8 June 2023
EMA/MB/225645/2023 corr.[1] - Adopted
Management Board

Minutes of the 119th meeting of the Management Board

Held virtually on 16 March 2023

The Chair of the Management Board opened the meeting, which was held as a virtual meeting. The Chair welcomed the new member for Italy, Mr Guido Rasi (Advisor to the Minister of Health, Ministero della Salute), the alternate for Slovakia, Ms Katarina Massanyiova (Director, Institute for State Control of Veterinary Biologicals and Medicaments) and the alternate representing the European Commission DG SANTE Ms Olga Solomon (Acting Director, Medical Products and Innovation SANTE.D).

1. Draft agenda for 16 March 2023 meeting

[EMA/MB/948302/2022] The agenda was adopted with no amendments.

2. Declaration of competing interest related to current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning topics. The Secretariat informed the board that all concerned members had been informed before the meeting. Should the need for a vote on the above topics arise, the chair would take up the matter again.
Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

3. Minutes from the 118th meeting, held on 14-15 December 2022 to be adopted via written procedure

[EMA/MB/17597/2023] The Management Board noted that the final minutes will be circulated for adoption by written procedure. Post-meeting note: the minutes were adopted on 30 March 2023.

1 The correction is an update in the List of Participants (shown at the end of this document), to reflect restrictions for some members, as announced and applied at the time.

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A. Points for automatic adoption

A. Update on impact of inflation rate on delegate reimbursement rules

[EMA/MB/74833/2023; EMA/MB/279597/2018, rev.4] The Management Board adopted an update of the Rules for reimbursement of expenses for delegates attending EMA meetings to reflect the increase of the cost of living (e.g. transport, food, accommodation, etc) in Europe.

B.1 Highlights of the Executive Director

The Board noted an oral update covering an update on EMA's activities related to COVID-19 and on shortages, the visit of the European Parliament's ENVI committee to EMA, the signing of the Memorandum of Understanding on cooperation between EMA, DG SANTE and HERA, the commission decision for EMA to coordinate support for establishing the African Medicines Agency, progress of the HMA/EMA Tactical Group on resourcing, reactivation of the HMA/EMA Transparency working group and some recent work programme deliverables. The Board was also informed of the City of Amsterdam's proposals for the establishment of an Erotic Centre near the EMA premises.

It was agreed that a formal letter would be sent on behalf of the Management Board to the Mayor of Amsterdam to express the concerns of the Board on the proposed plans for the Erotic Centre in close proximity of the EMA premises. A query on the Tecfidera (dymethil-L-fumarate, DMF) case was raised. It was outlined that the Court of Justice had decided on that morning in favour of EMA and the Commission, setting aside the General Court's first instance ruling that had annulled EMA's decision to invalidate a generic DMF marketing authorisation. The Court found that the CHMP and the Commission did not make an error of assessment in 2014 when they concluded that the monocomponent Tecfidera did not belong to the same global marketing authorisation as the old nationally authorised fixed combination product, Fumaderm. After the first instance ruling and whilst waiting for this important judgment, some generic marketing authorisations were granted either centrally or at national level; the network will have to reflect now on the implications of this judgment on the status of those generic authorisations.

B.2 Report from the European Commission

The Board noted an oral update from the representatives of DG SANTE and DG Research and Innovation (DG RTD) on their latest activities with relevance to medicines development and regulation.

The representative of DG SANTE provided the Board with an update on the preparation of the reform of the EU general pharmaceutical legislation and on the revision of the EU orphan and paediatric legislations, outlining at a high level the objectives of the revision, the quantitative facts supporting the revision, the structure, and the main elements of the legal proposals under preparation. An update was provided on the EU actions to increase the availability of medicinal devices, including the extension of the transition period of the Medical Device Regulations under certain conditions. The briefing also included an update on the implementation of the Veterinary Medicines Regulation, with a focus on the preparation of the delegated and implementing acts which need to be in place by 2025.

In reply to questions on the revision of the pharmaceutical regulation concerning electronic product information and EMA's committees, the representative of DG SANTE explained that the intention was for Member States will have flexibility to decide on the paper format depending on needs at national

level; proposals for simplification of EMA's committees' structure and better use of scientific expertise at EMA will not have any impact on the rapporteur model, fees, and the principle of Member State representation in the main scientific committees that will be maintained. The concerns expressed by some MB members in relation to sales at a distance and on Article 106 of the Veterinary Medicines Regulation were noted. In response to questions on availability, supply and affordability the representative of DG SANTE clarified the revision will not go into pricing and reimbursement considerations, but it will act as enabler for regulators to link more closely with national downstream decision makers. The representative of healthcare professionals stressed the need for the new legislation to focus also on treatment optimisation.

The representative of DG RTD presented the findings published in *The Lancet* of a recent Horizon 2020 funded study on the role of genotype-guided treatment to reduce the incidence of adverse drug reactions in real-life healthcare. The Board were informed about a new Horizon Europe project to "Improve safety in polymedication by managing drug-drug-gene interactions" (SafePolyMed). The Board welcomed the presentation and agreed to have a more detailed discussion with DG RTD at the next MB meeting on the role of pharmacogenomics and how to roll out the findings of such EU funded studies in daily clinical practice. EMA informed that members of the new CHMP Working Party on Methodology and of the European Specialised Expert Community on Pharmacogenomics will be informed about the studies.

B.3 EMA Annual Report 2022

[EMA/MB/70226/2023; EMA/46734/2023] The Board adopted the EMA annual report 2022.

A short presentation was given on the main topics in the EMA Annual Report 2022, which focuses on the EMA's strategic priorities and the response to public health emergencies such as COVID-19 and monkeypox. Key figures for EMA's activities on human and veterinary medicines were presented for information. In addition to the traditional print-ready PDF version, EMA will publish an interactive digital version of the report, with an enhanced timeline of activities in 2022 with advanced functionalities that will allow readers to explore each topic in more depth through embedded additional audio-visual materials, infographics and videos.

B.4 2022 EMA Annual Report on Independence

[EMA/MB/88253/2023; EMA/2588/2023] The Board endorsed the 2022 EMA Annual Report on Independence.

The annual review report describes the initiatives taken in 2022 to implement the three independence policies (for scientific committees' members and experts, policy 0044; for Management Board members, policy 0058; and for EMA staff). These include the update of EMA's independence policies to reflect EMA's new responsibilities in the area of medical devices and EMA's reinforced role in crisis preparedness and management. Recommendations for further improvement in 2023 were also identified. In response to a question on how Board members can seek assistance with e-Declarations of Interests, EMA clarified that members can either contact the MB secretariat, use the experts database functional mailbox, or use the communication tool built in the new Experts Management Database planned to go live at the end of March 2023.

B.5 Revised implementing rules to the Fee Regulation as of 1 April 2023

[EMA/MB/700128/2022; EMA/MB/622516/2022] The Management Board adopted a revision of the Fee Implementing Rules coming into force as of 1 April 2023.

The revision concerned an increase in the levels of fees and the related remuneration to National Competent Authorities (NCAs) to adjust for the inflation rate of 10.4% for 2022; The Board was informed that a further Amendment to Annex V on the remuneration for ETF members appointed as coordinators in scientific advice procedures outside of a declared public health emergency would be circulated after the meeting for adoption via written procedure.

In reply to a question whether fee exemptions for academia and not-for-profit organisation are under consideration, EMA clarified that these exemptions are currently applied on a case-by-case basis and that the Agency is considering how to apply them more systematically.

B.6 Review of activities of the Working Parties of the EMA - Update from the MB Review Group

[EMA/MB/94231/2023] The Board noted an update from the Topic Coordinators of the Management Board Review Group (MBRG) on Working Parties, María-Jesús Lamas Díaz and Peter Potúček, on the progress of the second phase of implementation plan.

At the October Management Board meeting in 2022, an update on the implementation of phase 1, lessons learned from this and the preparations for phase 2 for the Quality Domain had been presented to the Board. As an agreed follow-up to that meeting, further discussions had taken place with the Chairs and Vice-Chairs of the BWP and QWP to clarify how the expertise-based model would be applied to the operations and future structures the Quality Domain. Additionally, an ad-hoc meeting of the MBRG had been organised in February 2023 to better understand and address concerns raised by some Board members. Recognising the principle of reconstituting the working parties as expertise-based structures, it was agreed that the QWP and BWP should be subject to a renomination process through CHMP members (and CVMP for QWP). Both working parties are to remain established and each to have a membership of minimum 30 members. In the event of a surplus of experts nominated, the principle of widest possible geographical spread (EU/EEA) would be adhered to. In addition, any members of the QWP and BWP European Specialised Expert Community (ESEC) will be allowed to listen in to each and any meetings of the QWP/BWP as they require. Following the March Board meeting, the implementation of the Quality domain with the proposed solution for membership of BWP and QWP will start with the call for experts at the end of the Q2-2023. It is envisaged that the quality domain will become operational as of September 2023.

A few Board members asked about the vet representation within the new model. The MBRG reassured the Board that there has been careful consideration on the representation of vet experts and the proposed membership of 5-6 members for quality of veterinary medicines had been considered sufficient based on past experience and contributions within the QWP.

B.7 3rd report on the performance of pharmacovigilance tasks by the EU Member States and the EMA (2019-2022) – update on status of preparation and next steps

[EMA/MB/87854/2023] The Management Board noted an update on the preparation by EMA of the third report on the performance of pharmacovigilance tasks by the EU Member States and the EMA from 2019 to 2022. An outline of the content of the report was presented which will contain figures on key pharmacovigilance activities (eg ADR reporting, PRAC activities on RMPs, Signals) as well as on specific activities such as pharmacovigilance of COVID-19 vaccines and therapeutics, analysis of the impact of pharmacovigilance measures, and use of real world evidence, including via DARWIN EU. As the report is still being finalised, it will be circulated for endorsement by the Board via written procedure at the end of April. Following endorsement by both the HMA and the Board, the report will be shared with the EMA graphic designers for layout enhancement, before being submitted to the European Commission and published on the EMA website.

B.8 Report from the CVMP Chair

The Board noted an oral update from the Chair of Committee for Veterinary Medicinal Products (CVMP) on the achievements of the committee and its current and future perspectives. Recent achievements include the scientific opinions given to the European Commission in preparation of the several Implementing and Delegated Acts required before 2022, and the provision of relevant guidance to industry to comply with the Veterinary Medicines Regulation, which consisted of updating or developing 39 Guidelines, 4 Reflection Papers, and 2 Q&A Documents. In 2022, CVMP adopted 11 positive opinions for new Marketing Authorisations, 2 MRL extensions and 28 scientific advices. As regards future perspectives, CVMP is working with EFSA on an advice requested by the European Commission on vaccination strategies, surveillance and risk mitigation measures against Highly Pathogenic Avian Influenza. Activities relating to antimicrobial resistance are numerous and will be focussed via the new European Sales and Use of Antimicrobials Working Group (ESUAvet WG) which is currently under creation and will contribute to developing JIACRA (joint inter-agency antimicrobial consumption and resistance analysis) reports, the mandatory collection of sales and use data under the new veterinary regulation and provision of advice to CVMP on AMR related matters. Activities to reinforce the scientific and regulatory capacity and capability of the network and stakeholder engagement are other important CVMP priorities.

The representative of veterinarians' organisations expressed appreciation for the CVMP's work in supporting innovation in animal health, noting that availability of veterinary medicines is also important for public human health protection. In response to a question regarding the membership of the ESUAvet WG, EMA clarified that all 27 MSs are represented, but if MSs still want to nominate additional experts they should be accepted. Following a question about the turnover rate in the CVMP, the Chair clarified, that, despite the limited availability of veterinary experts in the regulatory network, vacancies at CVMP have always been filled by MSs.

B.9 Update on Agile transformation and Network portfolio

[EMA/MB/94296/2023; EMA/93979/2023] 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. In terms of organisational changes, the board was informed that, since 16 January 2023, Zaïde Frias is the new Chair of the Portfolio Board and will co-chair Agile

Ceremonies (Quarterly Portfolio Sync and Strategic Portfolio Review) with Karl Broich as the HMA NPAG representative. The EMA noted the Portfolio Report shows that the transition to agile has positively impacted timelines in the delivery of several programmes and projects. The delivery of the new Experts Management Database was also highlighted as a major achievement in the current reporting period.

B.10 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/66824/2023; EMA/76948/2023] The Management Board noted a progress report on the implementation of IT systems (CTIS) required by the EU Clinical Trial Regulation (CTR).
The Board received an update on the recent operational experience with CTIS and on the latest improvements implemented in the system since its mandatory use on 31 January 2023. Over 320 clinical trials authorised under the CTR are available in the system. EMA also reported on the next steps, including upcoming system releases planned for the first quarter of 2023, and further improvements planned throughout 2023 aimed at enhancing the CTIS user experience. An update on the change management campaigns supporting implementation of the CTR were presented and the Board welcomed EMA's ongoing efforts to support sponsors and Member States CTIS users through trainings, information events and the publication of related materials. A presentation on the Member States' perspective of CTIS implementation was presented by the member from Sweden who concluded that the continued collaboration in the Network and continued stakeholder dialogue have been key for the smooth transition.

The Board acknowledged the progress made since the December and January ad-hoc meetings and expressed appreciation for all the work and the weekly updates on the improvements of the system. EMA is exploring how best to measure the performance of the service desk in order to strengthen its operation. The representative of doctors' organisations explained the issues for non-commercial trials and thanked EMA for the constructive approach to finding a workaround solution. EMA explained that the ACT EU Steering Group is planning in 2023 to launch a scheme to support academic sponsors conducting multi-national clinical trials.

B.11 Update on Accelerating Clinical Trials in the EU (ACT EU)

EMA provided an update on the initiative Accelerating Clinical Trials in the EU (ACT EU) and its key developments.

The main focus areas for the ACT EU Steering Group (ACT EU SG) in 2023 will be: the successful implementation of the Clinical Trials Regulation (CTR) including use of Clinical Trials Information System (CTIS); launch of a scheme to support academic sponsors conducting large multi-national clinical trial; creation of the multi-stakeholder platform; and revision of the workplan to take account of learnings on the network needs and priorities. ACT EU brings a change management focus that complements and supports implementation of the CTR. The Multi-Stakeholder Platform (MSP) will be a sustainable platform that enables all stakeholders to collaborate for better clinical trials. The main objectives and composition of the MSP were presented. The kick-off meeting of MSP is planned as a hybrid meeting from 22 to 23 June 2023. The representative of DG SANTE stated that there will be a need in the future to revise and improve the quality and usability of the KPI reports under priority action 2 to ensure the successful implementation of CTR. EMA confirmed that the focus is to optimise the reporting. The representative of DG RTD was pleased to see that further development of a scheme to promote larger, multinational trials specifically in the academic setting, will also be central to the work of this priority action.

B.12 Big Data Steering Group progress report

The Board noted the progress update from EMA co-chair of the Big Data Steering Group (BDSG) on the significant achievements of BDSG and key initiatives.

The main highlights for 2023 of the BDSG workplan were presented and an overview was given on the different trainings provided in 2023 on data protection, Real World Evidence (RWE) and data science. Following the set-up of the DARWIN EU® Coordination Centre in February 2022, the first ten data partners were onboarded, and the network also initiated its first four studies using real-world data (RWD). The first studies start to demonstrate the benefits of DARWIN EU® and results from these studies have been shared with EMA committees. The network will onboard ten additional data partners throughout 2023. Furthermore, DARWIN EU® is participating in a pilot for the European Health Data Space (EHDS), exploring the network's role as a research and data node. In February 2023, the newly established Methodology Working Party (MWP) published its first workplan. The MWP is also establishing a methodology ESEC to build capability and capacities across the spectrum of methodology domains. ESEC will work closely with both the BDSG and the ACT EU SG to ensure training, communication and stakeholder engagement are streamlined and effective. The EU veterinary big data team is progressing its work taking into account the recommendations and conclusions from the 2nd Veterinary Big Data Stakeholder Forum in November 2022. Additionally, the EU veterinary big data discussion is moving from vision to action with the transposition of the European Veterinary Big Data strategy's 2022-2027 pillars into actionable workstreams.

List of written procedures during the period from 06 December 2022 to 08 March 2023:

- Consultation no. 13/2022 on the appointment of Hanne Bremer as CVMP alternate as proposed by Sweden ended on 04 January 2023. The mandate of the nominee commenced on 05 January 2023.
- Consultation no. 14/2022 on the appointment of Beata Maria Jakline Ullrich as CHMP alternate as proposed by Hungary ended on 04 January 2023. The mandate of the nominee commenced on 05 January 2023.
- Consultation no. 01/2023 on the appointment of Larisa Gorobets as CHMP alternate as proposed by Lithuania ended on 06 March 2023. The mandate of the nominee commenced on 07 March 2023.
- Consultation procedure for the adoption of the MB Decision on rules concerning the handling of declared interests of EMA staff and candidates before recruitment ended on 06 February 2023 at 18:00hrs (CET). The procedure was adopted.
- Consultation procedure for the endorsement for extending the MNAT concept to the post-authorisation 2nd phase ended on 07 February 2023. The procedure was adopted.

Documents for information

- [EMA/MB/948919/2022] C.1 Outcome of written procedures finalised during the period from 06 December 2022 to 08 March 2023
- C.2 Feedback from the Heads of Medicines Agencies
- [EMA/MB/66824/2023; EMA/900566/2022] C.3 2022 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2022
- [EMA/MB/26674/2023; EMA/26675/2023] C.4 Fifteenth six-monthly report on ex ante and retroactive evaluation of projects for the period 1 July to 31 December 2022
- [EMA/MB/72500/2023 EMA/71459/2023] C.5 EMA working document on buildings
- [EMA/MB/99789/2023] C.6 Summary of transfers of appropriations in budget
- C.7 ECA Annual report on EU agencies for the financial year 2021

List of participants at the 119th meeting of the Management Board, held in Amsterdam, 16 March 2023

Chair: Lorraine Nolan

	Participants
Belgium	*Apologies received from Belgium*
Bulgaria	Bogdan Kirilov *(member)*
Czechia	Irena Storová *(member)*
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	Filippou Dimitrios *(member)*
Spain	María-Jesús Lamas Díaz *(member)* Consuelo Rubio Montejano *(alternate)*[2]
France	Christelle Ratignier-Carbonneil *(member)* Frank Foures *(alternate)* Miguel Bley *(observer)*
Italy	Guido Rasi *(member)* Francesco Trotta *(alternate)*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Sergejs Akulics *(member)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)* Marcin Wisniewski *(alternate)*
Hungary	Mátyás Szentiványi *(member)* Beatrix Horváth (alternate)
Malta	Anthony Serracino-Inglott (*member)* John Joseph Borg *(alternate)*
Netherlands	Paula Loekemeijer *(member)* Aimad Torqui *(alternate)*[2]
Austria	Christa Wirthumer-Hoche *(member)* Günter Waxenecker *(observer)*
Poland	Grzegorz Cessak *(member)*
Portugal	Rui Santos Ivo *(member)* Maria João Morais *(observer)*
Romania	Razvan Prisada *(member)*
Slovakia	Peter Potúček *(member)*[2] Katarina Massányiová *(alternate)*
Slovenia	Momir Radulović *(member)*
Finland	Eija Pelkonen *(alternate)*

	Participants
Sweden	Björn Eriksson *(member)* Åsa Kumlin Howell *(alternate)*
European Parliament	Karin Kadenbach Anthony Borg
European Commission	Olga Solomon (DG SANTE) *(alternate)* Irene Norstedt (DG RTD) *(alternate)* Marco Capellino (DG SANTE) *(observer)* Tomasz Dylag (DG RTD) *(observer)*
Representatives of patients' organisations	Marco Greco Virginie Hivert
Representative of doctors' organisations	Denis Lacombe
Representative of veterinarians' organisations	Despoina Iatridou
EEA-EFTA states	Runa Hauksdottir Hvannberg (Iceland) Vlasta Zavadova (Liechtenstein) Audun Hågå (Norway)

2 Competing interest declared resulting in no participation in decision with respect to agenda points B.3, B.4 and B.5.

Guest speaker	Johan Schefferlie (CVMP Chair)

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 Marie-Agnes Heine Frances Nuttall Silvy Da Rocha Dias Georgy Genov Aniello Santoro Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin