08 April 2024
EMA/MB/87010/2024 - Adopted
Management Board

Minutes of the 122nd meeting of the Management Board

Amsterdam, 13-14 December 2023

The Chair of the Management Board opened the meeting, which was held as a face-to-face meeting. The Chair welcomed the new European Parliament representative Mr Giovanni La Via. The Board were informed that a demo and poster session on EMA's International activities and in the area of Artificial Intelligence would be organised during the lunch break on the second day.

1. Draft agenda for the 13-14 December 2023 meeting

[EMA/MB/490304/2023] 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. Potential competing interest relating to the agenda were identified concerning topic B.4 on 'Audit strategy/plan 2024-2026 & update of annual audit plan 2023' and B.8 on 'Programming 2024-2027'. The Secretariat informed the Board that all concerned members had been informed about the relevant restrictions before the meeting. Members were also asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

3. Minutes from the 121st meeting, held on 5 October 2023 adopted via written procedure

[EMA/MB/490331/2023] The Management Board noted the final minutes, adopted by written procedure ending on 13 December 2023.

4. Update on 30 Churchill Place

The Board welcomed the representatives of DG BUDGET, Ms Lenka Filipkova, Director of Directorate BUDG.A Expenditure and Mr Christophe Galand, Head of Unit in BUDG.A.3 Internal Policies, to participate in the discussion on the former EMA premises in London (30 Churchill Place). The discussion

on the latest developments of 30 Churchill was held *in camera* and thus was attended only by members or their alternates, the observers from EEA countries and a limited number of EMA staff.

The MB chair reminded the Board of the significant and challenging issue of managing 30 Churchill Place, particularly with the Chapter 11 bankruptcy proceedings by WeWork's US operations in November 2023. [redacted]

[redacted] the negotiations with WeWork will commence in mid-December, with the aim to find a solution by February/March 2024. As a standard step in building dossier process, a pre-information note had been sent to the budgetary authority (Council and European Parliament) [redacted]. The note alerted the Budget Authorities to the situation with WW US Chapter 11 bankruptcy, negotiations with WW UK branch and the potential requirement for an agreement on a proposed counterproposal. The note also underscored specific uncertainties, particularly the potential scenario where no agreement is reached with WW. [redacted] Upon conclusion of negotiations concerning the counterproposal with WW, the final building dossier, describing the negotiated position, will need to be submitted, to secure the necessary EU funding.

[redacted]

Recognizing the intricate and unpredictable circumstances involving WeWork, the Agency is actively engaged in negotiating a fallback contract with the sub-undertenants and the Topic Coordinators will be informed in January of the outcome of the negotiations. [redacted]

[redacted]

The Topic Coordinators expressed their concerns that focusing on immediate financial solution does not imply a disregard for long-term solutions. A sustainable, longstanding resolution is required, and the Topic Coordinators thus highlighted that a political solution is still needed. [redacted] The Board stressed the importance of prioritizing health-related initiatives over real estate matters in the budget for the coming years. Furthermore, the Board urged the Commission to persist in helping to find solutions despite certain constraints. [redacted]

[redacted]

The Chair concluded by expressing gratitude to the DG BUDGET and DG SANTE for its strong commitment to supporting the Agency in finding a solution in order to avoid disruptions to EMA's mission to protect human and animal health. The MB Chair noted that the approval of an amending budget might be required to accommodate increased expenditure, following the discussions with the Commission services. To streamline the process on preparation of the building dossier and negotiations on counterproposal, the Board agreed to delegate the approval of key documents to the Topic Coordinators actively working on Churchill Place with EMA. [redacted]

A. Points for automatic adoption/endorsement

A1. Revision of budget remarks for budget 2024

[EMA/MB/217963/2023] The Board adopted revised budget remarks for the 2024 budget of EMA. The revision includes amendments to the budget structure regarding reimbursement of persons attending meetings, expenditure of experts involved in scientific evaluations, appropriation for the reimbursements to the EDQM for the sampling and testing of human and veterinary medicinal products, and remuneration of professional services (scientific expertise) rendered by external experts.

A2. Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2024

[EMA/MB/56455/2023] The Board endorsed the financial compensation and workload estimation of the National Competent Authorities' participation in the linguistic checking of product related information for 2024. The financial compensation/remuneration is calculated based on the forecasted workload as stated in the Agency's Work Programme and the application of a fixed flat hourly rate revised for inflation.

A3. Amendment to model rules on types of post and post titles

[EMA/MB/337202/2023; EMA/MB/293131/2023] The Board endorsed an amendment to the Management Board decision on model rules on types and titles of establishment plan post. The model rules establish the equivalence between the Staff Regulation's types of posts and the post titles which are used at the Agency and this amendment aims to reflect the current situation of post titles (and their recruitment grades) at the Agency.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update on the Agency's continued activities on COVID-19, including the preparations for a workshop with international partners and key stakeholders in early 2024 on the process for annual updates of COVID-19 vaccines. In addition, the Board noted the progress made throughout 2023 to strengthen the framework for managing medicines shortages in the EU. A diverse set of tools and measures are now available, including the solidarity mechanism, which allows Member States to support each other in the face of a critical medicine shortage, the EMA Medicines Shortages Steering Group (MSSG) Toolkit for tackling shortages of medicines, as well as the recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections during the winter season. The presentation also included an update on the HMA/EMA Task Force's efforts to address assessment resource challenges in the Network and the Board acknowledged the commendable actions. In addition, the Board were also informed that a review of the EMA policies on handling competing interest (Policy 0044 and 0058) was being undertaken to provide further guidance on the handling of potential interests linked to activities involving research organisations. The draft revised policies would be presented to the Board at a future meeting for adoption. The Executive Director provided an update on the Agency's request for a derogation from Article 11(1) of the new Commission rules limiting teleworking outside the place of employment to 10 working days per year. The formal decision by Commission on EMA's derogation request has not yet been received and a written procedure to endorse the new model decision may need to be initiated in the new year. The Board noted the upcoming retirement of Anthony Humphreys and expressed sincere appreciation for his noteworthy contributions to the Agency and his unwavering dedication to advancing innovation and research in the EU. The Board welcomed Emmanuel Cormier, who was appointed as Head of Regulatory Science and Innovation Task Force on 1 November 2023. Furthermore, the Board were informed of the retirement of Stefano Marino, Head of the Legal Department, scheduled for April 2024 and expressed gratitude for his dedicated contributions to the Agency.

B.2 Report from the European Commission

The Board noted an update by the representative of the European Commission on the activities of DG RTD to support multinational clinical trials and cohort studies, including relevant activities in those areas at global level.

The representative of DG RTD provided an overview of the challenges that academic researchers face and noted that for addressing such challenges Member States should work together at the EU level, which is why the ERA4Health Partnership, an investigator-driven clinical trials partnership, was recently set up by the European Commission. In February 2024 the Partnership will organise a workshop to look at funding mechanisms for multi-country investigator-initiated clinical studies and pave the way for closer discussions between Member States on how national research funding authorities can join forces at EU level. Secondly, an update was provided on the preparations for the launch of the Pandemics Preparedness Partnership, which is expected to start operating in 2025 and aims to establish a readily accessible network of clinical trials sites for pandemic preparedness. Board members were invited to contact the European Commission if they would like to discuss how national research agencies could benefit from this upcoming EU partnership. Thirdly, the European and Developing Countries Clinical Trial Partnership (EDCTP) was presented, which aims to support clinical trials against infectious diseases in Africa and is celebrating its 20 years of activity this year. Finally, an update was given on some large EU-funded cohort studies for COVID-19, such as the ORCHESTRA project under Horizon 2020. It was noted that EMA is interacting with the EU-funded cohort projects by participating in the EC Cohorts Coordination Board. DARWIN EU and the EMA-ECDC vaccine monitoring platform will offer further opportunities to leverage these studies for regulatory purposes.

The representative of DG RTD also provided an update on the activities of DG SANTE of interest to EMA's MB, with a focus on: the pharmaceutical reform and the preparation for the revision of Annex I of Directive 2001/83/EC; the Joint Action "capacity building of the EU medicines regulatory network" starting on 1 January 2024; the Joint Action on "regulatory flexibilities" due to start in 2025; the revision of the variation framework for medicines, expected for adoption in the first half of 2024; the examination of the legal proposal on European Health Data Space (EHDS); the adoption by co-legislators of the EMA fees regulation, and the state of play of implementation of the Veterinary Medicinal Products Regulation.

Board members asked about what actions they can undertake to support better multi-country clinical trials and to have clinical trials capacity to address future public health emergencies, as well as key learnings from the EDCTP. The representative of DG RTD stressed the limitations of individual Member States in addressing these challenges in isolation and pointed to the role of medicines agencies in raising awareness with their fellow research funding agencies about the benefits of pooling financial resources together at the EU level. It was also highlighted that the ACT EU initiative is a huge opportunity for building further dialogue between the funding community and the scientific community. Experience with the EDCTP has been challenging in the past but it is brining benefits, and the African authorities are now driving it, although many African countries are still in the process of building their clinical research capacity. The representative of doctors' organisations asked how issues with de-escalation clinical trials can be discussed, as they are very complex to activate under the new Clinical Trials Regulation; the EC pointed at the ACT EU and the Cancer Medicines Forum, but asked for more written input which could be further discussed in other relevant fora under the Horizon Europe Cancer Mission. A Board member asked when the implementation of the EMA Fees Regulation will be discussed at the MB level, in particular the cost monitoring mechanism and working arrangements. EMA clarified that this will presented to the Board later in 2024 after the new rules have entered into force.

B.3 Update on the implementation of Veterinary Medicinal Products Regulation

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

During 2023 the Agency delivered two scientific and technical advice to European Commission, supported the development of Guidance to Applicants, continued updating existing guidance to bring it in line with new legislative requirements, rationalised workplans for CVMP and its working parties to ensure adequate prioritisation of review of existing versus drafting of new guidance documents and supported the establishment of HMA Veterinary Strategic Focus Group. In addition, work continued on the IT systems including the preparation for the collection of 2023 data on Antimicrobial Sales and Use, which is due from MSs by Q2 2024 in order for the Agency to prepare the first annual report under the new regulation. Board members were encouraged to submit nominations for one Network Product Owner for the Union Product Database and for several MS data managers and national contact points regarding Antimicrobial Sales and Use data.

Some Board members acknowledged that the operation of the Union Product Database, while improving, does remain resource intensive and that focus should be maintained to address this. EMA acknowledged the difficulties. The focus on data has to be the key priority in the immediate term, nonetheless the Agency remains committed to continued functionality improvement.

B.4 a) Audit strategy/plan 2024-2026 & update of annual audit plan 2023 b) Revised Internal Audit Charter of the Audit Capability of the European Medicines Agency

EMA/438866/2023; EMA/MB/496331/2023; EMA/209787/2017; EMA/MB/505479/2023] The Board adopted the update of annual audit plan 2023, the EMA Audit strategy/plan 2024-2026, and a revision of the Internal Audit Charter of the Audit Capability to reflect the Management Board's decision on the establishment of the MB Audits and Risks Group (MBARG) in June 2023. The Board also endorsed the proposed nomination of the representative of patients' organisations, Virginie Hivert, as Chair of MBARG.

The EMA explained that the updated annual audit plan 2023 foresees that the audits on management of the Pharmacovigilance and Risk Assessment Committee and on Medical Literature Monitoring will be postponed starting in January 2024 instead of December 2023, due to capacity issues. The EMA Strategic audit plan 2024-2026 and the risk-based audit plan 2024 were presented in detail to the Board.

The Chair of the MBARG thanked the EMA for taking into account their comments on the audit plans 2024 and 2024-26, which related to the need to provide more details on the qualification of the risks and their potential impact on the Agency's operations. She also thanked EMA for onboarding the MBARG members with extensive explanations. Changes in the resourcing of EMA's internal audit function were noted, and the focus of the EMA's leadership team to address this was welcomed. The representative of DG RTD inquired about the available resourcing capacity and options for increasing this, the representative of the European Parliament about the internal controls on energy costs and other board members asked whether or not the internal audit reports to the Executive Director.

EMA clarified that external auditors can be contracted whenever needed to supplement the capacity and/or expertise of the internal audit function. The latter reports on the results of internal and external assessments to the Management Board, whilst reporting administratively (i.e. day-to-day operations) to the Executive Director. In addition, EMA's senior management is regularly consulted when preparing

the EMA audit plan. EMA clarified that the impact of raising energy costs on EMA's budget are controlled via a range of different tools, including the annual fee review based on inflation in April, or by using inflation-indexed individual contracts. The newly established MBARG now provides an additional platform for additional Board monitoring and discussion of any topics related to audit.

B.5 Update on Cyber Security

The Deputy Executive Director provided an update on EMA's cyber security management activities following the cyberattack that took place back in December 2020. EMA has structurally strengthened its cybersecurity capacity and has established an Information Security Management Steering Committee (ISSC) to provide an agency-wide oversight, ownership, and direction to the implementation of its Information Security Strategy, which aims to mitigate key business risks. The four identified strategic objectives of the strategy include improve security processes for digital transformation; enhance employee security behaviour; boost cyber resilience; and implement stronger verification and security requirements for system access and data. Additionally, an EMA Security Operations Centre (SOC, 24 hours) was established in July 2022, enhancing incident detection and response with advanced analytics, integrated threat intelligence, and automated responses. The Agency also adopted a security training and awareness program to enhance preparedness, protection against cyber threats, and staff's overall cybersecurity skills, behaviours, and knowledge. In March 2023, the European Court of Auditors (ECA), the European Data Protection Supervisor (EDPS), and the EC's internal audit services (IAS) conducted audits on security best practices at the Agency. IAS noted EMA's effective security organization, independent information security service, cyber security architecture, and security operations centre. IAS also commended EMA's robust commitment to enhancing security capabilities. Additionally, EMA is actively considering security risks associated with the advancement of AI and its systems. In January 2024, the EU Cybersecurity Regulation will take effect, mandating security provisions for implementation by EU Agencies. A guidance document will be developed to facilitate regulation adoption by EU Agencies. EMA must prepare for implementation, beginning with the establishment of a Risk Control Framework. The Board welcomed this topic, and it was agreed to have another update at future meeting.

B.6 Update from HMA/EMA Transparency Working Group

The Board received an update from the HMA-EMA Transparency working group, established in May 2023, to revise the current HMA/EMA guidance document on identifying personal data and commercially confidential information within marketing authorisation applications (MAAs). The presented principles for revising the guidance encompass refining its scope, updating the principles applicable to the Protection of Personal Data (PPD) and Commercially Confidential Information (CCI) , and proposing changes to the annex to align with the current Common Technical Document (CTD) format. The timeline and next steps for the revision of the guideline were presented, with the Board acknowledging that a written procedure for endorsing the final draft document would be scheduled around March 2024, in advance of a three-month public consultation on the draft proposals. The HMA/EMA Working Group aims to finalise the revised HMA/EMA guidance by October 2024.

The Board commended the Working Group for producing this pivotal document, highlighting its significance as a key guidance resource for both centralised and decentralised operations, and emphasised its role in enhancing transparency. A Board member raised a query about the teaching materials for CCI rules, questioning whether they would encompass legal frameworks beyond the EU, as the EU-Network Training centre aims to broaden the training platform's audience outside EU. EMA would reflect on developing separate guidance for this purpose.

B.7 Report from PRAC chair

The Board noted an oral report from the Chair of the Pharmacovigilance and Risk Assessment Committee (PRAC).

The PRAC chair presented the key activities and achievements of the committee since its establishment in 2012, using the COVID-19 experience, and in particular the investigation of the unusual thromboembolic events with thrombocytopenia after vaccination, as a key example to explain the central role played by the committee. She then outlined on the other activities of the committee focussing on education and training, science, collaboration, engagement, and transparency. Looking at the future, she emphasised the importance of RWD/RWE and of AI for the work of the committee as well as for measuring the behaviour of doctors and patients, which is crucial to assess the impact of risk minimisation measures and inform future regulatory decisions.

Board members asked the PRAC Chair to elaborate on her suggestion to further streamline the efficiency of the interactions between CHMP and PRAC in the assessment of risk management plans, about the work of PRAC in the area of anti-epileptics in pregnancy, on the potential role of pharmacogenomic markers in reducing Adverse Drug Reactions, and on the use of trainings for further developing the expertise of the network in pharmacovigilance. The PRAC Chair recalled the Committee's work on valproate, the recent referral on carbamazepine, and the ongoing EMA framework studies on RWE to look into the use of these medicines in women of childbearing potential, which are expected to inform about what more can be done to prevent both the risk of congenital malformations and, in the longer term, of neurodevelopmental disorders like autism and speech disorders. As regards pharmacogenomic markers, the example of abacavir for which genomic markers made a difference in reducing ADRs was highlighted; it was noted that, even if such markers are not always very clear, when available they can help to steer the use of medicines to those that can benefit the most from them. The focus of the Committee on training was welcomed. Changes to meeting methodologies were noted as was the Committee's learnings from the experience. Both remote and face-to-face meetings have benefits; face-to-face meetings are more useful where high levels of interaction are needed. The representative of patients' organisations praised the work of PRAC in engaging with patients and asked if the pilot of the PRAC Risk Minimisation Alliance (PRISMA) will continue, which was confirmed by the PRAC Chair.

B.8 Programming documents 2023 and 2024-2027

Programming 2023

a) Preparation of written procedure on Amending Budget 01-2023

[EMA/MB/556503/2023] Article. 34 of the Agency's Financial Regulation (FR) stipulates that any amendments to the Agency's budget, beyond the modification authorised under Arts. 26(1)[1] and 38(1)[2], shall be the subject of an amending budget adopted by the same procedure as the initial budget of the Agency. The Agency continuously monitors revenue and expenditure and makes projections for the annual outturn to ensure compliance with key performance indicators for budget implementation.

As a result of the continuous budget monitoring carried out throughout 2023, a number of changes have been identified regarding fee income and operating expenditure. Accordingly, the Agency will

[1] Art. 26(1) sets out rules for budgetary transfers.
[2] Art. 38(1) sets out rules for the modification of the Agency's establishment plan.

request the Management Board's approval by written procedure of an amending budget before the end of the year and which reflects closer the anticipated budgetary outturn.

b) Preparation of written procedure for on non-automatic carry over 2023-2024

[EMA/MB/484957/2023] The Agency is currently experiencing delays in contracting services related to activities which could not have been anticipated and which are outside the Agency's control. Due to these unforeseen delays in contracting services for budgeted activities in 2023, the Agency anticipates proposing a non-automatic carry-forward to cover the pending contracts in 2024. Contract preparations are progressing, aiming for completion by the end of Mach 2024. The decision on the carry-forward will be based on the actual cash revenue and outturn for 2023. Consequently, the decision is planned to be submitted to the Management Bord in January 2024 for adoption via written procedure.

Programming 2024-2027

c) Final programming document 2024-2026

d) Preliminary programming document 2025-2027

[EMA/426707/2023; EMA/533652/2023; EMA/MB/536297/2023,EMA/MB/506256/2023] The Board adopted the 2024-2027 Programming document, including the final 2024 work programme, budget, and establishment plan. The Board's Topic Coordinators Grzegorz Cessak, Christelle Ratignier Carbonneil, Despoina Iatridou, Eija Pelkonen together with the Chair, had assessed the documents on behalf of the Board over the past few months and presented the findings of their review to the Board.

The Board acknowledged that the Agency would continue to deliver on all its strategic priorities. In the planning exercise for 2024-2026, EMA is strategically shifting its focus from crisis management to a proactive approach, anticipating and addressing upcoming challenges and opportunities. In 2024, a primary focus is preparing for the implementation of the revised Pharmaceutical Legislation, with the goal of future-proofing medicines regulation and advancing the agency's transition into a regulator that is digitally enabled and data-driven. The Agency will also focus on enabling high quality, robust and rapid assessment of key medicines, by using haematology and oncology products as pathfinders. Another key focus area involves translating innovation into accessible medicines through better use of data and evidence approaches. Building on COVID-19 lessons and technological advancements, the Agency aims to enhance clinical research and regulatory decisions in 2024, leveraging initiatives like ACT EU and DARWIN EU. Furthermore, EMA will engage with HTA bodies, promote advanced manufacturing, and leverage the opportunities offered by artificial intelligence.

The Board recognised that the 2024 budget increased by 4.5% compared to 2023, to a total of 478 million euros. The 2024 budget takes account the preparatory work for the new pharmaceutical legislation, reduces the interim budget due to decreased level of different types of absences, and sustained an increase in fee revenues. regards to 30 Churchill place, the budget however includes only provisions for legal consultancy. A written procedure for an Amending Budget may be initiated to address the evolving situation with the London premises after the Board meeting. Staff-related costs will stabilise in 2024, and operating costs will increase in 2024 due to changes in IT expenditures and increased payments to Member States, as well as additional funding for scientific studies and services including DARWIN EU. The 2025 draft fee revenue indicates an increase, aligning with the anticipated new Fee Regulation which comes into effect in 2025 which will also increase NCAs remuneration.

The topic coordinator Eija Pelkonen confirmed a balanced and robust budget for required activities in 2024, taking into account ongoing work on European Medicines Agencies Network Strategy (EMANS),

and ensuring continuous high-level investment in the Network portfolio. The need for constant monitoring of the 2024 budget and related revenues/expenditures to identify potential shifts in application trends in view of the new fee regulation entering into force in 2025 was highlighted.

Christelle Ratignier Carbonneil, IT Budget Topic Coordinator, informed that Board that the 2024 IT budget remains stable, excluding inflation adjustments and with a transition to a new framework contract likely leading to rate increases and knowledge transfers. Ongoing investments focus on implementing the new fee regulation, future proofing CTIS and UPD, enhancing cybersecurity, and modernising legacy systems, such as the Human Resource system and AskEMA. The Value Streams within the IT framework continue to deliver network requirements.

Regarding the Work Programme, Topic Coordinator Grzegorz Cessak, outlined the multi-annual EMA programming for 2024-2027, emphasising three pillars: Product-Related Activities focusing on medicines lifecycle and guidelines, Strategies and Public Health Activities contributing to the overall Network strategy, and the Network Portfolio organised under five Value Streams aligned with the organisation's fundamental purposes. During 2024, the Agency along with HMA, plans to review and update the EMAN Strategy, covering an additional three years until 2028, and anticipating the revision of pharmaceutical legislation. Implementation of COVID-19 lessons learned will also be a major focus in 2024, while the growing workload of non-COVID-19 related products continue to pose challenges for the Agency's staff and NCAs' experts.

The Topic Coordinators underlined ongoing efforts to address AI challenges, with a focus on robust security measures and a risk assessment framework for OpenAI services. Additionally, the presentation emphasized the importance of EMA's role in implementing the new eCTD v.4.0 format, suggesting increased support for national agencies. EMA's commitment to advancing pharmacovigilance through data analytics was also outlined. The Topic Coordinators highlighted that EMA's current approach of addressing growing activities through efficiency gains, staff reallocation, and increased use of short-term contracts is unsustainable in the long term. This may hinder the Agency's ability to fulfil its objectives, impacting areas such as international cooperation and policy implementation.

The Topic Coordinator Despoina Iatridou provided a veterinary perspective on the work programme. In 2024, EMA focuses on advancing the implementation of the Veterinary Regulation's, including enhancing IT systems and refining processes. Key veterinary priorities user-friendly improvements for UPD, and ongoing consultation for effective regulation assessment. The Agency is dedicated to fostering innovation in veterinary medicinal products, supporting stakeholders through Regulation transition, and maintaining an One Health Approach, addressing emerging health threats and combating antimicrobial resistance with a collaborative, evidence-based approach.

The Board appreciated all the efforts made in assessing and preparing the programming documents. Some concerns were raised with regards to some activities that were included under 'negative priorities'. EMA explained that it is a requirement as per the EC guidelines to include a 'negative priorities' section, which signifies areas where the Agency's focus may be limited due to resource constraints. A Board member emphasised the need for greater emphasis on the 30 Churchill Place issue in both the programming document and budget. EMA acknowledged the already substantial section on 30 Churchill Place and will reflect budget implications through the amending budget highlighted earlier and the subsequent building dossier for the Budgetary Authority. Another Board member inquired about planned IT investments in relation to cloud-based capabilities and sought information on the allocated budget for security management. EMA highlighted that its 2024 IT investments will concentrate on optimizing infrastructure, adopting cloud-native capabilities, and strengthening security. The Board also underlined the delayed Product Management Service (PMS) functionalities, inquiring about the possibility of allocating budget to accelerate progress and overcome existing limitations. EMA clarified that delays in PMS are a result of data complexity and quality issues,

extending beyond an IT problem. PMS falls under the Product Lifecycle Management value stream and EMA will discuss these concerns at the upcoming quarterly strategic meeting with NPAG, aiming to make necessary adjustments and address the issues. A question was raised regarding changes in reimbursement of meetings in 2024 compared to 2023. EMA clarified that the projections for 2024 and 2025 consider the latest forecast, indicating that EMA is planning and budgeting for an increase compared to the actual activity level in 2023. A member expressed concern about how the HTA regulation might impact revenue, seeking clarification on whether the 2025 forecasts will account for the compounding effects of the HTA Regulation. EMA indicated a need to evaluate whether the forecasts for 2025 can incorporate the possible impact of the entry-into-force of the HTA Regulation. The rapid pace of AI development was highlighted by Board members, stressing the importance of agility, and recommended allocating sufficient funds not just for establishing a legal framework around AI use but also for staff training. EMA agreed and foresees unprecedented evolution in AI in the upcoming year, emphasising that the upcoming multi-year AI workplan encompasses not only data analytics but also many more initiatives such as knowledge mining, communication support, and training for EMA staff and the Network.

Following the discussion at the Board, the Agency will reflect any comments received in the final document, circulate it to the Board and submit it to the European Commission and other institutions by 31 January 2024.

B.9 Review and update of European Medicines Agencies Network Strategy (EMANS) to 2028

The Board noted an oral report from EMA on the plans to review and update of European Medicines Agencies Network Strategy (EMANS) to 2028.

EMA explained that since another major revision of the EMANS will be required by the time the reform of the pharmaceutical legislation is adopted, EMA, HMA and EC have decided that, rather than creating a new strategy until 2030, they would review and update the current EMANS to 2025 to take the network through 2028 when the new legislation is likely to become applicable. A mid-point report on the implementation of the current EMANS will be published by the end of 2023 and will present an overview of the achievements in each of the six thematic areas, showing that the Network is broadly on track to deliver the full strategy to 2025, and to look at the challenges that lie ahead after 2025. A Working Group will then build on this environmental analysis to review and prioritise each strategic theme and discuss whether new or different themes should be included in the EMANS to 2028. In 2024 this analysis will be conducted by having some brief workshops with the leads of each thematic areas with the aim of generating an internal reflection paper. In Q2 a draft EMANS to 2028 will be prepared and opened for a public consultation over the summer, adoption is anticipated by the end of 2024.

B.10 Agile transformation and Portfolio status report

[EMA/MB/552550/2023; EMA/507481/2023] The Board noted the Portfolio Report to the Network which provides a status update on the ongoing initiatives (epics) within the five Agile Value Streams. CTIS is currently transitioning from the P3i governance into the new Agile way of working. The Chair of the Portfolio Board provided an update on the progress of the Agile Transformation and focused on the main deliverables of the Network Portfolio in 2023. The 'Research & Development' Value Stream Owner also provided a concise overview of its vision and objectives. The R&D Value Stream envisions enabling efficient medicines development and scientific evidence generation for e public and animal health in the EU. Key commitments include supporting research and innovation, promoting excellence in scientific evidence generation, streamlining clinical trial management, enhancing user experience, ensuring

transparency, and striving for continuous improvement through feedback. The main objectives focus on building capabilities for early-stage regulatory procedures, accelerating new medicines development, employing AI for knowledge mining, and supporting data-driven regulatory decision-making through the integration of individual patient and real-world data.

B.11 Report on Pharmacogenomics activities at EMA

The Board noted an oral report on Pharmacogenomics activities at EMA.

The report focussed on three main areas: (i) the importance of pharmacogenomics and its opportunity for improving public health via targeted treatments and increased safety; (ii) the pharmacogenomics activities of the European Medicines Regulatory Network, including the Pharmacogenomics Working Party (2001 – 2018), Methodology Working Party (2022- present), Methodology European Specialised Expert Community, and the EMA Pharmacogenomics Community; and (iii) the pharmacogenomics activities planned in 2024, such as DARWIN EU pilot studies leveraging genetic data linked to real-world data sources, developing and delivering on pharmacogenomics in the Methodology Domain and strengthening collaboration with DG RTD, including by organising a joint EMA/HMA/DG RTD workshop to discuss a research agenda in pharmacogenomics and how medicines regulators can facilitate the development and uptake of genomics and precision medicines.

One Board member stressed the difficulty in interpreting genomic markers and the need to raise awareness among healthcare professionals, to help them embrace the use of biomarkers as part of hospital services. The representative of doctors' organisations asked how currently available RWE data on genomic markers can be used to inform regulatory decisions across the whole life cycle of medicines. EMA acknowledged the challenge to address specific scientific questions with currently limited access to datasets but clarified that more data sources with individual genetic data will become accessible via DARWIN EU, i.e. in future there will be more opportunities to use biomarkers to inform decisions across the whole lifecycle of medicines. The representative of DG RTD recalled the work done by the European Commission to raise the awareness about the cost-saving benefits of pharmacogenomics, but acknowledged more needs to be done and could also be considered in the context of the new EU Partnerships on Personalised Medicines and on Transforming Health and Care Systems. The EC is ready to work together with EMA to organise a joint workshop on pharmacogenomics September 2024.

B.12 Big Data Steering Group (BDSG) progress report

a) Update on BDSG activities

The co-chair of the BDSG presented a progress report on the Big Data Steering Group, providing comprehensive updates for activities under the priority recommendations of data discoverability and data quality & representativeness. After the publication of the first metadata list for real-world data sources and studies, the Board were informed that EMA-HMA catalogues of data sources and non-interventional studies will be launched in Q1-2024, supported by a good practice guide. These catalogues will provide information on key real-world data sources, including data quality and representativeness, as well as details on observational studies. Stakeholder communication and engagement, including with patient organizations, will be intensified in 2024 to populate the real-world data catalogue and support change management efforts. EMA also presented the Data Quality Framework for EU medicine regulation, adopted by the Methodology Working Party, and subsequently endorsed by CHMP in November 2023. This framework emphasises the crucial role of data quality in enabling effective data-driven regulation and fostering trust among patients and healthcare professionals. This comprehensive framework outlines quality criteria applicable across various data

types and regulatory activities. It provides general considerations that can be applied to a wide range of data sources for characterizing and assessing data quality, intending to serve as an overarching framework for deriving more focused recommendations for specific regulatory applications. Produced collaboratively by EMA, HMA, and Towards the European Health Data Space (TEHDAS) Joint Action, the framework has undergone consultation with a wide range of stakeholders. The final framework document is planned to be published by end of the 2023.

b) Multi-year Network Artificial Intelligence workplan

[EMA/539885/2023] The Board adopted the multi-year Network Artificial Intelligence (AI) workplan. The network's AI vision aims to establish a medicines regulatory system leveraging AI for enhanced personal productivity, process automation, improved data insights, and strengthened decision-making for the betterment of public and animal health. Recognizing the rapid evolution of AI technology, the plan concentrates on key dimensions, including guidance and policy support, AI tools and technology frameworks, collaboration and training initiatives, and structured experimentation. In 2024, an informational webinar will be organised for all interested Member States to deliberate on the risk, data security, and data protection aspects associated with large language models. The AI workplan implementation and maintenance will be overseen by the BDSG, with regular updates to HMA and EMA Management Board. Following EMA Management Board, the multi-annual AI workplan to 2028 will be published on the BDSG and HMA webpages.

One Board member emphasized the importance of strengthening the focus on training components related to AI tools in the forthcoming EMANS and future work plan. Another member queried on the handling of confidential data in AI tools. Maintaining stringent controls over large language models is crucial to prevent data breaches. A dedicated webinar will be arranged by the EMA in 2024 to delve into these issues.

B.13 Report to the Management Board on ACT EU, the operation of CTIS and the Clinical Trial Regulation

[EMA/MB/540758/2023; EMA/MB/509165/2023] The Management Board noted the progress of the Accelerating Clinical Trials in the EU (ACT EU) initiative and the operation of the Clinical Trials Information System (CTIS).

The ACT EU 2023-2026 workplan, released in November 2023, details the objectives for the next four years, aiming to bring positive changes to EU clinical research. Upcoming activities include a clinical trials analytics workshop in late January 2024 and the formation of the multi-stakeholder platform advisory group.

Since 31 January 2023, CTIS is mandatory for initial clinical trial applications, with submissions steadily increasing from 100 in February 2023 to over 190 in October 2023. By 30 January 2025, all ongoing trials approved before 31 January 2022, must be moved to CTIS. EMA and national authorities are preparing support programs and campaigns to ensure sponsors meet their responsibilities and promptly transfer information on ongoing clinical trials to CTIS. A presentation on the Member States' perspective of CTIS implementation was presented by the member from Sweden, which mainly focused on all the achievements made since the beginning of the year.

The Board acknowledged the CTIS planning for 2024, focused on system performance improvement and user experience enhancement. A task force is set to streamline business rules, and a new public portal, aligned with the updated CTIS transparency regulations, will be introduced to enhance transparency. One comment by a Board member queried plans to extend support to academic clinical trials that have not yet transitioned into the CTIS. EMA underscored that support services would be

enhanced to provide stakeholders with necessary assistance including a dedicated webinar. A few Board members expressed a keen interest in a discussion on the Health Technology Assessment (HTA) Regulation, which will take effect within the next year. EMA and the MB Chair agreed to have this topic at a future Board meeting. The representative of DG RTD highlighted the importance of benefit monitoring and assessing the impact of the CTIS. EMA noted that these topics are currently under discussion within the ACT EU Steering Group, with plans to present outcomes at an upcoming Board meeting.

B.14 Update of HMA/EMA Task Force on Availability (TF-AAM), including Union list of critical medicines

The Board noted and commended the Agency's efforts in successfully publishing the first version of the Union list of critical medicines in mid-December 2023. EMA presented an overview of the first phase of the Union list of critical medicines in EU. Considering the volumes of authorised medicines in the Union, a phased approach was chosen. The first phase of the list includes over 240 active substances of human medicines, both innovative and generic, crucial for patient well-being and healthcare system functionality. The critical medicine status is determined by factors including disease severity, availability of alternatives. Following the publication of the first version of Union list, Commission DG HERA/GROW will conduct a supply chain vulnerability assessment for a subset of these critical medicines. In response to the identified vulnerabilities, the Critical Medicines Alliance and MSSG may issue recommendations and suggest measures to rectify these issues, strengthen security of supply for these critical medicines with the aim to ensure a consistent supply of critical medicines in the EU. During the second phase of the Union list a larger volume of active substances will be reviewed by the Member States, with the initiation scheduled for January 2024. Furthermore, a Critical Medicines Alliance will also be established in early 2024. One Board member proposed expanding the current criteria for criticality of a medicines to include the route of administration alongside active substance and ATC groups. EMA acknowledged this suggestion, noting its inclusion in the criteria for finalising the first phase of the list. Further discussion in the Task Force will explore whether to incorporate this additional detail in phase two based on insights gained during phase one.

A comprehensive summary of the key deliverables from the HMA/EMA TF-AAM was also highlighted to the Board, including the HMA/EMA multistakeholder workshop on shortages in March 2023, the publication of Good Practice Guidance for industry for the prevention of medicine shortages in May 2023, the creation of Shortage Prevention and Mitigation Plans (SPMP) templates, and the implementation of Good Practice Guidance for PC/HCPs organizations on the prevention of shortages of medicines.

B.15 Quality Innovation Group update

The Board noted an update from the EMA and HMA co-chairs of the Quality Innovation Group, including its achievements in 2023 and plans for the future.

The Quality Innovation Group is a small group of quality experts established in 2023 with the aim of acting as catalyst for the development in the EU of advanced manufacturing techniques which can enhance the quality of medicines by improving productivity and reducing costs, and ultimately leading to improving the availability of new medicines for patients. The QIG acts as a single contact point in the medicines regulatory network for developers to present their innovative manufacturing technologies, for experts to develop regulatory thinking and guidance about them and as a centre of excellence to support with product evaluations, global convergence, and development of trainings. In its first year of operation the Group focussed mainly on continuous manufacturing for biologicals,

decentralised manufacturing, digitalisation/automation and delivered two "listen and learn" focus group meetings, one workshop and report on continuous and decentralised manufacturing, the revision of guidance such as EU GMP Annex 11 on AI/ML and development of Q&A on process models, support to ITF meetings and 1:1 meetings with industry and academia stakeholders. It also collaborates closely with US FDA to share knowledge and develop joint guidance and advices on specific products. In 2024 the QIG plans to continue expanding on all current activities.

Board members welcomed the work of the Group. Some members suggested enlarging it beyond inspectors and others asked if SMEs are also active on advanced manufacturing besides big pharma. The QIG co-chairs clarified that indeed other experts, such as modelling experts, have been involved to date and that several SMEs are using innovative manufacturing technologies, especially for ATMPs, and they should be prioritised in terms of participation to future QIG listen and learn focus group meetings. The QIG co-chairs thanked the MB members for their full support and willingness to offer the time and capacity of their scientific experts to continue to participate in this new group also in 2024.

B.16 Annual report on the implementation of the EMA's Anti-Fraud Strategy

The Board noted an oral report on the implementation of the EMA's Anti-Fraud Strategy in 2023.

EMA presented the anti-fraud work conducted in 2023, which focussed on regular communication to staff on anti-fraud matters, targeted awareness raising sessions on anti-fraud and ethics in cooperation with HR, reporting in the Annual Report and other strategy documents, assessment of the adequacy and effectiveness of the anti-fraud controls in place and the conduct of fraud-specific risk assessments. No administrative inquiry was launched which means that there was no detection of fraud. EMA also led the work on anti-fraud within the Inter-Agency Legal Network by consolidating comments from the EU Agencies Network (EUAN) on the Working Arrangement with European Anti-Fraud Office (OLAF), with European Public Prosecutor Office (EPPO) and on the Updated draft anti-fraud strategy methodology published by OLAF for decentralised Agencies in November 2023. In early 2024 an audit of the implementation of the anti-fraud strategy will be delivered and offer inputs to shape the new 3-year strategy, which will be brought for adoption at the March MB meeting. Additional internal trainings on anti-fraud and ethics and regular fraud risk assessments will be developed in 2024, including in cooperation with OLAF.

B.17 Report on the data protection activities by EMA in accordance with the EU Data Protection Regulation

The Board noted an oral report on the data protection activities by EMA in 2023.

The EMA's Data Protection Officer presented all activities conducted in 2023, which focussed on: internal work prioritisation (Data Protection Workplan, quarterly reporting, DP coordination meetings), selection and acquisition of IT solutions & related services to ensure the security of the data, performing Data Protection Impact Assessments (with a significant increase from previous year), review of Internal Data Protection Guidance, developing Administrative Arrangement concerning data protection requirements for international personal data transfers, management of Data Breaches (noting a positive 50% reduction compared to the previous year) and development of tailored data protection training for EMA and the network experts. 2024 will focus on: providing guidance and training on use of AI and data protection, follow-up on the EudraVigilance audit recommendations, follow-up on the actions resulting from the EDPS investigation on Microsoft 365 and EU institutions' use of cloud-based services, finalisation of ongoing Data Protection Impact Assessments and continuation of data protection advice as needed across the Agency.

List of written procedures during the period from 27 September to 06 December 2023:

During the period from 27 September to 06 December 2023, the Board was consulted 6 times via written procedure, of which 1 consultation concerned membership in the CHMP, and 5 additional consultations, as listed below:

- Consultation no. 12/2023 on the appointment of Fulvio Marsilio as CHMP alternate as proposed by Netherlands ended on 27 September 2023. The mandate of the nominee commenced on 28 September 2023.
- Consultation procedure for the endorsement of the Amendment to Network Data Board (NDB) mandate ended on 3 November 2023 at COB (CET). The procedure was endorsed.
- Consultation procedure for the endorsement of COVID-19 Lessons Learned Report ended on 29 November 2023 at 12:00hrs (CET). The procedure was endorsed.
- Consultation procedure for the endorsement of the Revised Cooperation Agreement EMA-EDQM ended on 29 November at 17:30hrs (CET). The procedure was endorsed.
- Consultation procedure for the adoption of the First version of the Union List of critical ended on 6 December at 11:00hrs (CET). The procedure was adopted.
- Consultation procedure for the adoption of the minutes of the 121st Management Board meeting, held on 5 October 2023 will end on 13 December 2023 at 12:00hrs (CET). The procedure was adopted.

Documents for information

C.1 Feedback from the Heads of Medicines Agencies

C.2 [EMA/MB/432308/2023] Outcome of written procedures finalised during the period from 27 September 2023 to 06 December 2023

C.3 [EMA/MB/557093/2023] [EMA/557095/2023] a) summary of transfers in budget 2024

b) summary of implementation of assigned revenue

List of participants at the 122nd meeting of the Management Board, held in Amsterdam, 13-14 December 2023

Chair: Lorraine Nolan

	Participants
Belgium	Hugues Malone *(member)* Charles Denonne *(alternate)*
Bulgaria	*Apologies received from Bulgaria*
Czechia	Kateřina Podrazilová *(member)*
Croatia	Siniša Tomić *(member)*
Denmark	Lars Bo Nielsen *(member)* Birgitte Faber *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk *(member)*
Ireland	Rita Purcell (alternate)
Greece	*Apologies received from Greece*
Spain	María-Jesús Lamas Díaz *(member)* Consuelo Rubio Montejano *(alternate)*[1] Celia Caballero *(observer)*
France	Christelle Ratignier-Carbonneil *(member)* Frank Foures *(alternate)* Miguel Bley *(observer)*
Italy	Francesco Trotta *(alternate)*
Cyprus	Helena Panayiotopoulou *(member)* Irini Chrysafi Fanidou *(alternate)*
Latvia	Sergejs Akuličs *(alternate)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)*
Hungary	Beatrix Horváth (alternate)
Malta	John Joseph Borg *(alternate)*
Netherlands	Paula Loekemeijer *(member)* Aimad Torqui *(alternate)* [1] Roelie Marinus *(observer)*
Austria	Günter Waxenecker *(member)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)*
Portugal	*Apologies from Portugal* Maria João Morais *(observer)*
Romania	Razvan Prisada *(member)*
Slovakia	Katarína Massányiová *(alternate)*
Slovenia	Momir Radulović *(member)*
Finland	Eija Pelkonen *(member)* *Anna Siira (alternate)*
Sweden	Björn Eriksson *(member)* Åsa Kumlin Howell *(alternate)* [1] Hannes Eintrei *(observer)*
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)* Martina Ciccarello (DG SANTE) *(observer)* * Lenka Filipkova (DG Budget) *(observer)* * Christophe Galand (DG Budget) *(observer)*
Representatives of patients' organisations	Virginie Hivert *(member)* Marco Greco *(member)*
Representative of doctors' organisations	Denis Lacombe *(member)*
Representative of veterinarians' organisations	Despoina Iatridou
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.4 and B.8
* attended the meeting remotely for one agenda item.

Guest speaker	Sabine Straus (PRAC Chair) Marcel N. Hoefnagel (Chair of the Quality Innovation Group)

European Medicines Agency	Emer Cooke Ivo Claassen Stefano Marino Nerimantas Steikūnas Anthony Humphreys Emmanuel Cormier Alexis Nolte Peter Arlett Hilmar Hamann Zaide Frias Hilde Boone Steffen Thirstrup Franck Diafouka Martin Harvey-Allchurch Hilde Boone Marie-Agnes Heine Rebecca Harding Anne-Sophie Henry-Eude Steven Le Meur Falk Ehmann Frank Pétavy Monica Dias Evdokia Korakianiti Sabine Brosch Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin