ongoing activities implemented by the EMA/HMA Strategic Resource Oversight Group and the EMA/NCA Operational Resource Planning Group. A multistakeholder workshop on submission predictability is scheduled for September 2024. The Board expressed appreciation for all the ongoing work to try to resolve the capacity issues within the Network and a Board member suggested exploring the establishment of 'Centres of Excellence'.

The Board was also notified of the Agency's intention to target EU Eco-Management and Audit Standard (EMAS) registration in 2024 based on a successful Internal Environmental Audit in December 2023.

The increased interplay and need for coordination between pharmaceutical, chemical, food and environmental legislation was also highlighted to the Board as well as the recently published joint framework for the One Health agenda in the EU, drafted together with ECDC, ECHA, EEA and EFSA. A cross-agency task force will implement the joint framework over the next three years (2024-2026).

The Executive Director provided information on the progress of the review and update of the European Medicines Agency Network Strategy (EMANS) to 2028, with the aim of having an updated version

ready for public consultation in Q3-2024.The Board was informed about EMA's first successful "Development Day", held on 4 June, which aimed to promote continuous development, knowledge sharing, and collaborative learning. An update was also given on the 10th anniversary of the EU Network Training Centre.

The Board noted that a written procedure for adoption of a revised Union Product Database Access Policy and Joint Controllership Arrangement would be launched over the summer period.

B.2 Report from the European Commission

The Management Board noted an oral update from the representative of DG RTD on EU-funded research projects on biotechnology and biomanufacturing activities.

Between 2021-2023 the European Commission invested €1.5 billion from the Horizon Europe programme and approved almost 600 projects on health biotech. Four projects in this area - CELL-PID on gene therapy, ATECT and T2EVOLVE on CAR T-cell therapy, ARISE on tissue engineered cardiac valves - were presented in more detail as examples of pioneering research involving successful translation of research results into medicinal products. In March 2024 the Commission also published a Communication on boosting biotechnology and biomanufacturing in the EU, which puts forward a series of actions to create the right environment for the EU biotech sector to grow further. The Communication is proposing actions in eight key areas. Actions in the areas of "research and technology transfer", "streamlining regulatory complexity", "public acceptance through increased public knowledge" and "economic security" were presented to the Board in detail.

Secondly, as an example of DG RTD intervention in times of public health emergencies, the Management Board was also informed that in response to the mpox outbreak in the Democratic Republic of Congo, on 30 April 2024 the Global Health European and Developing Countries Clinical Trials Partnership (EDCTP3) Joint Undertaking activated its emergency funding mechanism. This provides support to projects working on research and development of vaccines, therapeutics and development of surveillance strategies, rapid diagnostics and epidemiological studies. A decision by the Commission on the submitted project proposals is expected by the end of June.

Following the EC presentation, the Board discussed a number of questions on how the EU could strengthen the competitiveness of the European health biotech sector. Members suggested addressing challenges with regards to ethics committee approval and GMO assessment and pointed to the need to have an integrated approach across various regulatory requirements. One member referred to the work of the EMA Quality Innovation Group in supporting novel manufacturing techniques. EMA recalled the role of its Innovation Task Force and SME Office to support health biotech developers. Several Board members suggested continuing the discussion together with the European Commission, including via the existing relevant fora in the medicines regulatory network.

The Management Board noted an oral update from the representative of DG SANTE on the progress in Council on the examination of the pharmaceutical package, the work of DG SANTE on medical devices, future guidelines on public procurement of medicinal products, preparation for the implementation of the Regulation on Substances of Human Origin (SoHO) and the Communication on the European Health Union published on 22 May 2024.

As regards the pharmaceutical package, discussion in Council has focussed so far on shortages, incentives and provisions on authorisation and it will continue under the Hungarian EU presidency. The Regulation amending the MDR and IVDR was adopted by EP and Council and will soon enter into force; this includes provision to bring forward a targeted evaluation of these regulations. As announced in the Pharmaceutical Strategy, guidance for the public procurement of medicines to better support security of supply is currently in development. The key provisions of the SoHO Regulation with relevance to the

pharmaceutical sector were outlined to the Board. On 22 May the Commission adopted a Communication on the European Health Union, which summarises the significant developments in EU health policy over the last 4 years.

In relation to the new obligations for certain IVD medical devices manufacturers to notify discontinuation or interruption of supply, one member noted the risk of potential "diluted responsibilities" for industry as the supply chain for medical devices is very complex and many devices are imported from third countries. Some members suggested extending the public procurement guidelines also to medical devices and stressed the need to carefully assess the current market surveillance system for medical devices as part of the upcoming review study. In reply to a question on how to amend EU legislation to ensure stronger production of critical medicines in Europe, the representative of DG SANTE noted that, whilst the EU is bound by WTO obligations, there are tools for the EU to make markets more functional when there are particular needs/limitations, for example using adapted tender criteria or the derogations to EU state aid legislation under the 'Important Project of Common European Interest' initiative.

B.3 Update on 30 Churchill Place, including amending Budget 03-2024

[EMA/MB/229817/2024], [EMA/MB/245112/2024] The Management Board noted the latest developments regarding EMA's former premises.

EMA presented the latest updates and key deliverables regarding its former premises in the UK (30 Churchill Place) following the agreement between WeWork and the Agency on a proposal for potential variations to WeWork's lease for which the building dossier had been submitted and approved by the Budgetary Authority (European Parliament and Council) in April 2024. The Board acknowledged the excellent support provided by the European Commission, in particular relating to the request to increase the EU contribution to EMA for 2024 and 2025 based on the building dossier. Contract negotiations remain ongoing and preparations are continuing to conclude and sign the new lease with WeWork.

In addition, the Management Board adopted the Amending budget 03-2024, in response to the rent suspension for EMA's sub-tenant WeWork for the 30 Churchill Premises. This amendment ensures the necessary budget appropriations are in place, supported by an additional EU budget contribution, to meet rent obligations to Canary Wharf for Q3 2024, as highlighted in the building dossier. Amending Budgets 01-2024 and 02-2024 have already been approved to cover rent payments for Q1 and Q2 2024 respectively.

B.4 Assessment of the Executive Director's Annual Activity Report (AAR) 2023 and Draft annual accounts 2023 and launch of written procedure

a) Assessment of the Executive Director's Annual Activity Report (AAR) 2023.

[EMA/MB/250703/2024], [EMA/MB/250703/2024], [EMA/24036/2024] The Board noted the Executive Director's Annual Activity Report (AAR) 2023 and adopted the Board's Assessment of the Executive Director's AAR 2023 which had been prepared by the MB topic coordinators Franck Foures, Virginie Hivert, Lars Bo Nielsen and Momir Radulović.

The AAR 2023 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 consolidated annual activity report (AAR) is submitted to the Management Board for assessment and, by 1 July, the assessed AAR is 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 2023. They recognised the agency's vital contributions to the EU's policy agenda, including advancements in cancer treatment, antimicrobial resistance, and the implementation of the EU Beating Cancer Plan. They emphasized significant achievements, including successful approvals of marketing authorizations, orphan status designations, and PRIME-designated medicines. The Board recognised EMA's cooperation with international bodies like WHO and ICMRA, and the progress in IT and data analytics, including the development of DARWIN EU® and efforts to integrate with the European Health Data Space. The Board acknowledged the results presented in the AAR 2023 and commended the Agency and the European Medicines Regulatory Network (EMRN) for their achievements in implementing the EMANS and the Regulatory Science Strategy to 2025. The Board also welcomed the finalisation of the implementation of the Agency's extended mandate, including the establishment of a governance structure for the management of shortages of medical devices in the EU. The Board noted the Agency's financial and human resources performance, with a successful budget implementation and positive staff engagement based on a staff survey ran in 2023. Audits and internal controls confirm overall reliability, some improvements are identified, particularly in information security management and the effectiveness of internal control systems. The Board also acknowledged the establishment of a Management Board Audits and Risks Group (MBARG) in 2023. The Board continued to express its concern about the Agency having to divert significant resources to manage its former premises in the UK, a third country.

b) Draft annual accounts 2023 and launch of written procedure.

[EMA/MB/249660/2024], [EMA/MB/249887/2024] The Management Board noted the draft annual accounts 2023.

During the assessment by the Topic Coordinators, the Agency's accounts were also reviewed with input from the EMA's Accounting Officer. The Board was informed about the positive outcome of the audits on the provisional accounts 2023 carried out by the external auditor and the European Court of Auditors (ECA), and that the Agency expects to receive a positive opinion on the reliability of its 2023 accounts. The Board also noted the significant impact of the situation of its former premises in UK (30 Churchill place) on the draft annual accounts but recognised that this did not compromise the budget of the Agency and its work programme in 2023 due to the supporting annual European Union contribution.

As per Article 102.3 of the Agency's Financial Regulation, the Accounting Officer will finalize 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 finalized accounts, along with the Management Board's opinion, to the Commission's Accounting Officer, the Court of Auditors, the European Parliament, and the Council no later than 1 July 2024.

B.5 Annual report 2023 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection, and

scientific advice procedures for medicinal products for human and veterinary use

[EMA/MB/182122/2024], [EMA/MB/202002/2024] The Management Board endorsed the Annual report 2023 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use.

EMA recalled that the annual KPIs are defined in the Cooperation Agreement between National Competent Authorities (NCAs) and EMA. Some areas of concern were highlighted, these relate to compliance with agreed timetables for human scientific advice and evaluation of initial marketing authorisation applications for human medicines, GMP and pharmacovigilance inspections. Corrective actions are being taken in many of these areas, for example by trying to facilitate the work for assessors and CHMP members and to improve predictability of submissions, but the results of these initiatives do not appear in the 2023 report yet. On the veterinary side, the situation is generally positive and stable.

One member commented that KPIs might also have to be extended to cover the quality of the evaluation work performed by the NCAs. In response to a request from a Board member, EMA agreed to further update the MB in October on actions taken to improve submission predictability.

B.6 Update on MB Audits and Risks Group (MBARG) activities and Annual report of internal audit and advisory activities at the European Medicines Agency 2023

a) Update on MB Audits and Risks Group (MBARG) activities.

The Management Board noted an update on the MB Audits and Risks Group (MBARG).

The representative of patient organisations, as MBARG Chair, presented the key MBARG activities between December 2023 and June 2024. During this period the MBARG discussed several topics, including the selection procedure for the head of audit at the Agency, the status of the implementation of the 2024 audit plan, the annual report 2023 of internal audit and advisory activities at EMA and the introduction of the new quality management policy (item B.9 below). MBARG members had the opportunity to comment and to give some input on both the annual audit report 2023 and the quality management policy. Several bite-size discussions between EMA and MBARG members are planned later in 2024 to present additional audit-related topics in more detail. Concern was expressed by the MBARG Chair about the current limited resource situation in the audit team at EMA.

b) Annual report of internal audit and advisory activities at the European Medicines Agency 2023.

[EMA/MB/62775/2024], [EMA/MB/235277/2024] The Management Board adopted the Annual report of internal audit and advisory activities at the European Medicines Agency 2023.

The EMA Head of Audit *ad interim* presented the outcome of the 2023 audit activities report and provided an update on the status of implementation of the 2024 risk-based audit plan. In 2023 the EMA's internal audit function carried out four internal audits and three Targeted Independent Reviews. Secondly, it coordinated two engagements by IAS with regard to 'Information security at EMA' and on 'adequacy of the cooperation and coordination mechanisms aimed to prevent, detect and respond to serious cross-border threats to health' as well as an ECA audit on 'EU Agencies' response to the Covid-19 pandemic' (report expected in Q3 2024). In liaison with other organisational entities, the internal audit coordinated and contributed to Agency and Network-wide initiatives such as: BEMA V self-

assessment and assessment, WHO Listed Authorities and EU agencies' network Working Group on Process Mining. Several lunch time talks for EMA staff had been organised in 2023 on various topics, such as whistleblowing and fraud protection, process mining, risk management and governance.

As regards the status of implementation of the 2024 audit plan, an overview of the completed, ongoing and upcoming audits and targeted independent reviews was provided, with a focus on the 2022 IAS audit on 'HR and ethics' and the recently completed internal audit on 'Environmental management at EMA'. An overview of the resourcing of the internal audit function, including the initiatives planned to reinforce the team in short and medium term, was presented to the Board. In relation to the resourcing concerns, one member suggested exploring the possibility to redeploy some staff from core business to support with key audit engagements as relevant.

B.7 New Fee Regulation

EMA presented the key contents of the six documents below which were submitted for adoption or endorsement.

a) New fee Regulation Working arrangements

[EMA/MB/183645/2024] The Management Board adopted Working Arrangements pursuant to Article 8 of Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency applicable from 1 January 2025 with the revisions presented during the meeting.

After EMA's presentation, the representative of patients' organisations asked for some clarifications about the definition of entities not engaged in economic activity. Rewordings and changes were requested by some MB members on certain parts of the document, in particular on the preamble, paragraphs regarding fees for rolling review and for inspections, as well as paragraphs concerning the submission of performance and financial information, which were implemented by EMA during the meeting. The European Commission agreed to these changes on the basis that the paragraph regarding submission of performance and financial information will be updated once the Management Board approves the common format for reporting such information.

b) Cooperation Agreement

[EMA/MB/244306/2024] The Management Board adopted the revised template for the Cooperation Agreement between EMA and the National Competent Authorities of the Member States regarding the provision of services by rapporteurs and experts to the Agency.
One member requested an overview of the projected impact on NCAs of the new fees Regulation and EMA provided an estimate of the increase in remuneration for NCAs in 2025, according to the Agency's projections.

c) Memorandum of Understanding

[EMA/MB/244310/2024] The Management Board adopted the revised template for the Memorandum of Understanding between the European Medicines Agency and the National Competent Authorities of the Member States on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities for services to be provided to the Agency.

d) MB decision on the common format for reporting performance and financial information

[EMA/MB/183562/2024] The Management Board discussed a draft Decision of the Management Board on the common format to provide performance and financial information to the Agency in accordance

with Article 10 and Annex VI to Regulation (EU) 2024/568 for the monitoring of the costs and performance indicators of selected procedures.

Several members expressed concerns on the proposed common format to be used for submission of financial and performance information to report significant changes in the costs of services rendered to the Agency, noting the differences in recording costs across NCAs and the potential for additional workload to collect the requested cost data. It was also noted that as per the Regulation the provision of data on costs, as a "may provision", was intended to be triggered at the request of the NCAs. It was proposed that a Working Group with MB members be set up in order to further discuss and agree on a common methodology. EMA acknowledged that a decision on the common format is not as urgent as the working arrangement and expressed willingness to work with volunteering MB members to find a common agreement.

The Management Board agreed to create a WG with MB members to further work on the MB decision. Once the MB decision is agreed, key elements from the MB decision will be included in the Working Arrangements.

e) MB Decision on the financial arrangements on remuneration for (co-)rapporteur services

[EMA/MB/183670/2024] The Management Board adopted a MB decision on the financial arrangements on remuneration for (co-)rapporteur services provided by committee members appointed by the Commission to represent patients' organisations or healthcare professionals in COMP and PDCO. The representative of patients' organisations welcomed the new decision as recognising the important work done by civil society members in these committees.

f) Revision of budget remark for budget 2025

[EMA/MB/10351/2024] The Management Board endorsed a revision of budget remarks for the budget 2025 in accordance with Article 36 of the Agency's Financial Regulation. The revision concerns the nomenclature for pharmacovigilance fees and the EU contribution to support fee reductions for orphan medicines.

B.8 Review of remuneration scheme for training development and delivery: lessons learnt and next steps

The Management Board noted an oral report from the co-chairs of the EMA/HMA EU Network Training Centre (EU-NTC) on the first year of experience with the new system of remuneration for development and delivery of trainings for experts in the EU medicines regulatory network. Between June 2023 and June 2024, the EU-NTC received a total of 12 requests for remuneration in the following areas: Pharmacovigilance, Paediatrics, Methodology, Inspections. All of them were granted remuneration by the EU NTC Training Steering Group as they met the remuneration criteria. 19 experts from 14 NCAs benefitted from the remuneration. The pilot with the new remuneration system will continue until end 2024 and a further update will be presented to the Management Board in June 2025.

B.9 Quality Management Policy (Policy 0001)

[EMA/228979/2024] [EMA/MB/66906/2024] The Management Board endorsed a revision of the Quality Management Policy (Policy 0001) of EMA. The revision was proposed by EMA after suspension of quality management activities during the Business Continuity Planning period and it was prepared taking into account the recommendations stemming from the BEMA assessment in 2023, as well as

experience to date. The revised Policy, which had already been reviewed by the MBARG members in May 2024, has been simplified in language and structure in order to be more easily understandable and implementable for EMA staff, while retaining in full the core principles of the ISO 9001 standard and of the EMA's Internal Control Framework.

B.10 Report from the COMP

The Management Board noted an oral report from Violeta Stoyanova-Beninska, Chair of Committee for Orphan Medicinal Products (COMP).

The COMP chair provided an overview of the COMP's activities to date, including support for protocol assistance, evaluation of orphan designation applications and of maintenance of orphan designation after marketing authorisation, challenges in drug development for rare and very rare diseases, the landscape of orphan products in the ATMP area, the experience of COMP in designating orphan products, the communication activities about the COMP assessments and the collaboration of the committee with the rare diseases community at international level. The representative of patients' organisations, as former COMP observer, praised the work of the committee in fostering collaboration with the rare diseases community and paying constant consideration to the patients' needs.

Other Board members asked the COMP Chair for her views on how best to designate orphan status in products with multiple indications, how to foster developments in ultra-rare diseases and neglected infectious diseases, why different trends exist between the US and Europe in authorising orphan drugs and to elaborate on the COMP's collaboration with US FDA. The COMP Chair recalled the benefit of incentivising drug development in as many new indications as possible and explained that EMA is cooperating with US FDA via the cluster on orphan products and the cluster on rare diseases, where both general topics and product-specific issues are being discussed. Differences between EU and US can be accounted for by many factors, including the fact that the US orphan legislation is about 20 years older than the EU legislation, it allows sub-setting of diseases and it does not require demonstration of significant benefit, as well as by very different pricing and reimbursement policies in both regions. As regards support for neglected diseases, reference was made to the need to promote basic research into the understanding of such diseases and to existing EU tools, such as the Innovative Health Initiative, aiming to translate such research into medicinal products.

B.11 EMA independence policies: Principles for the revision of EMA's policies on the handling of declarations of interests of scientific committees' members and experts (Policy 0044) and Management Board members (Policy 0058)

[EMA/MB/247295/2024] The Management Board noted and discussed the principles for the revision of EMA's policies on the handling of declarations of interests of scientific committees' members and experts (Policy 0044) and Management Board members (Policy 0058)

EMA proposed principles to guide the revision of its current independence policies (Policy 0044 and 0058) to implement the findings of the Court of Justice of 14 March 2024 in Case C-291/22 P (Hopveus appellate judgment), notably regarding the extent of restrictions foreseen for experts with declared interests on the product under evaluation as well as on those that are rival to the product concerned. In addition, following the judgement of the Court of Justice of 22 June 2023 in Joined Cases C-6/21 P and C-16/21 P (Aplidin appellate judgement), the Agency is further reflecting on how certain activities within research organisations should be declared and handled and relevant changes were also proposed to that effect.

These revisions aim to strike the right balance between safeguarding impartiality and independence, and access to the best scientific expertise to support EMA's assessments, whilst ensuring compliance with the recent judgements.

Many Board members expressed concerns regarding the potential impact of the judgments on the EMA's ability to involve relevant external experts, particularly for Scientific Advisory Groups (SAGs) focusing on rare diseases and novel therapies. The Board agreed on the necessity of adopting a balanced approach that maintains a robust pool of experts while upholding stringent conflict of interest standards. EMA encouraged the Board to submit additional written comments after the meeting and invited volunteers to contribute to the revision of policies. The Agency will proceed with drafting the revised policies, and further discussions will take place at the next Board meeting in October.

B.12 Report to the Management Board on ACT EU, the operation of CTIS and the Clinical Trial Regulation

[EMA/MB/215546/2024], [EMA/MB/215547/2024] The Management Board noted the progress of the ACT EU initiative and the progress report on the operational advancements and recent enhancements made to the Clinical Trials Information System (CTIS) in accordance with the EU Clinical Trials Regulation (CTR).

EMA presented on behalf of the ACT EU Steering Group and provided a progress update on the ACT EU priority actions. A Multi-Stakeholder Platform Advisory Group (MSPAG) was established as part of the ACT EU multi-stakeholder platform with an aim to provide regulators and stakeholders with a platform to exchange views on clinical trials. The MSPAG will meet three times per year to provide strategic and operational advice on ACT EU activities, with the next meeting taking place on 4 July. The Board was also informed that consolidated advice pilots were launched on 10 June aiming to offer applicants harmonised EU advice on how to improve their applications for clinical trial and/or marketing authorisation(s). A workshop with the Clinical Trial Advisory Group (CTAG) is scheduled on 25 June to discuss issues raised by sponsors regarding the implementation of the Clinical Trials Regulation and this meeting will be followed by a dedicated discussion at the Steering Group on proposed actions. An overview of other ACT EU priority actions was presented, including the planning of a multi-stakeholder workshop on ICHE6(R3) for GCP modernization in January 2025.

The Board received updates on the latest developments regarding the CTIS, noting a steady increase in the monthly volume of clinical trial submissions. The representative from Sweden, acting as the HMA mentor for clinical trials, reminded the Board of the mandatory deadline for transitioning clinical trials approved under the Clinical Trial Directive to CTIS by 31st January 2025. It was highlighted that sponsors of trials should take into account the need for a possible three-month evaluation period by Member States in their transition planning. The Board acknowledged EMA's proactive engagement with relevant stakeholders through scheduled public events and workshops to ensure that the deadline is met, as well as the EMRN's commitment to supporting CTIS users with training sessions and the distribution of relevant materials. The representative from DG SANTE emphasised the significant challenge posed by the 31st January 2025 deadline for transitioning to the Clinical Trials Regulation (CTR), and urged Member States to ensure adequate resources are in place as both sponsors and Member States must be prepared to comply with the Regulation.

Finally, the Board was informed that revised CTIS transparency rules will take effect on 18th June 2024, coinciding with the launch of a new CTIS public portal. A significant change noted was the removal of the 'deferral mechanism', which previously allowed sponsors to delay the publication of

certain data for up to seven years to protect confidential information, thus ensuring quicker access to key clinical trial information for stakeholders.

B.13 Big Data Steering Group (BDSG) progress report, including: Update on AI activities

The BDSG co-chair presented the BDSG progress report which focused on the continued implementation of Big Data and AI work plans, including the network data governance review, clinical raw data analysis pilot and network survey.

The BDSG has made substantial progress on delivering the AI work plan, including reviewing numerous comments from the public consultation on the draft reflection paper launched in 2023. In April 2024, an AI Masterclass webinar on the use of Large Language Models was organized. The BDSG is set to endorse a guidance on the use of Large Language Models for the Network. Other key deliverables include the establishment of the AI Special Interest Area within the Methodology Working Party. An AI-enabled Scientific Explorer knowledge mining tool for EU regulators focusing on scientific advice letters was launched in March 2024. EMA presented a demo of the Scientific Explorer tool to the Board. The Board commended both the EMA and the Network for their work on Scientific Explorer and other AI tools, which have significant potential to support the Agency and assessors in the NCAs.

The Board was also informed about ongoing discussions to streamline the Network's data governance approach and on interim learnings from the Clinical Trial raw data analysis pilot which will be published in Q3-2024. An overview of survey and consultation activities was presented, including a draft reflection paper on non-interventional studies using real-world data (RWD), with public consultation open until 31 August 2024. The consultation on the Real-world Data Quality Framework was completed in May, with the final version anticipated by the end of 2024. Key public events in 2024 include a presentation on RWE methods (14 June) and an upcoming workshop on Pharmacogenomics (24 September).

B.14 Report on International activities at EMA

The topic was postponed to the next Board meeting.

List of written procedures during the period from 12 March 2024 to 03 June 2024:

- Consultation no. 03/2024 on the appointment of Antonio Gómez-Outes as CHMP alternate as proposed by Spain ended on 05 April 2024. The mandate of the nominee commenced on 06 April 2024.
- Consultation procedure for the endorsement of the draft HMA/EMA guidance document on the identification of personal data and commercially confidential information within the structure of the MAA ended on 22 March. The procedure was endorsed.
- Consultation procedure for the adoption of the minutes of the 122nd Management Board meeting, held on 13-14 December 2023 ended on 08 April 202 . The minutes were adopted.
- Consultation procedure for the adoption of the minutes of the 123rd Management Board meeting, held on 21 March 2024 will end on 11 June 2024.

- Consultation procedure for the endorsement of the draft shortage prevention (SPP) and mitigation (SMP) plans will end on 13 June 2014.

Documents for information

- [EMA/MB/131031/2024] Outcome of written procedures finalised during the period from 12 March to 3 June 2024.
- [EMA/MB/255124/2024], [EMA/231561/2024] Network Portfolio Report
- [EMA/251256/2024] Summary report of implementation of assigned revenue June24
- [EMA/MB/49527/2024], [EMA/49471/2024] EMA working document on buildings
- [EMA/251253/2024] Summary report transfers of appropriations June24
- [EMA/MB/167876/2024] Management Board liaison on PRAC composition – Liaison after 12 years of PRAC in 2024

List of participants at the 124th meeting of the Management Board, held in Amsterdam, 12-13 June 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)* Danica Kramarić *(alternate)*
Denmark	Lars Bo Nielsen (*member*) Mette Aaboe Hansen (*alternate*) Tina S. Engraff (*observer*)
Germany	Lars-Christoph Nickel *(alternate)* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk *(member)*
Ireland	Rita Purcell *(alternate)*
Greece	Evangelos Manolopoulos *(member)* Spyridon Th. Sapounas (*alternate)*
Spain	María-Jesús Lamas Díaz *(member)* Celia Caballero *(observer)*
France	Christelle Ratignier Carbonneil *(member)* Franck Foures (*alternate)* Alexandre de la Volpilière (*observer)* Miguel Bley *(observer)*
Italy	Robert Nisticò *(member)* Marta Giovanna Toma *(observer)*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Sergejs Akuličs *(alternate)*
Lithuania	Rugile Pilviniene *(alternate)*
Luxembourg	Anna Chioti *(member)*
Hungary	Beatrix Horváth (*alternate)*
Malta	John Joseph Borg (*alternate)*
Netherlands	Aimad Torqui[1] *(alternate)* Roelie Marinus *(oberver)*
Austria	Jan Neuhauser (*alternate)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)* Magdalena Pajewska-Lewandowska (*observer*)
Portugal	Rui Santos Ivo (*member*) Maria João Morais (*observer*)
Romania	Razvan Prisada *(member)*
Slovakia	Roman Dorcik[1] *(member)* Katarína Massányiová *(alternate)*
Slovenia	Momir Radulovic *(member)*
Finland	Eija Pelkonen (*member*)

[1] Restrictions applied for agenda item B.7

	Participants
	Anna Siira (*alternate*)
Sweden	Björn Eriksson *(member)* Åsa Kumlin Howell[1] *(alternate)*
European Parliament	Karin Kadenbach Giovanni La Via
European Commission	Rainer Becker (DG SANTE) (*alternate*) Kristina Kurgonaite (DG SANTE) (*observer*) Irene Norstedt (DG RTD) (*alternate*) Tomasz Dylag (DG RTD) (*observer*)
Representatives of patients' organisations	Marco Greco Virginie Hivert
Representative of doctors' organisations	Denis Lacombe
Representative of veterinarians' organisations	*Vacant position, pending new nomination from the Council*
EEA-EFTA states	Rúna Hauksdóttir Hvannberg (Iceland) Sindri Kristjansson (Iceland) Vlasta Zavadova (Liechtenstein) Audun Hågå (Norway)

Guest speaker	Violeta Storanova (COMP Chair)

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Zaíde Frias Hilmar Hamman Emmanuel Cormier Alexis Nolte Nerimantas Steikunas Melanie Carr Steffen Thristrup Hilde Boone Franck Diafouka Martin Harvey-Allchurch Claudia Galeazzo Zahra Hanaizi Spyridon Drosos Paola Samassa Jean-Michel Mastio Michael Lenihan Piero Borlotti Esther Martínez Jean-Michel Mastio Michael Lenihan Jane Moseley Rebecca Harding

	Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin