13 December 2023
EMA/MB/490331/2023 - Adopted
Management Board

Minutes of the 121st meeting of the Management Board

Amsterdam, 5 October 2023

The Chair of the Management Board opened the meeting, which was held as a virtual meeting. The Chair welcomed the new members and alternates for Belgium Mr Hugues Malonne (Chief Executive Officer of Belgian, Federal Agency for Medicines And Health Products) and Mr Charles Denonne (Head Of International Relations Division, Federal Agency for Medicines And Health Products), for Czechia Ms Katerina Podrazilova (Director of Czechia State Institute For Drug Control), for Hungary Ms. Rita Pálffy-Poór (Deputy Medical Chief Officer of Hungarian National Centre For Public Health And Pharmacy) and for Finland Ms Anna Siira (Director of Marketing Authorisations at Finnish Medicines Agency).

The Chair and the Board took a moment to acknowledge and pay tribute to the late former Deputy Executive Director of the Agency, Mr Noël Wathion, who passed away in August.

1. Draft agenda for the 5 October 2023 meeting

[EMA/MB/308874/2023] 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 'EMA HR Strategy'. 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 120th meeting, held on 7-8 June 2023 adopted via written procedure

[EMA/MB/257775/2023] The Management Board noted the final minutes, adopted by written procedure ending on 21 August 2023.

The Management Board were informed and agreed to the final composition of the Management Board Audit and Risks Group (MBARG). The MBARG members are Anna Chioti (Luxembourg), Rita Purcell (Ireland). Momir Radulovic (Slovenia), Denis Lacombe (representatives of doctors' organisations) and Virginie Hivert (representatives of patients' organisations).

4. Update on 30 Churchill Place

The Board was updated [redacted] on the latest developments regarding the former EMA premises in London (30 Churchill Place), in particular the financial situation of EMA's sub-tenant WeWork. [redacted] Heightened concerns were expressed regarding WeWork's increasingly precarious financial position, prompting a thorough examination of the necessary steps EMA might need to take. Furthermore, EMA informed the Board that WeWork has onboarded advisors in real estate and restructuring who will engage with their landlords globally, including EMA. WeWork and their advisors will explore reviewing, renegotiating or terminating existing leases across many countries. The Agency is awaiting a written position from WeWork's advisors regarding their intentions with 30 Churchill Place. EMA highlighted the deterioration of the situation, and the potential budgetary implications for the upcoming year 2024, particularly if WeWork would not comply with the upcoming rent payments, which for Q1-2024 is due in December 2023. This scenario will require financial support from the European Commission. [redacted]

[redacted] The need for a political resolution has been continuously stated in the Agency's yearly annual activity reports and the relevant Management Board assessments. [redacted] Board members were concerned about the continued financial risks in the future. In addition significant concerns were expressed once again about the Agency being compelled to assume the role of a commercial landlord, diverting attention from its public health mandate. [redacted] The representative of DG SANTE acknowledged the considered challenge presented for the Agency, while appreciating the efforts made, which was echoed by other Board members, and stated that the Commission would support the Agency going forward.

The Chair proposed to nominate Topic Coordinators to assist and support the Agency as discussions continues with WeWork. [redacted]

A. Points for automatic adoption/endorsement

There were no items included under this agenda item.

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. This included a high-level summary of the report on lessons learned from the COVID-19 Public Health Emergency (PHE), which will be shared with the Board for endorsement bya written procedure after the meeting. The Board was also briefed on EMA's latest actions in addressing shortages of medicines and medical devices. The joint efforts of the HMA/EMA Task Force to compile a list of critical medicines for the EU were highlighted. To ensure sufficient supplies of antibiotics, in particular to prepare for the upcoming winter season, the Medicine Shortages Steering Group (MSSG) have issued recommendations for pro-active actions and EMA and DG HERA are monitoring supply & demand and engaging with relevant marketing authorisation holders.

The presentation also highlighted some EU institutional and international activities. Reference was made to the upcoming annual hearing of EMA's Executive Director at European Parliament's ENVI committee and the recent visit of Dutch Minister of Health, Welfare and Sports. The Agency also acknowledged the provisional agreement between the European Parliament and the Council on the EMA Fees Regulation.

The Board was informed of EMA's support for establishing the African Medicines Agency, the commemoration of the 20th anniversary of the DG SANTE/EMA confidentiality arrangement with the United States Food and Drug Administration (US-FDA), the International Coalition of Medicines Regulatory Authorities (ICMRA) summit and plenary meeting in Melbourne in November 2023 and the next phase of the Instrument for Pre-accession Assistance (IPA) programme.

An update on the European Medicines Agencies Network Strategy (EMANS) to 2025 was provided, in particular the intention to prepare a mid-point report highlighting key achievements from January 2021 to July 2023, and to prepare a review and revision of EMANS to 2028. An EMA-HMA drafting group was established for this purpose. The Board was also informed about the relaunch of the clinical data publication for new active substances authorised from September 2023.

Finally, 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 Agency has formally submitted a derogation request to DG HR proposing more flexibility towards teleworking from abroad, for the Agency by retaining and attracting the best talent from the competitive and flexible employment market in which it operates. The Agency's request had been supported by a majority of Management Board members via the written procedure. The representative of DG SANTE recognised the particular situation of the Agency. However, she noted that the EU Staff Regulations which also apply to the Agency, and require EU staff members to reside in the place of employment (as per Article 20 of the Staff Regulations). Therefore, the Commission cannot support the Agency's request for a derogation with regard to ta higher number of teleworking days outside the place of employment. The Executive Director confirmed that the Agency has at all times implemented Article 20 and that the requested derogation for additional teleworking from abroad captures the exceptional situation of the Agency and reflects the needs of its staff.

The German Board member (who is also the Chair of the HMA Management Group) informed that comments from the HMA on the EMA-HMA COVID-19 lessons learned report are being consolidated and will be provided shortly.

B.2 Report from the European Commission

The Board noted an update from the representative of DG SANTE on: status of the legislative procedure on the reform of the pharmaceutical legislation and preparation of supporting implementing legislation; the Joint Action "capacity building of the EU medicines regulatory network" which is planned to start on 1 January 2024; the recent recognition by US FDA of 30 veterinary inspectorates in the EU under the EU-US Mutual Recognition Agreement on pharmaceutical GMP inspections; the preparation of a new Commission communication on availability of medicines and security of supply; the implementation of the ECJ judgment on Tecfidera; the status of legislative procedure on the regulation for a European Health Data Space (EHDS); and the upcoming project 'COMBINE' led by DG SANTE to clarify the interplay between CTR, MDR and IVDR as regards the authorisation of clinical trials of medicines with medical devices and in-vitro diagnostics.

Members of the Board asked about the timeline for the finalisation of the new EMA fees regulation, following the provisional political agreement on 25 September, for clarifications on the process for the revision of Annex I of the Directive EU 2001/83 and for the preparation of the upcoming Commission Communication on shortages. Questions were also asked on the next steps for the implementation of the ECJ judgment on Tecfidera. The representatives of veterinarians' organisations and doctors' organisations inquired respectively about progress on implementing legislation for Regulation EU 2019/6 and on interplay between the 'COMBINE' project and the ACT-EU programme. The representative of DG SANTE provided clarifications on all these questions.

The Board noted an update from the representative of DG RTD on the work of the EU research partnerships in support of the ACT-EU objective of streamlining the organisation of clinical trials during public health emergencies. This work is to be carried out by two EU partnerships under the Horizon Europe programme: the European Research Area for Health (ERA4Health) and the Pandemics Preparedness Partnership. Under ERA4Health, in whose Advisory Body EMA is participating, calls for proposals to support multinational academic clinical studies are in preparation and the European Commission is working in parallel to improve coordination of national research programmes for financing multi-national clinical trials and for accelerating ethics committee approval during public health emergencies. The Pandemics Preparedness Partnership could be added to the Horizon Europe work programme 2024 and start operating in 2025. It will focus on establishing and supporting an "ever-warm" network of clinical trials sites able to quickly "pivot" to study medical countermeasures in response to a public health emergency.

Members of the Board asked for clarifications on the work to improve coordination of national research programmes for multi-country clinical trials, in particular whether this will fall under the ACT-EU umbrella and whether any support from the Board and the Heads of Medicines Agencies would be needed. They also inquired about the type of EU funding that could be provided for ever-warm investigator networks. The representative of DG RTD explained that this work is formally outside the ACT-EU umbrella but will connect to it. The European Commission is currently co-funding by 30%, but DG RTD hopes to be able to increase to 50% in future. She welcomed the offer by Board members to better support at national level the use of national research programmes to fund multi-country clinical trials, recognising that this objective has also an important political and international dimension. At global level, regional clinical trials networks are being promoted by the European Commission in Sub-Saharan Countries, Latin America and Asia and will be crucial for better preparedness in case of a new pandemic.

B.3 EMA Mid-year report 2023 from the Executive Director (January – June 2023).

[EMA/343593/2023, EMA/MB/428476/2023] The Board noted the EMA mid-year report 2023 from the Executive Director.

The report provides an overview of the Agency's performance and achievements in implementing the work programme 2023 during the first half of the year, with detailed analyses of workload trends, budgetary performance, and staffing dynamics. In the first half of 2023, the EMA and the European medicines regulatory network (EMRN) lifted COVID-19 business continuity measures following the WHO's declaration that COVID-19 was no longer a public health emergency. The presentation also highlighted EMA's achievements and results in various areas, including antibiotics shortage prevention in collaboration with DG HERA, continued work on veterinary legislation implementation, antimicrobial resistance, and digital innovations. The DARWIN EU® network completed its first year, already showing some tangible benefits of real-world data studies. Some other EMA initiatives comprise of cloud migration and the implementation of the Scaled Agile Framework. In the first half of 2023, the Court of Justice ruled in EMA's favour on three significant cases: "Tecfidera," "Aplidin," and "Hopveus."

The presentation also focused on key figures from the reports. A 26% decrease in scientific advice and protocol assistance requests compared to the corresponding period last year was noted. Positive growth in specific areas was also highlighted with applications for biological products having more than doubled, reaching nine submissions by mid-2023 compared to four in 2022. There was also an uplift in initial evaluation applications for veterinary medicines, rising from nine in 2022 to fifteen in 2023. Inspections saw increases in GMP inspections and plasma master file inspections. Reintroduction of face-to-face meetings and adjustments in information and transparency activities were noted, as well as increased access to documents requests.

The Board questioned the decrease in scientific advice requests and potential reasons for this. The Agency intends to closely monitor this trend to discern whether this signifies a consistent pattern or is a normal fluctuation, considering that application volumes typically vary throughout the year. Unlike previous years, the Agency no longer anticipates a significant influx of COVID-19-related scientific advice requests. One Board member suggested that the report should consider factors contributing to procedural delays, specifically emphasizing the punctuality of the submission by applicants that may be affecting the KPIs. Another Board member was pleased to see that three court cases received positive feedback from Court of Justice.

B.4 EMA HR Strategy

[EMA/405736/2023, EMA/MB/340866/2023] The Board endorsed the EMA Human Resources (HR) Strategy. To uphold the Agency's mission amid the evolving post-COVID-19 landscape, addressing emerging technological trends and workforce challenges, a targeted new Human Resources (HR) Strategy had been prepared. This strategic plan builds on the efforts made in the past few years and outlines additional key actions to be taken from 2023 to 2025. The focus is on attracting, retaining, and developing top talent, all while establishing a sustainable organisation that addresses both present and future requirements of the agency and its workforce. The strategy takes into account the HR strategy of the Commission, and the EU ambitions outlined in the communication on the European Year of Skills.

A Board member inquired about the Agency's strategies for enhancing organisational and team connectivity, given the growing prevalence of remote work and the emerging trends observed in national agencies. EMA explained that to enhance team connections amid the rise in remote work, the HR strategy focuses on balanced flexible work arrangements, a supportive environment, on site and

remote team collaboration and employee well-being. Weekly in-person office collaborations and a modern, sustainable workspace reinforce team cohesion. Emphasising diversity and inclusion values, coupled with the Agile approach, the Agency empowers managers to lead effectively and foster a connected work environment, even in remote settings.

B.5 Clinical Trials in the EU

a) Report to the Management Board on ACT EU, the operation of CTIS and the Clinical Trial Regulation

[EMA/MB/410694/2023, EMA/265440/2023] 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. Since January 31 2023, over 1,700 initial clinical trials have been submitted at an average rate of 210 per month. This builds on improved system performance and a reduction in critical issues. The current risk mitigation and monitoring are at Level 1, in accordance with the plan. The Board commended EMA for its continuous endeavours in assisting stakeholders through workshops, training sessions, and consistent communication.

EMA presented on behalf of the ACT EU Steering Group and provided a progress update on the ACT EU priority actions for 2023, in particular on the outcome of the Multi-Stakeholder Platform (MSP) kick-off meeting in June 2023 and the formation of the MSP Advisory Group. The presentation also highlighted the key priorities of the ACT EU workplan for 2023-2026 which were endorsed by the ACT EU Steering Group and incorporate feedback received during MSP kick-off workshops in June 2023.

A presentation on the Member States' perspective of CTIS implementation was presented by the member from Sweden who highlighted that collaboration at the Network level remains crucial as CTIS submissions for initial trials exceed 1300, and revised transparency rules, supported by stakeholders, aim to create a sustainable public portal.

b) Revised CTIS Transparency rules

[EMA/MB/263067/2023] The Management Board adopted revised transparency rules for the publication of information on clinical trials submitted through the Clinical Trials Information System (CTIS).

The updated rules aim to provide faster and more efficient access to clinical trial information for stakeholders, including patients and healthcare professionals. Key changes include eliminating the deferral mechanism, ensuring early publication of vital trial data useful to patients, simplifying processes for sponsors while striking a balance between transparency and protecting confidential information. The changes were prompted by stakeholder feedback and experience after the launch of the system. These revised rules will come into effect after technical implementation in CTIS, with an expected completion date in the second quarter of 2024. Users will be informed of the effective date before implementation.

Several Board members echoed the unanimous support of the Board for the new transparency rules and conveyed their appreciation for the consultation with patient and healthcare professional organisations. The Chair also extended gratitude for the valuable input from DG-SANTE in this collaborative endeavour.

B.6 Report from the Big Data Steering Group (BDSG)

The BDSG co-chair provided a progress report the Big Data Steering Group, covering updates on membership and the workplan, DARWIN EU® advancements, ongoing and planned Artificial

Intelligence activities, and details about the upcoming 4th annual multi-stakeholder Big Data Forum. The recently adopted 4th joint HMA-EMA Big Data Steering Group workplan, spanning until 2025, aligns with the Network Strategy to 2025. With regards to DARWIN EU®, EMA is looking for additional data partners with access to real-world healthcare data. The Board noted that EMA is in the process of creating two new public catalogues with a release date in Q1-2024: one for real-world data sources and another for non-interventional studies.

An outline of the draft reflection paper on the use of artificial intelligence (AI) in the lifecycle of human and veterinary medicines was presented to the Board. A public consultation on the paper is currently ongoing until 31 December 2023. The Board were also informed that an AI workplan was being developed by the BDSG and will be presented at the December MB meeting.

B.7 Agile transformation and Portfolio status report

[EMA/MB/432961/2023, EMA/415215/2023] The Board noted the Portfolio Report to the Network, outline the updates on the advancement of IT Programs and Projects, Agile Value Streams, and the supervision 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 for 'Monitoring' delivered a brief presentation outlining the vision and objectives established for the value stream from 2023 to 2025. This included insights on the collaboration model within the network, the methodology for developing value plans, and an analysis of the benefits derived from the value stream.
The Board extended appreciation to all contributors and acknowledged the considerable impact it has had throughout the Network. During the discussion, a Board member noted a concern regarding the dashboard reporting, specifically highlighting a worsening risk level, particularly for Product Management Service (PMS) and Union Product Database (UPD). EMA is actively collaborating with the team, consistently aligning roadmaps to proactively address and mitigate the issue, to ensure readiness of European Shortages Management Platform (ESMP) in February 2025.

B.8 Establishing principles for external expert remuneration

[EMA/MB/427970/2023] The Board endorsed the principles to establish a framework to renumerate external experts as per Article 93 of EMA Financial Regulation.

As part of the actions of the HMA/EMA Task Force on resourcing, and to support the timely availability of highly qualified experts, EMA has looked into the possibility of additional measures to renumerate external experts in line with Article 93 of the EMA Financial Regulation. High-level principles to remunerate external experts were presented with use-cases where it could be applied, e.g. supporting training, remuneration of patients and healthcare professionals in EMA's work. Once the framework is endorsed by the Board, implementation will require a formal Executive Director's Decision. Implementation of the framework will be subject to budget availability.

A member of the Board inquired whether the renumeration would be case-specific or set by predefined criteria. Another Board member asked if NCA experts could apply to such assignments as external experts, and if Heads of NCAs would be consulted for their formal agreement in such cases. EMA clarified that a case-by-case approach with defined tasks and specific criteria would be developed, aiming for a well-structured process to allow the selection of the best available experts. NCA experts can only apply for tasks beyond those covered under the EMA-NCA cooperation agreement, and experts would also have to adhere to any national rules regarding additional activities beyond the NCA's designated responsibilities. The DG SANTE representative supported and endorsed the principle, contingent on budget availability and expressed caution about carefully defining tasks to avoid

payment duplication, considering the current double daily allowances for patient and healthcare professionals. EMA assured that the new principles would replace (and not duplicate) the current double daily allowances for patient and healthcare professionals. The patient organisations' representative expressed appreciation for the proposed principles and the Board's willingness to allocate budget to support patient and healthcare professionals' work in future.

List of written procedures during the period from 03 June to 26 September 2023:

During the period from 03 June to 26 September 2023, the Board was consulted 10 times via written procedure, of which 6 consultations concerned membership in the CHMP and CVMP, and 4 additional consultations, as listed below:

- Consultation no. 06/2023 on the appointment of Gergana Lazarova as CHMP alternate as proposed by Bulgaria ended on 28 July 2023. The mandate of the nominee commenced on 29 July 2023.

- Consultation no. 07/2023 on the appointment of Lyubina Racheva Todorova as CHMP member as proposed by Bulgaria ended on 24 July 2023. The mandate of the nominee commenced on 25 July 2023.

- Consultation no. 08/2023 on the appointment of Peter Mol as CHMP member as proposed by Netherlands ended on 25 July 2023. The mandate of the nominee commenced on 26 July 2023.

- Consultation no. 09/2023 on the appointment of Patrick Vrijandt as CHMP alternate as proposed by Netherlands ended on 25 July 2023. The mandate of the nominee commenced on 26 July 2023.

- Consultation no. 10/2023 on the appointment of Knud Torjesen as CVMP alternate as proposed by Norway ended on 21 July 2023. The mandate of the nominee commenced on 22 July 2023.

- Consultation no. 11/2023 on the appointment of Paolo Gasparini as CHMP alternate as proposed by Italy ended on 16 August 2023. The mandate of the nominee commenced on 17 August 2023.

- Consultation procedure for the adoption of the Agency's Final Accounts 2022 ended on 27 June 2023, at 12:00hrs (CET). The procedure was adopted.

- Consultation procedure for the adoption of the ETF composition for preparedness ended on 21 July 2023 at 12:00hrs (CET). The procedure was adopted.

- Consultation procedure for the adoption of the minutes of the 120th Management Board meeting, held on 7-8 June 2023 ended on 21 August 2023 at 12:00hrs (CET). The procedure was adopted.

- Consultation procedure for the adoption of the Decision of the EMA to request a derogation from Article 11(1) of Annex 1 of the Commission ex-ante agreement (2023) ended on 20 September 2023 at 17:00hrs (CET). The procedure was adopted.

Documents for information

C.1 Feedback from the Heads of Medicines Agencies

C.2 [EMA/MB/336972/2023] Outcome of written procedures finalised during the period from 03 June to 26 September 2023

C.3 [EMA/405323/2023] Summary of transfers of appropriations in budget 2023

C.4 [EMA/MB/222154/2023, EMA/222155/2023] Sixteenth six-monthly report on ex ante and retroactive evaluation of projects for the period 1 January to 30 June 2023

C.5 [EMA/1016/2023] EMA Security policy

List of participants at the 121st meeting of the Management Board, held in Amsterdam, 5 October 2023

Chair: Lorraine Nolan

	Participants
Belgium	Hugues Malone *(member)* Charles Denonne *(alternate)*
Bulgaria	Bogdan Kirilov *(member)*
Czechia	Katerina Podrazilova
Croatia	Siniša Tomić *(member)*
Denmark	Lars Bo Nielsen *(member)* Mette Aaboe Hansen *(alternate)* 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)* Sonia García Pérez *(observer)*
France	Christelle Ratignier-Carbonneil *(member)* Frank Foures *(alternate)* Miguel Bley *(observer)*
Italy	Francesco Trotta *(alternate)*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Indra Dreika *(member)* Sergejs Akuličs *(alternate)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)* Marcin Wisniewski *(alternate)*
Hungary	Rita Pálffyné-Poor *(member)* Beatrix Horváth (alternate)
Malta	Anthony Serracino Inglott *(member)* John Joseph Borg *(alternate)*
Netherlands	Paula Loekemeijer *(member)* Aimad Torqui *(alternate)* Roelie Marinus *(observer)*
Austria	Jan Neuhauser *(alternate)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)*
Portugal	Rui Santos Ivo *(member)*
Romania	Razvan Prisada *(member)*
Slovakia	Peter Potúček *(member)* Katarína Massányiová *(alternate)*
Slovenia	Momir Radulović *(member)*
Finland	Eija Pelkonen *(member)* Anna Siira *(alternate)*
Sweden	Björn Eriksson *(member)*

	Participants
	Åsa Kumlin Howell *(alternate)*
European Parliament	Karin Kadenbach
European Commission	Olga Solomon *(alternate)* Irene Norstedt (DG RTD) *(alternate)* Tomasz Dylag (DG RTD) *(observer)* Martina Ciccarello (DG SANTE) *(observer)*
Representatives of patients' organisations	Virginie Hivert *(member)* Marco Greco *(member)*
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)

European Medicines Agency	Emer Cooke Ivo Claassen Stefano Marino Nerimantas Steikūnas Anthony Humphreys Alexis Nolte Peter Arlett Hilmar Hamann Zaide Frias Steffen Thirstrup Franck Diafouka Hilde Boone Martin Harvey Allchurch Michael Lenihan Nathalie Rampal Olmedo Juan García Marie-Agnes Heine Laura Pioppo Pedro Pina Ferreira Rebecca Harding Salvador Ruíz Carrillo Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin