11 June 2024
EMA/MB/158744/2024
Management Board - Adopted

Minutes of the 123rd meeting of the Management Board

Held virtually on 21 March 2024

The Chair of the Management Board opened the meeting, which was held as a virtual meeting. The Chair welcomed the new member for Czechia, Mr Jakub Velik (Acting Director of State Institute for Drug Control of Czechia), member and alternate for Greece, Mr Evangelos Manolopoulos (President of National Organization For Medicines) and Mr Spyridon Sapounas (Vice-President of National Organization For Medicines) and member for Slovakia, Mr Roman Dorčik (Acting Executive Director of State Institute For Drug Control of Slovakia).

The Chair informed the Board that the Management Board (MB) Topic Coordinators for the Annual Activity Report (AAR) of the previous year, Virginie Hivert, Lars Bo Nielsen and Momir Radulović had agreed to continue their engagement also for the 2023 AAR. In addition, the Chair also informed the Board that a call for expression to be Topic Coordinator for the 2023 AAR was still open for other Board members. *Post-meeting note*: Franck Foures expressed interest to join the Topic Coordinators for the 2023 AAR after the MB meeting.

1. Draft agenda for the 21 March 2024 meeting

[EMA/MB/52682/2024] The agenda was adopted with no amendments.

2. Declaration of competing interest related to the current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning topics *B.6 'Revised implementing rules to the Fee Regulation as of 1 April 2024'*. 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 122nd meeting, held on 13-14 December 2023 to be adopted via written procedure

[EMA/MB/87010/2024] The Management Board noted that the final minutes will be circulated for adoption by written procedure. *Post-meeting note:* The minutes were adopted via written procedure on 8 April 2024.

A. Points for automatic adoption/endorsement

A.1 Derogation from new Commission rules on prevention of harassment

[EMA/MB/72036/2024, EMA/MB/80000/2024, Ares(2023)8842369-22/12/2023]
The Management Board adopted the derogation from the new Commission rules on prevention of harassment, with some minor wording modifications as proposed by the European Commission representative ahead of the meeting.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update from EMA's Executive Director, who started her presentation by highlighting two key topics for discussion at the Board meeting regarding the EMA's former London premises and the outcome of recent Hopveus judgement case that will have implications on EMA's independence policies (Policy 0044 and 0058).

The Board was provided with an update on EMA's latest activities on medicine shortages in the EU, including the MSSG discussions on shortages of antibiotics and GLP-1 receptor agonists, preparations for the European Shortages Monitoring Platform (ESMP) and the second phase of the union list of critical medicines.

Regarding EMA's international activities, the Agency continues to play a supportive role in the establishment of the African Medicines Agency (AMA) by aiding two pilot initiatives for joint assessments and joint GMP inspections. The Board was also informed of the upcoming in-person meeting in Washington D.C between the United States Food and Drug Administration (US FDA), the European Commission, EMA and EFSA. A Board member asked about EMA's status within FDA's Project Orbis. EMA clarified that confidentiality arrangements have been signed with all members of Orbis, formalising EMA's status as an observer in Orbis. The Board was also informed that EMA submitted the final documents to the World Health Organization (WHO) as part of the WHO Listed Authority process. The Executive Director also highlighted the measures identified by the HMA/EMA Strategic Resource Oversight Group to address the resource constraints within the Network. The Board also received an overview of important events organised by the Agency in the areas of rare diseases, cancer, psychedelic medicines and veterinary medicines.

Finally, EMA provided the Board with an update on forthcoming milestones for clinical trials regarding the activities of ACT EU and CTIS. The three-year transition period initiated upon the implementation of the Clinical Trials Regulation (CTR) will conclude on January 30, 2025. The EU regulators continue to urge sponsors to submit ongoing trial applications into CTIS, considering the time required for Member States to complete the authorisation process which can take up to three months. The Commission highlighted CTIS has to ensure that Member States and sponsors can comply with the obligations they have under the CTR

B.2 Report from the European Commission

The Board noted an oral report from the representative of DG SANTE on a number of Commission initiatives of relevance to medicine regulators. The Board was informed about the status of the legislative process on the new EU pharmaceutical legislation and about the Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' published on 20 March.

An update was provided on the "one substance, one assessment" legislative package published on 7 December 2023 under the Chemicals Strategy for Sustainability, the MB was informed in particular about the legal proposal on a common data platform on chemicals, which aims to make data on chemicals more readily searchable, interoperable and reusable. This will require EMA to contribute certain environmental and non-clinical data held on relevant substances. DG SANTE will remain in close contact with EMA on this file.

Provisional agreement was reached between the co-legislators on 14 March 2024 on the new European Health Data Space Regulation. EMA will be both a data user and data holder for the purpose of secondary use of electronic health data and will be required to provide health data that it holds under a secure processing environment. The MB was also briefed on recent developments in the area of medical devices related to the legal proposal for targeted amendments to Regulations (EU) 2017/745 and (EU) 2017/746 (i.e. gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices) which had been agreed by Council and is expected to be adopted by the European Parliament in April.

As regards the one substance one assessment legislation, several Board members sought clarifications on the scope and (lack of) impact assessment of the legal proposal on the common data platform and asked if the Commission could provide an integrated overview of all cross-sectoral EU legislation with medicines in scope. Members highlighted the specific nature and greater complexity of the Benefit/Risk assessment under the pharmaceutical legislation compared to hazard/risk assessments in food and feed. It is critical to ensure that assessments of chemicals used in food or under REACH do not unduly impact availability of medicines or medical devices. The representative of DG SANTE clarified that the common data platform regulation, as per the EC legal proposal, applies only to data held by EMA. DG SANTE will further reflect on how to best keep the Management Board informed of EC initiatives of horizontal nature with impact on medicines. As regards medical devices, some Board members suggested to look into the root causes of why industry is not able to comply with the new regulations. The representative of DG SANTE clarified that the Commission has committed to prioritising the planned evaluation of this legislation, which is not due by law until 2027, and to have the first findings by end 2025.

The Board also noted an oral report from the representative of DG RTD on the Innovative Health Initiative (IHI) Regulatory Science Summit organised on 27-28 February in Brussels to discuss the current issues that regulators see and identify how future IHI research projects could address these concerns. The Summit focused on five main themes: rare diseases, paediatric healthcare, real-world data, artificial intelligence (AI) and regulatory sandboxes. The Summit focused on further measures that could be undertaken to optimise approaches and tools for the development of medicines, devices and diagnostics in each of these five areas, e.g. on paediatric and neonatal research and research for rare diseases. Overall, the event was very successful in fostering open discussions between industry and regulators in a trusted environment and will inform the development of calls for future IHI projects. The Board was also made aware of the published "Guide for applicants and project consortia on Regulatory considerations for IMI/IHI projects", which aims to inform applicants on regulatory aspects to be considered when preparing project proposals and while implementing these. The guide also provides an overview of existing opportunities for regulatory support services at EMA and US FDA.

Board members recommended emphasising the need to seek the involvement of regulatory agencies in R&D projects using AI, so that MSs can remain abreast of the latest technological developments. The representative of DG RTD recognised the challenges of bias in the use of AI in medical research and the need for early involvement of e-regulators. It was highlighted that all calls under IHI and the Horizon Europe programme require applicants to seek regulatory involvement. Following a question from a MB member, DG RTD committed to bring the topic of involvement of medical societies in projects on biomarkers for discussion in the upcoming European Partnership on Rare Diseases, which is set to start in September 2024, and at the International Rare Diseases Research Consortium (IRDiRC).

B.3 Update on 30 Churchill Place

[EMA/MB/101181/2024, EMA/MB/101159/2024, EMA/341018/2023] The Management Board noted the recent developments regarding EMA's former premises.

EMA provided an update on the latest developments as regards its former premises in the UK (30 Churchill Place). This included a briefing on the re-negotiation of the sublet contract with WeWork UK to find a mutually acceptable solution mitigating as much as possible the impact on the EU budget. [redacted] Following intense and lengthy negotiations between EMA and WeWork UK, WeWork would continue to lease the full London premises at a reduced rent and also cover all operational costs of managing the premises and taxes. EMA presented a summary of the agreement and informed the Board that negotiations are expected to be finalised very shortly [redacted]. The Board received a comprehensive explanation of the budgetary implications of the proposed new lease agreement with [redacted].

The Board was informed that multiple institutional interactions had occurred since the December MB meeting on the topic of 30 Churchill Place, including a meeting of the MB chair with the Head of Cabinet of Commissioner Hahn, David Mueller, which was also attended by the MB Topic Coordinator Giovanni La Via, EMA's Executive Director and EMA's Head of Administration and representatives from Directorate-General (DG) BUDGET. [redacted] EMA's Executive Director also had other meetings with various high-level representatives from the EU institutions related to its former UK premises [redacted]. EMA also had been invited to formal hearings in January 2024 with the European Parliament (EP) and Council Budget Committee to update the Budgetary Authority on the developments following EMA's submission of pre-information note regarding 30 Churchill Place in early December 2023.

In line with the Agency's Financial Regulation, EMA must request the EP's and Council's approval by means of a 'building dossier' submission before concluding real-estate projects that have an annual budgetary impact. The Agency presented the pre-final version of EMA's building dossier for 30 Churchill

Place regarding the proposed new lease conditions negotiated with WeWork, to the Management Board for endorsement pending conclusion of a few outstanding points with WeWork.

The MB Topic Coordinators acknowledged the Agency's continued efforts over the past months in finding the best possible solution. Recognising the need for the current arrangement with WeWork, the Topic Coordinators emphasized that this does not diminish the imperative for a long-term resolution to be found, so that EMA can fully focus on its regulatory role and public health mandate rather than having to deal with commercial real-estate matters in a third country. The Topic Coordinators stressed again that EMA's budget should not be affected by the 30 CP situation as a consequence of Brexit [redacted]. Several members of the Board echoed the Topic Coordinators' comments and asked the Commission for reassurance that any shortfall in EMA's budget would be covered by the EU budget. The representative of DG SANTE reassured that funding would be provided by the Commission in addition to EMA's regular budget and will be earmarked specifically to address the budgetary challenges posed by the London premises. [redacted]

[redacted]

Following the detailed presentation and discussion, the Management Board endorsed in principle the presented pre-final draft building dossier and the direction of travel. The Board agreed to delegate the final adoption of the finalised building dossier to the Topic Coordinators on 30CP before its submission to the EP and Council. *Post-meeting note*: The 30CP Topic Coordinators met on 26 March 2024 to discuss the final building dossier document for submission to the Budgetary Authority on 27 March 2024. The Topic Coordinators adopted the documents which had a few minor non-consequential changes compared to the Building Dossier that had been presented to the Board at its March meeting.

The Management Board also adopted the Amending budget 02-2024, which is required due to the rent suspension for EMA's sub-undertenant WeWork for its 30 Churchill Premises, to allow EMA to create the necessary budget appropriations supported by an additional EU budget contribution, to pay rent to Canary Wharf. Further adjustment of the EU contribution 2024 may be required through another Amending Budget to reflect the definitive amount, pending confirmation by the Budgetary Authority based on the ongoing procedure for the 3OCP building dossier.

The Chair concluded the discussion by expressing gratitude to all EMA staff involved in this extremely complex and difficult situation and raised concerns on the high number of resources that the Agency needs to dedicate to its former premises in the UK. Therefore, the Chair again highlighted the Management Board's request for a long term political or commercial resolution to enable EMA's resources to be fully dedicated to the Agency's mission of safeguarding public and animal health in the EU.

B.4 EMA Annual Report 2023

[EMA/56717/2024, EMA/MB/90273/2024] The Board adopted the EMA Annual Report 2023.

The EMA explained that this Annual Report has a different format than previous years, i.e. with additional audio-visual material and a simplified and shortened technical section. The more comprehensive Annual Activity Report (AAR), contains the full set of figures and is to be published in June. An advance copy of the AAR 2023 was also included for information under agenda item C9 of this MB meeting to support the review of the Annual Report.

The Annual Report presents the Agency's major achievements in 2023 as regards core regulatory activities and focussing on the following three strategic priority areas for EMA, i.e.: cancer medicines, data-driven medicine regulation, and transparency and communication. EMA presented a number of highlights and key figures from Chapter 2, which focuses on marketing authorisations and safety monitoring, inspections and compliance, medical devices, the work of the network, the overview of activities in communication and stakeholders and some highlights in the area for EMA's administration. Other major EMA achievements, initiatives and events are included in an extended timeline in the report. EMA and the Board praised the collective efforts, commitments and dedication of the staff and experts of the entire network of European medicines agencies for their collective work in protecting and promoting public and animal health in the Union in 2023. Board members welcomed the report and one EEA member asked if the graphics and maps could also include all EEA countries which are part of the Network. EMA committed to integrate this comment in the final published version. In line with the approach taken since 2020, a digital version of the 2023 Annual Report will also be published after all the necessary layout and editorial work has been finalised.

B.5 Model rules on Working time and hybrid working

[EMA/MB/426360/2023, EMA/MB/69035/2024] The Management Board adopted the Model rules on Working time and hybrid working.

EMA presented the key changes in the new model rules compared to the current EMA working time and teleworking rules, including mandatory weekly presence, disconnection periods, and amendments to core hours. The Board was reminded that EMA had requested a derogation from the Commission rules as regards the maximum days for teleworking from abroad, which had not been accepted.

The Board was also informed on measures undertaken by the Agency to adequately inform staff and managers before the new rules' implementation on 1 April 2024. One Board member expressed concern regarding the potential impact of these new rules on the current EMA workforce, in view of lack of flexibility as regards teleworking from abroad. EMA explained that current projections indicated that the impact on staff numbers was likely to be minor.

B.6 Revised implementing rules to the 'current' Fee Regulation as of 1 April 2024

[EMA/MB/182939/2023, EMA/MB/118262/2023] The Board adopted the revised Implementing Rules to the Council Regulation EC No 297/95 on fees payable to the European Medicines Agency and other measures applicable as of 1 April 2024, mainly to adjust the levels of all administrative fees and renumeration to the NCAs to an inflation rate of 3.4% for 2023.

B.7 New Fee Regulation (EU) 2024/568

The Board noted a status update from the EMA and the Commission on preparation for the implementation of the new EMA Fees Regulation.

The representative of DG SANTE updated the Board on the publication of Regulation EU 2024/568 in the Official Journal of the EU in February 2024 and noted that it will become applicable as of 1 January

2025. The European Commission stands ready to review, once available, the 'Working Arrangements' for which a favourable opinion from the Commission is required and will remain in close contact with the Agency during the implementation phase.

EMA explained that the preparatory work includes the redrafting and updating of various documents including the Cooperation Agreement with National Competent Authorities (NCAs) and the new Working Arrangements that will replace the Implementing Rules under the current Fee Regulation. The document on Working Arrangements will further clarify the terminology and requirements of the new regulation for various procedures (including Scientific Advice, Rolling review, Annual fee, Certificates and Parallel distribution), in addition to outlining conditions for fee incentives and provide a description of payment modalities and EMA's remuneration to NCAs. The draft Working Arrangements are expected to be submitted for opinion to the Commission in March and then finalised in April-May based on EC feedback. At the June meeting, the Board will be asked to approve a "package" consisting of Working Arrangements, template for the Cooperation Agreements and new MB Decision on renumeration for non-NCA rapporteurs.

A Board member asked if NCAs could receive the documents well in advance of the June meeting, in order to have more time to review. Another member commented that the process for the cost-based revision of the regulation started in 2016 and that, in the future, the network requires faster modalities to adapt fees and remuneration. The representative of patients' organisations asked EMA to clarify whether payments to non-NCA rapporteurs would go to the individuals or the organisations they represent. EMA replied both options are possible and this choice will need to be indicated by the experts in their service agreement with EMA.

B.8 2023 EMA Annual Report on Independence

[EMA/MB/114673/2023, EMA/MB/62731/2024] The Management Board endorsed the 2023 EMA Annual Report on the Independence.

This report reflects the status of each of the independence policies (for scientific committees' members and experts, for Management Board members, and for EMA staff) including their implementation as of the end of 2023. Following the transfer of the expert panels in the field of medical devices (EXPAMED) to the EMA in 2022, the report now also reflects on the status and application of the European Commission's policy concerning this activity. The report provides facts and figures, including on controls carried out in 2023, and identifies recommendations for further improvements in 2024, including planned initiatives to align policy revisions with recent court rulings. The representative of DG SANTE thanked EMA for the excellent report and its work on handling competing interests.

B.9 EMA independence policies

[EMA/MB/82986/2024] The Management Board noted the most recent developments regarding the forthcoming revision of EMA's independence policies.

Based on the Aplidin appellate judgement of 22 June 2023 and subsequent guidance from the Court of Justice, EMA presented to the Board the proposed principles to steer the revision of EMA's independence policies regarding the management of declarations of interest concerning activities in research organisations. Since the judgment, the Agency has had extensive reflections on how experts' activities in research organisations should be declared in the Declaration of Interest form and, as appropriate, the principles to manage declared interests, to uphold the impartiality of EMA's evaluations whilst ensuring continued access to the best available expertise. The same principles would be applied, as appropriate, to the policy for Management Board members and the rules for the handling of declared interests of EMA staff.

EMA also notified the Board that the recent Hopveus appellate judgment will also impact the management of competing interests of committee members and experts, necessitating further amendments to Policy 0044. Consequently, a comprehensive proposal for revision of the policies, taking into account both the Aplidin and Hopveus judgments, will be brought to the Management Board meeting in June. In the meantime, EMA is implementing interim measures to adhere to the court rulings and ensure the legality of CHMP assessments and subsequent European Commission decisions.

The Board expressed concerns about the potential impact of the Hopveus appellate judgment on EMA's ability to involve relevant external experts, especially for Scientific Advisory Groups (SAGs). Regarding the Aplidin case, a Board member raised concerns about the participation of experts in academic trials or investigations submitted for regulatory review by EMA (e.g., SA, PRIME), noting the potential exclusion of valuable clinicians. EMA clarified that while restrictions on certain products may apply, such experts can still contribute to EMA activities in various other roles-. The goal in the revision is to ensure a balanced approach to handling competing interests while maintaining access to valuable expertise.

B.10 Update on the preparations for implementation of the Health Technology Assessment Regulation

The Board noted an update from the European Commission and EMA on the preparations for implementation of the Regulation (EU) 2021/2282 on Health Technology Assessment (HTA).

Maya Matthews, Head of Unit SANTE C2 on "state of health in the EU, European semester and health technology development " at the European Commission, presented on the implementation of HTA Regulation . She was joined by Ruta Janeckaite and Anna Strömgren from DG SANTE Unit C2. The HTA Regulation, h entered into force in January 2022, will become applicable in a stepwise manner: as of 12 January 2025 for centrally authorised cancer medicinal products with new active substances and for ATMPs; as of 13 January 2028 for orphan medicinal products; and as of 13 January 2030 for all other centrally authorised medicinal products with a full dossier. It will also apply to certain medical devices and in vitro diagnostic medical devices for which the relevant expert panels at EMA have provided an opinion. DG SANTE is preparing six Implementing Acts which need to be adopted by January 2025. These will cover cooperation and exchange of information with the EMA, conflict of interest, Joint Clinical Assessment (JCA) and Joint Scientific Consultation (JSC) on medicinal products and medical devices. The Agency will be engaging with the HTA Coordination Group (HTACG) and its subgroups, facilitated by the HTA secretariat which is provided by the EC.

EMA presented to the Board how it is contributing to the preparatory activities for the implementation of the HTA Regulation by working closely with the European Commission, the HTACG and its subgroups, as well as its many stakeholders. Preparatory work at EMA is based on a strong foundation of many years of collaborative project work with HTA bodies. Immediate priorities for EMA for the implementation are: preparation of the pre-submission interface for products in scope of JCA; discussion on timing and content for exchange of information with the HTACG secretariat during the CHMP assessment; contribution to the Implementing Acts on information exchange with EMA and on managing competing interests, respectively. An EU Network Training Centre session on "Introduction to the new HTA Regulation and future collaboration at the regulatory/HTA interface" was planned for 2 May 2024. Bilateral exchanges between DG SANTE C2 and EMA are regularly organised to progress implementation of the HTA Regulation regarding the regulatory/HTA interface. It was noted that activities under the HTA Regulation are also part of theme 1 of the European Medicines Regulatory Network Strategy to 2025

Some Board members noted that since some NCAs also perform HTA activities the management of MSs resources will need to be discussed in detail and be well coordinated. EMA confirmed its intention

to maximise the efficiency of the interface with the HTACG and that it will be having detailed discussions with the Commission regarding the involvement of some network experts who could have a dual role, e.g. biostatisticians. EC also recognised the resource challenge and stressed the commitment of DG SANTE to do its utmost to support MSs.

B.11 EMA biennial report on stakeholder engagement activities 2022-2023

[EMA/MB/97667/2024, EMA/53289/2024] The Management Board noted the EMA biennial report on stakeholder engagement activities 2022-2023.

The Board was briefed on the EMA's assessment of its engagement with stakeholders during the years 2022 and 2023. This report consolidates all interactions with key stakeholder groups, including patient and consumer organisations, healthcare professional organisations, academia, and EU industry trade associations, into a single document for the first time. It covers various aspects of engagement, including discussions on multi-stakeholder initiatives like the EU clinical trial initiative ACT-EU, as well as tailored engagement efforts with each stakeholder category. The Board acknowledged the significance of stakeholder contributions in EMA's activities, underlining the vital role of collaboration, transparency, and stakeholder engagement for trust-building and effective decision-making. The report is scheduled for publication in the second quarter of 2024.

B.12 Final Strategic Internal Audit Plans by Internal Audit Service (IAS)

[Ares(202)397942 – 18/01/2024] The Board noted an update from the Internal Audit Service of the European Commission on the IAS Strategic Internal Audit Plan (SIAP) regarding the EMA in 2024-2026.

Jeffrey Mason, Director of 'Audit in Commission, Executive Agencies, EU Agencies and other autonomous bodies II' at IAS presented the audit plan for EMA. The work plan builds on a thorough assessment of the risks for EMA conducted between autumn 2023 and January 2024 and based on a review of EMA's documentation as well as several interviews with EMA's senior management. The Plan identifies three potential audit topics, which means IAS plans to undertake one audit per year, subject to a re-assessment on a yearly basis. The first audit topic will be the management of the lease of EMA's former office premises in London. Under this topic IAS plans to assess the initiatives taken by EMA to address the potential financial liabilities in the framework of the Financial Regulation and how EMA manages its resources for the lease management activity, bearing in mind property management is not within the core business of the Agency. Work is planned to start before the summer break and to finish by the end of 2024. The second audit topic will be on Clinical Trials Information Systems (CTIS). The audit is likely to cover the adequacy of the CTIS platform to support the implementation of the Regulation including relevant guidance and the operation of the CTIS system. The third topic will be 'Quality and risk management in EMA' and aims to assess the effectiveness and efficiency of the quality and risk management system of EMA to ensure that the Agency achieves its business objectives. Timing of topics 2 and 3 will be either 2025 or 2026, to be decided at a later stage. A reserve audit topic, to be considered based on available resources relative to the three priorities, is "maintenance and obsolescence management of legacy IT systems in EMA".

Board members expressed their reassurance with the choice of the priority topics for future IAS audits.

List of written procedures during the period from 07 December 2023 to 11 March 2024:

- Consultation no. 13/2023 on the appointment of Els Dewaele as CVMP member as proposed by Belgium ended on 03 January 2024. The mandate of the nominee commenced on 04 January 2024.
- Consultation no. 01/2024 on the appointment of Kristina Lehmann as CVMP alternate as proposed by Finland ended on 31 January 2024. The mandate of the nominee commenced on 01 February 2024.
- Consultation no. 02/2024 on the appointment of Alia Michaelidou-Patsia as CVMP alternate as proposed by Cyprus ended on 07 March 2024. The mandate of the nominee commenced on 08 March 2024.
- Consultation procedure for the adoption of revised Rules of Procedure of Committee for Medicinal Products for Human Use (CHMP) ended on 9 February). The procedure was adopted.
- Consultation procedure for the adoption of Amending Budget 01-2023 ended on 21 December 2023. The procedure was adopted.
- Consultation procedure for the adoption of Amending Budget 01-2024 ended on 5 January 2024. The procedure was adopted.
- Consultation procedure for the adoption of non-automatic carry forward of appropriations from 2023 to 2024 ended on 26 January 2024. The procedure was adopted.

Documents for information

C1. [EMA/MB/52716/2024, EMA/MB/52718/2024] Report to the Management Board on ACT EU, the operation of CTIS and the Clinical Trial Regulation

C2. [EMA/MB/97669/2023] Big Data Steering Group progress report

C3. [EMA/MB/585245/2023] Outcome of written procedures during the period from 07 December 2023 to 11 March 2024.

C4. Feedback from the Heads of Medicines Agencies

C5. [EMA/MB/74127/2024, EMA/554124/2023] 2023 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2023

C6. [EMA/MB/53025/2024, EMA/53026/2024] Seventeenth six-monthly report on ex ante and retroactive evaluation of projects for the period 1 July to 31 December 2023

C7. [EMA/109778/2024] Network Portfolio Report

C8. [EMA/MB/101595/2024] Summary of transfers of appropriations in budget

C9. [EMA/MB/109470/2024, EMA/24036/2024] Draft Annual Activity Report (AAR) 2023

C.10 ECA Annual report on EU agencies for the financial year 2022

List of participants at the 123rd meeting of the Management Board, held in Amsterdam on 21st March 2024

Chair: Lorraine Nolan

	Participants
Belgium	Hugues Malone *(member)* Charles Denonne *(alternate)*
Bulgaria	Bogdan Kirilov *(member)*
Czech Republic	Jakub Velik *(member)*
Croatia	Siniša Tomić *(member)*
Denmark	Lars Bo Nielsen *(member)* Mette Aaboe Hansen *(alternate)* Stine Gregers Hørsøe *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk *(member)*
Ireland	Rita Purcell *(alternate)*
Greece	Evangelos Manolopoulos *(member)* Spyridon Sapounas *(alternate)*
Spain	María Jesús Lamas Díaz *(member)* Consuelo Rubio Montejano *(alternate)*[1] Celia Caballero Estévez *(observer)*
France	Christelle Ratignier Carbonneil *(member)* Franck Foures *(alternate)* Miguel Bley *(observer)*
Italy	*Apologies from Italy*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Sergejs Akuličs *(alternate)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)* Marcin Wisniewski *(alternate)*
Hungary	Rita Pálffyné-Poor *(member)* Beatrix Horvath *(alternate)*
Malta	Anthony Serracino Inglott *(member)*
Netherlands	Paula Loekemeijer *(member)* Aimad Torqui *(alternate)*[1] Roelie Marinus *(observer)*
Austria	Günter Waxenecker *(member)*
Poland	Grzegorz Cessak *(member)*
Portugal	Rui Santos Ivo *(member)* Carolina Albuquerque *(observer)*
Romania	Răzvan Prisada *(member)* Monica Negovan *(alternate)*[1]
Slovakia	Roman Dorčík *(member)*[1] Katarína Massányiová *(alternate)*
Slovenia	Momir Radulović *(member)*
Finland	Eija Pelkonen *(member)* Anna Siira *(alternate)*

	Participants
Sweden	Björn Eriksson *(member)* Åsa Kumlin Howell *(alternate)*[1]
European Parliament	Karin Kadenbach *(member)* Giovanni La via *(member)*
European Commission	Irene Norstedt (DG RTD) *(alternate)* Tomasz Dylag (DG RTD) *(observer)* Rainer Becker (DG SANTE) *(alternate)* Kristina Kurgonaite (DG SANTE) *(observer)* *Jeffrey Mason (IAS) *(guest speaker)* *Volker Rokos (IAS) *(observer)* *Michail Konstantopoulos (IAS) *(observer)* *Maya Matthews (DG SANTE) *(guest speaker)* *Ruta Janeckaite (DG SANTE) *(observer)* *Anna Stroemgreen (DG SANTE) *(observer)*
Representatives of patients' organisations	Marco Greco *(member)* Virginie Hivert *(member)*
Representative of doctors' organisations	Denis Lacombe (*member*)
Representative of veterinarians' organisations	*Apologies received*
EEA-EFTA states	Rúna Hauksdóttir Hvannberg (Iceland) Vlasta Zavadova (Liechtenstein) Audun Hågå (Norway)

[1]Competing interest declared resulting in no participation in decision with respect to agenda points B.6.

*Attended the meeting for one agenda item.

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Hilmar Hamann Zaide Frias Emmanuel Cormier Michael Berntgen Nerimantas Steikunas Melanie Carr Hilde Boone Stefano Marino Franck Diafouka Claudia Galeazzo Zahra Hanaizi Spyridon Drosos Marie-Agnes Heine Martin Harvey-Allchurch Rebecca Harding Salvador Ruíz Carrillo Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin