8 September 2023
EMA/MB/257775/2023 - Adopted
Management Board -

Minutes of the 120th meeting of the Management Board

Amsterdam, 7-8 June 2023

The Chair of the Management Board opened the meeting, which was held as a face-to-face meeting. The Chair welcomed the new member for Austria, Mr Günter Waxenecker (Head of the Austrian Medicines and Medical Devices Agency) and Ms. Indra Dreika (Director of the State Agency of Medicines of the Republic of Latvia).

1. Draft agenda for the 7-8 June 2023 meeting

[EMA/MB/129985/2023] 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.7 on 'MB Decision on the establishment of Management Board Audits and Risks Group' ('MBARG')'. 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 prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

3. Minutes from the 119th meeting, held on 16 March 2023 adopted via written procedure

[EMA/MB/225645/2023] The Management Board noted the final minutes, adopted by written procedure ending on 8 June 2023.

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4. Information session on the European Commission proposals for the revision of the EU pharmaceutical legislation

The Board noted an oral report from a representative of DG SANTE presenting an overview of the legal proposals for the revision of the EU pharmaceutical legislation published on 26 April 2023, intended to support the Board in better understanding how the proposed changes might impact on EMA in the future. The presentation to the Board was for information only and without prejudice to the upcoming official legislative procedure.

The presentation was organised into the following four areas: a) general objectives and reform of the EMA, including orphan and paediatric medicines; b) changes to the centralised procedure, including new pre- and post-authorisation activities; c) security of supply, inspections and Temporary Emergency Marketing Authorisation (TEMA); d) environmental risk assessment (ERA), cooperation between Agencies, colourants, AMR, international activities and impact on EMA resources.

Board members asked further clarifications on: the modulation of regulatory data protection periods related to market launch, especially for small markets; the new proposed EMA committees structure; the functioning of proposals concerning repurposing; the evidence base for proposing a reduction of evaluation timelines to 180 days; how ERA could be enforced as a stand-alone criterion separate from benefit/risk assessment; how the Commission sees the impact on national budgets of the transferable exclusivity voucher for priority antimicrobials; the additional resources foreseen for EMA in the financial statement. The representatives of patients' organisations stressed the need to maintain a transversal view of the fields of both, rare diseases and paediatrics and to build upon the 20 years' experience of rare disease patients' representation in the new committees' structure. The representative from DG SANTE provided detailed explanations on all the points above and added that proposals on market launch incentives are addressing calls from the European Parliament and Member States in the Council (several Council conclusions) for patients' equitable access to medicines and affordability. Those on the restructuring of EMA should allow better use of the existing assessment resources within the network, without any impact on fees and on the rapporteur model.

The Chair thanked the DG SANTE representative for the very clear and comprehensive presentation on the EC legal proposals, which was much appreciated by all members.

A. Points for automatic adoption/endorsement

A.1 Management Board meeting dates 2024-2025

[EMA/MB/38032/2023] The Board adopted the proposed meeting dates for 2024 and noted the meeting dates for 2025.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update on the Agency's response to COVID-19, recognising the roll-back of certain pandemic-related activities. This was prompted by the World Health Organization (WHO) ending the Public Health Emergency of International Concern (PHEIC) status for COVID-19 and MPox in May 2023. In addition, both the EMA and the European Medicines Regulatory Network (EMRN) have

now discontinued their COVID-19 Business Continuity plans (BCPs), allowing for the reinstatement of certain activities that were halted during the pandemic, including for example, the resumption of Clinical Data Publication. The EMA informed the Board about the development of an action plan to further enhance transparency measures in this area, which was welcomed. The Agency will exceptionally publish Periodic Safety Update Reports (PSURs) and PSUR assessment reports for COVID-19 medicines. EMA remains committed to supporting the EU's COVID-19 response and ensuring timely review of (adapted) vaccines and therapeutics. The Emergency Task Force (ETF) will conclude ongoing COVID-19 reviews and the ETF composition will be adapted with more focus on preparatory work for future crises. Although the discontinuation of BCPs has been agreed, EMRN resources, particularly for assessment and inspection work, remain challenging. An update was provided on the work of the HMA/EMA Tactical Group on resourcing. A member of the Board inquired about the backlog of scientific guidelines and EMA explained that a review and prioritisation process of the Committee workplans will be discussed at the next Scientific Coordination Board meeting with the aim of adopting them by the end of the year.

Furthermore, the Board was provided with an update on EMA's actions in the area of shortages. This update covered activities of the Medicine Shortages Steering Group (MSSG), as well as the HMA/EMA Taskforce on Availability of Authorised Medicines (TF-AAM) and the newly established Medical Devices Shortages Steering Group (MDSSG). EMA informed the Board about the issue of good practice guidance for industry to help ensure medicines supply continuity. The Board commended the work of HMA/EMA TF-AAM and highlighted the need to focus on prevention approaches to avoid shortages and availability issues.

The presentation highlighted also EU institutional and international cooperation activities. This included feedback from exchanges with the European Parliament's COVI and SANT committees, the granting of the Discharge of EMA's 2021 accounts as well as extending the OPEN initiatives to involve international partners in CHMP operations. There was a query about whether the Agency plans to expand its engagement with international regulators beyond OPEN to tackle global issues. EMA outlined ongoing efforts to develop an international strategy with the aim to sustain and broaden engagement with global partners. The Agency is also collaborating with the European Commission (EC) to promote EU collaboration with international partners through the EU Global Health Strategy and WHO international treaty on pandemics. During the closing remarks of the presentation, the Board was reminded that the Court of Justice will deliver its judgment on the Aplidin appellate proceedings on 22 June.

B.2 Report from the European Commission

The Board noted an oral update from the representative of DG Research & Innovation on progress in personalised medicine and how regulators could help foster its uptake. The representative of DG Research & Innovation also provided an update on behalf of DG SANTE on key ongoing legislative, legal and policy files of interest to the Board.

An internal review of the extensive experience at the European Commission in funding research on personalised medicines highlighted that failure of consortia to engage with regulators at early phases of research may lead to project results which are not fit for regulatory requirements. Examples include clinical trial endpoints and new methodologies adapted to small populations not accepted for authorisation. The next frontier of personalised medicines is personalised prevention and a number of EU projects and calls in that area were presented. EMA and National Competent Authorities were encouraged to engage early on in these projects in order to be prepared to assess such new developments, advise on clinical validation requirements and ultimately help ensure that what is

publicly funded is supportive to generation of future authorisations. Increased cooperation with regulators should be implemented in a sustainable way, which is mindful of the resource implications. Strategies for the roll-out of personalised medicine in daily practice will be discussed in conferences to be organised by the consecutive EU presidencies. The inclusion of regulatory sandboxes in the proposed pharmaceutical legislation is welcome as they will allow future consortia from Horizon Europe to experiment within a dedicated framework with EMA as facilitator.

The update on behalf DG SANTE consisted of a status update on relevant legislative files these included: EMA fees, Substances of Human Origin, and the European Health Data Space. Updates were also given on the ongoing WHO listed authorities (WLAs) project, follow up activities by the European Commission to implement the recent court rulings on Tecfidera and the extension of the EU-US Mutual Recognition Agreement on pharmaceutical GMP inspections to veterinary products.

The Board welcomed the work on the veterinary Mutual Recognition Agreement with US FDA, which is expected to lead to major simplification. The proposal to increase cooperation on personalised medicines between funding institutions and regulatory agencies was also supported. Some members stressed the need for regulators to be more proactive, for example via the EMA-HMA EU Innovation Network (EU-IN). The representative of doctors' organisations noted that scaling up personalised treatments in oncology may be complex and to achieve better progress the patient should become the starting point in the drug development model. Representatives from EMA explained ongoing efforts to ensure that research consortia are encouraged to seek scientific advice. Regulators are also involved during the project design phase to discuss scientific principles and help to prioritise the research questions relevant for subsequent authorisation. In addition, a European Specialised Expert Community on methods and a subgroup on genomics will soon be established by EMA and this will help to increase regulatory expertise in the area of personalised medicine.

B.3 Assessment of the Executive Director's Annual Activity Report 2022 and launch of written procedure for the annual accounts.

[EMA/MB/209000/2023; EMA/MB/239468/2023; EMA/137754/2023; EMA/MB/60027/2023] The board noted the Executive Director's Annual Activity Report (AAR) 2022 and adopted the Board's Assessment of the Executive Director's AAR 2022 which had been prepared by the topic coordinators Gytis Andrulionis, Despoina Iatridou, Virginie Hivert, Lars Bo Nielsen and Momir Radulović.

The AAR 2022 provides information on the management and control systems of EMA and on the work programme implementation. It is prepared in accordance with Article 48 of the EU Financial Regulation and forms part of the next discharge process. The consolidated annual activity report (AAR) is submitted to the Management Board for assessment and by no later than 1 July the consolidated AAR together with its assessment shall be sent by the Management Board to the Court of Auditors, the Commission, the European Parliament and the Council.

The topic coordinators presented the main points of the proposed Board's assessment. The Board acknowledged the results presented in the annual activity report 2022 and despite the challenges posed by the COVID-19 pandemic, the Board recognised the Agency's ability to maintain the high quality of its core operations and make further advancements in adapting and streamlining regulatory processes. The Board commended the Agency, scientific committee members, experts, EMRN and patient representatives for their remarkable commitment and dedication during the COVID-19 pandemic. The topic coordinators also highlighted notable accomplishments, including the support for

the European One Health Action Plan against antimicrobial resistance and its contributions to the EU's Beating Cancer Plan, the preparatory work and contribution of the Agency and the NCAs to the revision of the general EU pharmaceutical legislation for human medicines.

As part of the review, the Topic Coordinators also discussed the Agency's accounts with the Accounting Officer. The Board noted the preliminary observations of the Court of Auditors on the provisional accounts for the financial year 2022 presented by the EMA Accounting Officer. In accordance with Article 102.3 of the Agency's Financial Regulation, the Accounting Officer will draw up the final accounts of the Agency, which will be submitted for the opinion of the Management Board via written procedure for adoption after the June meeting. The Executive Director shall then send the final accounts, together with the opinion of the Management Board, to the Accounting Officer of the Commission, the Court of Auditors, the European Parliament and the Council by 1st July at the latest.

B.4 Annual report 2022 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use

[EMA/174448/2023; EMA/MB/202946/2023] The Management Board endorsed the Annual report 2022 on Key Performance Indicators for the evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use.

EMA noted the annual report is presented in the context of the implementation plan endorsed by the Management Board on 10 June 2010 with the aim to provide transparent reporting of the performance of NCAs under the Cooperation Agreement with EMA for services provided. In terms of areas for improvement, the Board was informed that delays for GMP inspection reports as well as challenges with timely appointing of Rapporteurs and Scientific Advice coordinators remain. Delays in starting scientific advice procedures were highlighted as a major concern by industry. A working group with EMA and all National Competent Authorities is looking into solutions. Most of the other KPIs in the report have been met and EMA thanked the network for their support and collaboration.

Board members welcomed the report and asked further clarification on the delays in starting scientific advice procedures and their main causes. Lack of predictability of industry submissions and postponement of planned submissions cause difficulties at national level as the necessary assessment resources are reserved in advance and cannot be re-allocated quickly. EMA noted it is working with industry to ensure more predictability in submission timelines and is also working with assessment teams, especially Multi-National Assessment Teams, to become more adaptable and quicker to be deployed.

B.5 Remuneration of training development

[EMA/243422/2023; EMA/MB/243436/2023] The Management Board adopted the addendum to the EMA-NCA cooperation agreements to remunerate the development and delivery of certain trainings.

The EU Network Training Centre (EU NTC) is a joint EMA and HMA initiative aiming at providing a central resource and platform for scientific and regulatory training, pulling together the numerous training activities of the EMA and National Competent Authorities (NCAs) into a comprehensive system. The EU NTC Training Steering Group (TrSG), co-chaired by EMA and HMA, has highlighted as one of its priority areas the need to ensure the sustainability of the EU NTC. The EMA co-chair of the EU Network

Training Centre (EU NTC) Steering Group presented a proposal to better incentivise the development and delivery of training. To accomplish this, it is recommended to introduce the possibility of additional financial support. This will be enabled through an addendum to the existing cooperation agreements to establish appropriate remuneration for the provision of selected training services by the NCAs.

The Board expressed its support for the initiative and welcomed it as an important step to complement the current voluntary-basis EU NTC model. The HMA co-chair indicated that this was a highly positive development and an important opportunity to enhance the quality of the training materials and consider professionalising them in the future. The opportunity to use more innovative methods to make them more appealing and engaging for learners was noted. The alternate member representing DG RTD, speaking on behalf of DG SANTE, clarified that there is no overlap between the remuneration of training development and the EMA fees proposal. Nonetheless, as these costs were not taken into account in the calculations for the fee proposal, it is important that the estimated amount does not increase over time. EMA confirmed that the proposal applies to training in both the human and veterinary domains. The proposed flat rate for remuneration will be evaluated over time to assess its impact and whether any adjustments are necessary.

B.6 Annual report of internal audit and advisory activities at the European Medicines Agency 2022

[EMA/74278/2023; EMA/MB/178511/2023] The Management Board noted the positive opinion of the interim Head of Audit that the internal controls at the Agency during the Business Continuity Period provide reasonable assurance regarding the achievement of the business objectives and adopted the Annual Report of Internal Audit and Advisory Activities at the European Medicines Agency 2022.

EMA's interim Head of Audit provided an update to the Board on audit engagements in 2022, noting that despite some internal changes and resource constraints in the EMA audit function all audit engagements that were adopted by Board have been delivered. In addition, an audit of EMA's Human Resources management was performed by the European Commission's Internal Audit Service, and the Agency's annual accounts had been subject to an audit by the European Court of Auditors. In 2022 the internal audit function continued strengthening its involvement and collaboration with other stakeholders, in particular the Steering Group of Benchmarking of the European Medicines Agencies (BEMA), and the Working Group of Quality Managers of the EU Agencies' network.

Major audit recommendations are more frequently being closed due to quarterly meetings with senior management to review corrective actions. Implementation of the recommendations of the 2022 external assessment of the internal audit will be presented to the Management Board in December 2023.

B.7 MB Decision on the establishment of a Management Board Audits and Risks Group' ('MBARG')

[EMA/MB/105013/2023; EMA/MB/164148/2023] The Management Board adopted a Decision on the establishment of a Management Board Audits and Risks Group' ('MBARG'). This group will consist of three to six Board members tasked with assisting the Board to review the progress on the implementation of audit recommendations as well as providing objective and independent review and oversight of the EMA's strategic processes in relation to risk, internal controls and governance. Members welcomed the decision, which is expected to increase governance, and were informed that a call for expression of interest will follow by written procedure.

B.8 Update on Agile transformation and Network portfolio

[EMA/253049/2023; EMA/MB/253058/202] The Board noted the Portfolio Report to the Network, which provides a progress update on the implementation of IT Programmes and Projects, Agile Value Streams, and monitoring of IT Operations. The Chair of the Portfolio Board presented high-level metrics on the Agile transformation in relation to the recent Programme Increment (PI) planning meetings, System Demo sessions and Quarterly Strategic Portfolio Review discussions. The Value Stream Owner of 'Product Life Cycle Management' (PLM) provided a concise overview of the vision and objectives set for the value stream during the 2023-2025 period.

The Board expressed gratitude to all the parties involved and acknowledged the significant impact it has already made within the Network.

B.9 • Network data governance: revised EU Network Data Board (EUNDB) and Big Data Steering group (BDSG) mandates

[EMA/96120/2023; EMA/96104/2023; EMA/MB/226451/2023; EMA/239258/2023] The Management Board endorsed the mandates of the EU Network Data Board & joint HMA/EMA Big Data Steering Group. The Board also noted the updated mandate of the DARWIN EU ® Advisory Board.

These mandates were reviewed by relevant parties and minor amendments were implemented to provide clarity regarding the scope, allocation of responsibilities, composition, and stakeholder engagement approach of both entities. The EU Network Data Board leads on data standards, and responsibilities pertaining to data and its utilisation, with the goal of maximising value for the EU/EEA regulatory agencies. Its participation is primarily for EU Member States. The Big Data Steering Group primarily focuses on analysing various types of data, including real-world data and raw data from clinical trials, as well as employing advanced analytics, such as artificial intelligence. The Heads of Medicines Agencies (HMA) had endorsed the mandates already at its meeting in May 2023 and the mandates were now also presented to the EMA Management Board for endorsement.

• Report from the Big Data Steering Group (BDSG), including, the experience with Real World Evidence (RWE) studies

The BDSG co-chair presented a report summarising the experience gained in conducting RWE studies since the launch of the proof-of-concept interactions with PDCO, COMP, CAT, CHMP and SAWP in September 2021 up to 7 February 2023. This review was conducted to understand the needs of EU decision makers regarding real-world evidence (RWE), evaluate the current EMA-RWE framework's capacity to meet those needs, assess the value of provided RWE, review available sources and pathways for real-world data (RWD), and identify opportunities for process improvements in receiving and conducting RWE studies. The findings will inform enhancements to better serve EU decision makers and improve the overall effectiveness of the system. The report also presents learnings and recommendations to further enable the use of RWE and support EU network decision-making, including the extension of RWE in the future via national data sources to provide a comprehensive EU network perspective. These recommendations will be considered by the Big Data Steering Group and the DARWIN EU ® Advisory Board.

EMA assured the Board that several quality control and assurance processes were in place, both internally and externally, including through framework contractors. To ensure transparency, all studies will be implemented in the European Union electronic Register of Post-Authorisation Studies (EU PAS

Register). A Board member raised a question regarding EMA's consideration of using AI for these studies. EMA explained that a draft reflection paper on AI in medicines regulation is currently being finalised, which will cover AI through the lifecycle of a medicinal product.

B.10 Clinical Trials in the EU

a) Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/238743/2023; EMA/MB/238741/2023] The Management Board noted a progress report on the operational advancements and recent enhancements made to the Clinical Trials Information System (CTIS) in accordance with the EU Clinical Trials Regulation.

The monthly volume of clinical trials submissions through the CTIS continues to rise. The Board acknowledged the launch of a public consultation in May 2023 aimed at reviewing the transparency rules concerning the disclosure of information regarding clinical trials submissions in CTIS. Additionally, the Board expressed appreciation for EMA's endeavours to involve stakeholders through planned public events and workshops in 2023, as well as their commitment to assisting CTIS users through training sessions, events, and the dissemination of relevant materials.

A presentation on the Member States' perspective of CTIS implementation was presented by the member from Sweden who concluded that collaboration in the Network as well as continued stakeholder dialogue remain key for the smooth transition.

b) Update on Accelerating Clinical Trials in the EU (ACT EU)

The member from Sweden, on behalf of the ACT EU Steering Group (ACT EU SG) chair, reported on the progress on the ACT EU focus areas for 2023. A closed workshop on clinical trials in public health emergencies will be held on 9 June and the kick-off workshop of the ACT EU multi-stakeholder platform will take place on 22-23 June. This workshop will propose a model for the ACT EU multi-stakeholder platform and advance discussions on priority topics identified by stakeholders. Another focus area is linked to supporting the successful implementation of the Clinical Trial Regulation and one of the main activities include the public consultation on the review of CTIS transparency rules with a deadline of 28 June 2023.

B.11 Beating Cancer

- **Cancer Medicines Forum (CMF) – presentation by the representatives of doctors' organisations**
- **Cancer medicines as pathfinder – EMA initiatives**

The Management Board noted an update by EMA and the representative of doctors' organisations on complementary activities supporting the research, development and authorisation of cancer medicines.

EMA provided a short overview of the challenges in the oncology area, such as complex evidence generation, and the ongoing initiatives to address these challenges. In 2023, EMA set cancer as a pathfinder to optimise, under the current legal framework, the way in which the EMA's committees asses complex medicinal products. This 'pathfinder' initiative focuses on the following three areas: optimal application of existing collaboration and regulatory tools, support to the network by building capacity and increasing the quality of the scientific assessments, supporting relevant evidence

generation, including through the use of real-world evidence, pragmatic trials, guidance on patient-focused drug development and the Cancer Medicines Forum with academia.

The representative of doctors' organisations presented on the EMA's Cancer Medicines Forum, of which the European Organisation for Research and Treatment of Cancer (EORTC) is a member. The objective of the Cancer Forum, which was created in March 2022, is to identify research questions which are critical for doctors. Examples include treatment optimisation studies, discussion on the uptake of academic trials and their contribution to regulatory decision making. More generally the forum provides an opportunity for academic organisations to better support the work of regulators. He further explained the concept of Treatment Optimisation which refers to a field of research that aims to answer questions for clinicians on the real-life use of authorised medicines. Treatment optimisation can lead to decreased side effects and significant savings for healthcare systems but may be of very limited interest for commercial sponsors. One example of a treatment optimisation clinical trial funded by the EC and run by EORTC members demonstrates the usefulness of robust clinical research in the post approval phase (DE-ESCALATE addresses dose de-escalation of anti-androgene treatment for prostate cancer); another example is the MOIO study addressing the schedule of immunotherapy across tumors. This exemplifies that such trials must be enabled by society, in the best interest of the patients . Several recommendations for future activities on treatment optimisation by the Cancer Medicines Forum were presented, and a plea for more supranational funding and more multi-disciplinary discussion on treatment optimisation studies was made by the representative of the doctors' organisations.

Members acknowledged the challenges for clinicians regarding treatment optimisation and the representative of doctors' organisations suggested doing more and faster trials, e.g. pragmatic trials. The representative of the European Parliament inquired about options to inform patients more and to increase the communication on optimisation trials. The DG R&I representative suggested creating a matrix mapping of the research answers needed and where public funding is most urgently required. Another update on cancer medicines will be provided to the Board at a future meeting.

B.12 Report from the CHMP Chair

The Board noted an oral update from the chair of EMA's Human Medicines Committee (CHMP) on recent achievements and ongoing challenges for the committee. . Specifically, the Chair focused on the lessons learned by the CHMP following the COVID-19 pandemic and acknowledged that the pandemic exerted significant pressure on the medicines regulatory system but was ultimately a success story for EMA, the CHMP, regulatory network, and the overall EU system. The CHMP chair highlighted three key accomplishments to that success: the scientific quality of the assessments, the efficiency of the procedures, which enabled the Committee to recommend the approval of treatments and vaccines that played a vital role in the global fight against COVID-19, and effective professional communication.

Looking ahead, the Chair of the CHMP emphasised the importance of artificial intelligence, real-world data and real-world evidence as essential tools in the regulatory landscape, presenting both challenges and opportunities. Additionally, the Chair also highlighted the need to enhance network capacity. Future-proofing the system to address these challenges was stressed, which includes prioritising education and training, improving communication and collaboration among various groups, and maximising the use of EU clinical experts to broaden the pool of available expertise.

The Chair highlighted Oncology European Specialised Expert Community's (ESEC) crucial role in addressing network capacity issues through upskilling and training the EMRN, as well as the need for collaborative efforts to streamline and enhance current processes. Retention of expertise was

emphasised due to high turnover of committee members and experts, as well as the need to ensure adequate experts' remuneration at national level.

The Board expressed appreciation for the Committee's outstanding work during the pandemic, commending the Chair for the Committee members' unwavering commitment. The Board acknowledged the importance of enhancing network capacity and optimising the use of external experts, including academia, and enquired about the ongoing pilot project using additional external expertise. The Chair explained that the Lead NCA Rapporteur, with support of EMA, will be responsible for the selection, of any external experts to be involved in the assessment teams for EMA procedures. The declaration of interests process will apply to such experts and renumeration will be determined on a case-by-case basis according to the fee sharing scheme submitted by the Lead NCA. The pilot project, focusing on oncology, was agreed by the Management Board in December 2022 and the outcomes will be shared at the December 2023 meeting for the Board to assess the feasibility of extending this initiative.

List of written procedures during the period from 09 March 2023 to 02 June 2023:

- During the period from 09 March 2023 to 01 June 2023, the Board was consulted 9 times via written procedure, of which 4 consultations concerned membership in the CHMP and CVMP, and 5 additional consultations, as listed below:
- Consultation no. 02/2023 on the appointment of Petr Vrbata as CHMP alternate as proposed by Czechia ended on 13 March 2023. The mandate of the nominee commenced on 14 March 2023.
- Consultation no. 03/2023 on the appointment of Andreja Kranjc as CHMP alternate as proposed by Slovenia ended on 28 April 2023. The mandate of the nominee commenced on 29 April 2023.
- Consultation no. 04/2023 on the appointment of Renāte Kušķe as CVMP alternate as proposed by Latvia ended on 01 May 2023. The mandate of the nominee commenced on 02 May 2023.
- Consultation no. 05/2023 on the appointment of Carolina Prieto Fernández as CHMP alternate as proposed by Spain ended on 10 May 2023. The mandate of the nominee commenced on 11 May 2023.
- Consultation procedure for the adoption of the minutes of the 118th Management Board meeting, held on 14-15 December 2022 ended on 30 March at 12:00hrs (CEST). The procedure was adopted.
- Consultation procedure for a favourable opinion of the Rules of Procedure of the Executive Steering Group on Shortages of Medical Devices (the 'Medical Device Shortages Steering Group – MDSSG') ended on 06 April at 12:00hrs (CEST). The procedure was adopted.
- Consultation procedure for the adoption of the Revision of Fee Implementing Rules ended on 26 April, at 12:00hrs (CEST). The procedure was adopted.
- Consultation procedure for the endorsement of the 3rd report on the performance of pharmacovigilance tasks by the EU Member States and the EMA (2019-2022) ended on 02 May at 12:00hrs (CEST). The procedure was adopted.
- Consultation procedure for the adoption of the minutes of the 119th Management Board meeting, held on 16 March 2023. The consultation will end on 08 June 2023 at 08:00hrs (CEST).

Documents for information

- Feedback from the Heads of Medicines Agencies
- [EMA/MB/106869/2023] Outcome of written procedures during the period from 09 March 2023 to 02 June 2023
- [EMA/MB/240843/2023] Summary of implementation of assigned revenue
- [EMA/1016/2023] Security Policy (Policy 0076)

List of participants at the 120th meeting of the Management Board, held in Amsterdam, 7-8 June 2023

Chair: Lorraine Nolan

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	*Apologies received from Bulgaria*
Czechia	*Apologies received from Czechia*
Croatia	*Apologies received from Croatia*
Denmark	Lars Bo Nielsen *(member)* Mette Aaboe Hansen *(alternate)* Birgitte Faber *(observer)*
Germany	*Apologies received from Germany* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk *(member)*
Ireland	Rita Purcell (alternate)
Greece	Filippou Dimitrios *(member)*
Spain	Consuelo Rubio Montejano *(alternate)* *Sonia Garcia*
France	Christelle Ratignier-Carbonneil *(member)* Frank Foures *(alternate)* Miguel Bley *(observer)*
Italy	Francesco Trotta *(alternate)*
Cyprus	Helena Panayiotopoulou *(member)* Irini Chrysafi Fanidou *(alternate)*
Latvia	Indra Dreika *(member)* Sergejs Akuličs *(alternate)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)*
Hungary	Mátyás Szentiványi *(member)* Beatrix Horváth (alternate)
Malta	John Joseph Borg *(alternate)*
Netherlands	Paula Loekemeijer *(member)* Aimad Torqui *(alternate)* Roelie Marinus *(observer)*
Austria	Günter Waxenecker *(member)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)*
Portugal	Rui Santos Ivo *(member)* Maria João Morais *(observer)*
Romania	Razvan Prisada *(member)*
Slovakia	Peter Potúček *(member)*
Slovenia	Momir Radulović *(member)*
Finland	Eija Pelkonen *(alternate)*
Sweden	Björn Eriksson *(member)*

	Participants
	Åsa Kumlin Howell *(alternate)*
European Parliament	Karin Kadenbach
European Commission	Irene Norstedt (DG RTD) *(alternate)* Tomasz Dylag (DG RTD) *(observer)* Martina Ciccarello (DG SANTE) *(observer)* Marco Capellino (DG SANTE) *(observer)*
Representatives of patients' organisations	Virginie Hivert
Representative of doctors' organisations	Denis Lacombe
Representative of veterinarians' organisations	Despoina Iatridou
EEA-EFTA states	Rúna Hauksdóttir Hvannberg (Iceland) Vlasta Zavadova (Liechtenstein) Audun Hågå (Norway)

Guest speaker	Harald Enzmann (CHMP Chair) Florian Schmidt (DG SANTE)

European Medicines Agency	Emer Cooke Ivo Claassen Stefano Marino Nerimantas Steikūnas Anthony Humphreys Alexis Nolte Melanie Carr Peter Arlett Hilmar Hamann Zaide Frias Steffen Thirstrup Franck Diafouka Hilde Boone Martin Harvey Allchurch Karl Hamilton Francesco Pignatti Paola Samassa Marie-Agnes Heine Rebecca Harding Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin