EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 March 2020
EMA/MB/152592/2020 Adopted
Management Board

Minutes of the 107th meeting of the Management Board

Held in Amsterdam on 19 March 2020

The Chair of the Management Board opened the meeting which was, for the first time in the history of the Management Board, held fully in form of a teleconference due to the extraordinary circumstances of the COVID-19 outbreak. EMA has invoked its Business Continuity Plan (BCP), amended to take into account the COVID-19 crisis, and exceptional measures have been taken to protect the staff members and all delegates, experts and members of this Management Board. Amongst those measures, it was decided to invite all members to hold the 107th meeting of the board in a virtual mode. This entails that the participation and remote voting will be allowed as a temporary measure, based on the current exceptional circumstances. Further details to the existing Rules of Procedure will be discussed under point B.17 Amendments to the existing Rules of Procedure of EMA Management Board and Scientific Committees. The Chair asked for confirmation of the number of participants and of the quorum, and upon receipt of assurance by the Management Board secretariat, asked participants to state if they had any objection to hold the meeting and to take decisions (by consensus or by voting) in such a way. No objection was raised. In light of the unanimous agreement of all members to hold the meeting in a virtual mode, the Chair confirmed the validity of the notice of the meeting and proceeded to welcome the new members and alternates: Nicola Magrini, member for Italy, Asa Kumlin Howell, alternate for Sweden and Vlasta Zavadova, observer member, Liechtenstein.

The Chair invited nominations for Topic Coordinators for the Analysis and Assessment of the Executive Director's Annual Activity Report (AAR) 2019 to be delivered at the June meeting. Nancy De Briyne (vet representative) and María Jesús Lamas Diaz (Spain) were re-appointed. She further invited members to contact the Management Board Secretariat to express interest to replace Thomas Senderovitz (Denmark) as one of the three board representatives at EUTMB together with Nancy de Briyne and Andrzej Rys.

Post meeting note: Gytis Andrulionis (Lithuania) will join the topic coordinators for the AAR, and Hugo Hurts (Netherlands) volunteered for EUTMB membership.

1. Draft agenda for 19 March 2020 meeting

[EMA/1404/2020] The agenda was adopted without amendments. The Chair reminded the board of the methodology to be applied during the meeting in order to successfully handle the agenda in the 90 minutes allocated to the teleconference, which she had previously announced in a message when

informing the board on the virtual format of the meeting. All oral reports had been cancelled, and relevant presentations were provided to members ahead of the meeting. Points presented for information would be noted without discussion, unless on request by a member. For all points requiring endorsement or adoption, documents and background information had been provided to the Board well ahead of the meeting to prepare the board for a decision on 19 March. A list of these points had been compiled to provide a short guidance summarising the rationale for the presentation for endorsement/adoption at the March meeting of the Management Board. After a brief introduction, members would be asked for their agreement, and the result minuted. Should the Board wish for more time for reflection, a one week written procedure would follow after the meeting.

2. Declaration of competing interests 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 *B.6. 2018-2019 EMA Annual Reports on Independence, B.7.a. Revised implementing rules to the Fee Regulation as of 1 April 2020 including amendment to Annex I of Cooperation Agreement, B.8.b. Lessons learnt from presence of N-nitrosamine impurities in Sartan medicines, B.10. EMA Regulatory Science Strategy to 2025, B.13. Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation b) Audit methodology, B.15. 10th Annual Report Veterinary MUMS/limited market* and *B.17. Amendments to the existing Rules of Procedure of EMA Management Board and Scientific Committees.* 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 interests were declared.

3. Minutes from the 106th meeting, held on 18-19 March 2019 adopted via written procedure

[EMA/MB/542228/2019] The Management Board noted the final minutes, adopted by written procedure on 2 March 2020.

4. EMA Preparedness on Brexit

Item cancelled.

5. Update on 30 Churchill Place

Item cancelled.

A. Points for automatic adoption/endorsement

A.1 Model rules on the non-application of the Commission Decision on the maximum duration for the recourse to non-permanent staff in the Commission services

[EMA/MB/12651/2020; Ares(2019)6057171; C(2019) 6929; EMA/MB/23627/2020] The Management Board adopted the Model rules on the non-application of the Commission Decision on the maximum

duration for the recourse to non-permanent staff in the Commission services, prepared as an ex ante agreement for agencies by the European Commission.

A.2 Revision of budget remarks for budget 2020

[EMA/MB/36206/2020] The Management Board endorsed the revision of budget remarks for budget 2020 to reflect the fact that rent and building related maintenance are charged as one amount for the building in Amsterdam, instead of separately as in the lease agreement for the premises in London.

B. Points for discussion

B.1 Highlights of the Executive Director

Item cancelled.

B.2 Report from the European Commission

Item cancelled.

B.3 Future-proofing of the EMA

[EMA/MB/91553/2020] The Management Board noted an update on the Future-proofing exercise at EMA and the new organisation chart which came into force on 1 March 2020.

B.4 Preparation for the proceedings for the nomination of the Executive Director

[EMA/MB/88036/2020] The Board noted the preparation for the proceedings for the nomination of the Executive Director which will take place in an extraordinary meeting of the Management Board exclusively dedicated to the nomination of the future Executive Director from a shortlist of candidates provided by the European Commission. Members were invited to volunteer to join the Chair to prepare the questions by the Board which will be used in the interviews of the candidates. Xavier De Cuyper, Thomas Senderovitz, Zuzana Baťová, Catarina Andersson Forsman, Hugo Hurts and Rui Santos Ivo were nominated.

B.5 EMA Annual Report 2019

[EMA/MB/83673/2020; EMA/68349/2020] The Management Board adopted the Annual Report 2019 which had been circulated for comments to the Board on 28 February with the invitation to provide comments by Friday,13 March 2020. No comments were received. The document will undergo finalisation of design and layout and will be published in a printed as well as digital version.

B.6 2018-2019 EMA Annual Reports on Independence

[EMA/MB/85003/2020; EMA/425399/2019] The Management Board noted the Annual reports on independence which cover 2018 and 2019. It endorsed its recommendations for further improvement which will result in changes to the various EMA policies relating to independence for Scientific Committees' members and experts, Management Board members and Agency staff, among which will

be a revision of the definition of financial interest, introduction of a definition of partner, and for experts provisions concerning representatives of patients' organisations involved in repurposing projects. The report will be published following adoption by the Management Board at its June 2020 meeting of the revised EMA policies on independence and agreement on the implementation plan.

B.7 a) Revised implementing rules to the Fee Regulation as of 1 April 2020 including amendment to Annex I of Cooperation Agreement

[EMA/MB/516696/2019; EMA/MB/332998/2019; EMA/MB/686213/2019] The Management Board adopted the Revised implementing rules to the Fee Regulation, including annexes, and the Addendum No 5 to the Cooperation Agreements between the National Competent Authorities (NCAs) and EMA. In accordance with legal provisions on adjustment to inflation, fees covered by Council Regulation (EC) No 297/95 and related remuneration to national competent authorities increase by 1.6%, rounded off to the nearest € 100, and to the nearest € 10 for administrative charges. Annex II on scientific services and Annex V on scale of fees to be paid by the European Medicines Agency to national competent authorities (NCA) are amended to introduce consultations on medical devices (in relation to human medicines) and assessment on whether a full MRL evaluation is required or not for a chemical-unlike biological substance (in relation to veterinary medicines). As a consequence of the amendment to Annex II of the Fee Implementing Rules, the Cooperation Agreements between the National Competent Authorities (NCAs) and EMA will also need to be amended and signed by EMA and each NCA. The Board also noted that for clarity and to ensure completeness and consistency amongst the cooperation agreements, Article 2(2) will be amended to say explicitly that renewals are for a period not exceeding 5 years. Several legal references and other terms used in the agreements will also be updated.

The Board was informed that a change to bank details will entail an amendment of the corresponding individual cooperation agreement, and, when relevant, the agency's services will contact NCAs to sign such amendments.

b) Renewal of the Cooperation Agreement between EMA and National Competent Authorities

[EMA/MB/677663/2019] The Management Board noted the proposal by the Agency not to object to the renewal of the Cooperation Agreement between EMA and National Competent Authorities so that on 31 December 2020 the cooperation agreements are tacitly renewed for a subsequent 5-year period, and to review its content after the new Fee Regulation is adopted.

B.8 Update on the presence of nitrosamine impurities in medicines

a) Proposed approach for the management of nitrosamine presence in medicines

The Management Board noted the Update on the presence of nitrosamine impurities in medicines, containing proposals for the approach for the management of nitrosamine presence in medicines and responses to the identified challenges, including a set of proposals, and in particular the organisation of a meeting with MSs and EC representatives at senior management level once the CHMP has concluded its Art 5(3) review process. The aim of this meeting is to discuss and agree on the follow-up to and

the implementation of the CHMP outcome of the Art 5(3) review process in a consistent and coordinated way across the EU Medicines Regulatory Network.

b) Lessons learnt from presence of N-nitrosamine impurities in Sartan medicines

[EMA/MB/91583/2020; EMA/INS/GMP/91551/2020; EMA/INS/GMP/91552/2020; EMA/93691/2020] The Management Board endorsed the report *Lessons learnt from presence of N-nitrosamine impurities in sartan medicines* and noted the *High-level Impact Assessment* and *Impact Assessment summary*. Following endorsement of the report by EMA MB, the Lessons Learnt will be submitted to HMA for endorsement by written procedure. The next steps include an external stakeholder targeted consultation on the report recommendations, followed by publication of the report. In parallel, EMA and the Lessons Learnt Exercise group will prepare a more detailed impact assessment of the recommendations which will be tabled at the June 2020 HMA meeting.

B.9 Review of activities of the Working Parties of the EMA

[EMA/MB/74978/2020; EMA/72861/2020; EMA/675923/2019; EMA/100564/2020] The Board adopted the EMA Management Board Review Group's high-level principles and proposals for the review of activities of EMA Working Parties which had been revised taking into account comments received in a written procedure following discussion at the December meeting of the Board. The Management Board endorsed the extension of the mandate of the EMA Management Board Review Group on Working Parties to act as an oversight group to monitor progress throughout the implementation phase and review the guideline process and stakeholders' engagement by Q4 2020.

Concerning the doubt that current timelines might be affected by the current COVID-19 crisis, EMA agreed that it might be challenging to reactivate Working Parties which had been suspended in the Brexit BCP by Q2, and that Q3 appeared to be more realistic. Addressing another question, the interests of the Scientific Committees will be taken into account as their Chairs get involved in the implementation phase and through their relevant domain report to the SciCoBo where all Committee Chairs are represented.

B.10 EMA Regulatory Science Strategy to 2025

[EMA/MB/100523/2020; EMA/68752/2020] The Management Board endorsed the EMA Regulatory Science to 2025, which will be published on the Agency's website together with a detailed analysis of the stakeholder feedback received during the public consultation. The strategy document sets out working proposals on the key areas with which EMA intends to engage, in order to ensure that it has the regulatory tools to continue supporting the network and fulfilling its ongoing mission despite new scientific challenges. At EMA the strategy will be implemented within the 2021-2025 Multiannual Work Programme in the usual planning cycle, starting with the 2021+ Annual Work Programme, 2021+ Committee Work Plans and 2021+ Working Parties Work Plans. In parallel the RSS will also connect to similar developments for the NCAs by flowing into the EMRN strategy, to be adopted by the Management Board and HMA in September and October after a stakeholder consultation and its follow-up. Finalisation is expected by October 2020.

The representative of DG SANTE reminded all of the importance of working together also to synchronise work with the EU Pharma Strategy currently under development. This will be particularly important in Q4, at the time of its adoption and publication, as the strategies will need to be interconnected and areas prioritised to achieve a common strategy.

B.11 Progress report on the drafting paper of the European Medicines Regulatory Network (EMRN) Strategy to 2025

Item cancelled.

B.12 Potential impact of the Coronavirus infection on the availability of human and veterinary medicinal products – status report

The discussion was deferred to a dedicated teleconference of HMA to take place after the meeting of the Management Board.

B.13 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

a) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation

[EMA/MB/40090/2020; EMA/40089/2020] The Management Board noted the Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation providing a summarised overview of progress on CTIS and recent developments, building mainly on the reports that have been monthly circulated to the Board.

b) Audit methodology

[EMA/MB/92568/2020; EMA/65000/2020] The Management Board endorsed the audit methodology and tender specification for the selection of an independent auditor, within a framework contract of the European Commission. The tender specification was drafted in consultation with the CTIS governance.

B.14 Update on preparation for implementation of Veterinary Medicinal Products Regulation

Item cancelled.

B.15 10th Annual Report Veterinary MUMS/limited market

[EMA/MB/66702/2020; EMA/371094/2019] The Board endorsed the tenth annual/decade report on the operation of the Minor Use Minor Species (MUMS)/limited market scheme for veterinary medicines, covering the period 1st September 2009 – 31st December 2019. The report marks 10 years of a successful activity to increase availability of veterinary medicines. As a consequence of changing rules due to Regulation (EU) 2019/6, the policy and guidance will need to be updated, with a decision by the Management Board in 2021.

B.16 Big Data: update on establishment of the Steering Committee

[EMA/MB/95793/2020; EMA/95333/2020] The Board noted the update on the establishment of the HMA-EMA joint Big Data Steering Group and its mandate.

B.17 Amendments to the existing Rules of Procedure of EMA Management Board and Scientific Committees

[EMA/MB/138850/2020; EMA/144543/2020; Annex to EMA/MB/138850/2020] Upon a joint proposal of the EMA Secretariat and DG SANTE for the European Commission, the Management Board adopted amendments to the existing Rules of Procedure of EMA Management Board and Scientific Committees. The Rules of Procedure need to be amended in order to formally confirm the possibility for the Scientific Committees and the MB to continue their workings in a virtual setting in the context of an emergency situation, possibly coupled with the activation of the Agency's COVID-19 Business Continuity Plan. To add flexibility to the system, the proposed amendments deal with the possibility, irrespective of an emergency situation, to give a proxy vote to another member, or to the alternate of a member, provided that the appointed individual is present at the relevant meeting of the body concerned. The amendments to the Rules of Procedure of the Committees also allow that in an emergency situation, in order to preserve the operativity of the Committees, scientific opinions and recommendations may be adopted when an absolute majority of the members of the committee (i.e. 50% of the votes plus one of the members eligible to vote), rather than a 2/3 majority, is present and votes in favour. The Committees will be invited to take note of the decision of the Management Board and adapt the new provisions to the existing Rules of Procedure of each Committee as appropriate, with the assistance of the EMA Secretariat including the Agency's Legal Department.

List of written procedures finalised during the period from 23 November 2019 to 20 February 2020

- Consultation no 17/2019 on the appointment of Paul McNeill as a CVMP alternate as proposed by Ireland ended on 2 December 2019. The mandate of the nominee commenced on 3 December 2019.
- Consultation no 18/2019 on the appointment of Manuela Leitner as a CVMP alternate as proposed by Austria ended on 5 December 2019. The mandate of the nominee commenced on 1 February 2020.
- Consultation no 19/2019 on the appointment of Boris Kolar as a CVMP alternate as proposed by Slovenia ended on 11 December 2019. The mandate of the nominee commenced on 1 January 2020.
- Consultation no 01/2020 on the appointment of Christine Miras as CVMP alternate as proposed by France ended on 14 January 2020. The mandate of the nominee commenced on 15 January 2020.
- Consultation no 02/2020 on the appointment of Simona Stankeviciute as CHMP alternate as proposed by Lithuania ended on 14 January 2020. The mandate of the nominee commenced on 17 January 2020.
- Consultation no 03/2020 on the appointment of Christodoulos Pipis as CVMP member as proposed by Cyprus ended on 28 January 2020. The mandate of the nominee commenced on 29 January 2020.
- Consultation no 04/2020 on the appointment of Carina Bergman as CVMP alternate as proposed by Sweden ended on 29 January 2020. The mandate of the nominee commenced on 30 January 2020.
- Consultation no 05/2020 on the appointment of Andrea Golombiewski as CVMP alternate as proposed by Germany ended on 19 February 2020. The mandate of the nominee commenced on 20 February 2020.
- Consultation no 06/2020 on the appointment of Elita Poplavska as CHMP alternate as proposed by Latvia ended on 20 February 2020. The mandate of the nominee commenced on 21 February 2020.
- Consultation procedure for endorsement of the EMA Information Management Strategy 2020-2022 and Information Management Strategic Plan 2020-2022 was launched on 8 January 2020 and ended on 22 January 2020.
- Consultation procedure for the endorsement of high-level principles and preliminary set of proposals of MB Review Group on Working Parties. The procedure was launched on 20 December 2019 and ended on 20 January 2020.
- Consultation procedure for adoption of the mandate of HMA-EMA Joint Big Data Steering Group. The procedure was launched on 10 February 2020 and ended on 17 February 2020.

Documents for information

- [EMA/MB/687822/2019; EMA/687823/2019] Report on EU Telematics
- [EXT/138162/2020] Feedback from the Heads of Medicines Agencies
- [EMA/MB/67255/2020; EMA/640614/2019] 2019 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2019
- [EMA/MB/54359/2020; EMA/54360/2020] Report on ex ante and ex post evaluation of projects for the period 1 January to 31 December 2019
- [EMA/MB/91576/2020] Outcome of written procedures finalised during the period from 23 November 2019 to 20 February 2020
- [EMA/MB/60088/2020] Summary of transfers of appropriations in budget 2019
- [EMA/MB/48438/2020; Ares(2019)6989184; O/97/2004; Ares(2019)6254121] Adoption by analogy of Commission decisions on the duties of Commission drivers and Commission decision on procedures for dealing with professional incompetence
- [EMA/MB/62989/2020; Ares(2020)465850] Strategic internal audit plan 2020-2022 by the Internal Audit Service
- [EMA/MB/63039/2020;Ares(2020)608953] Follow-up of outstanding recommendations from past audits in the European Medicines Agency (EMA) by the Internal Audit Service– Note on audit conclusions
- [EMA/MB/69538/2019] Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2019

List of participants at the 107th meeting of the Management Board, held in Amsterdam, 19 March 2020

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Greet Musch *(alternate)*
Bulgaria	Bogdan Kirilov (member)[1]
Czech Republic	*Apology received from Irena Storová (member)*
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)* Nikolas Jørgensen *(observer)*
Germany	Karl Broich (member) Wiebke Löbker *(observer)*
Estonia	Kristin Raudsepp (member)
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	Eleftherios Pallis *(member)* [1]
Spain	María Jesús Lamas Diaz *(member)* César Hernández *(alternate)* María Jesús Alcaraz Tomas *(observer)*
France	Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Nicola Magrini *(member)*
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	*Apology received from Gytis Andrulionis (member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Mátyás Szentiványi *(member)* [1] Beatrix Horvath *(alternate)*
Malta	Anthony Serracino-Inglott *(member)* John-Joseph Borg *(alternate)*
Netherlands	Hugo Hurts *(member)* Michiel Hendrix *(observer)*
Austria	Thomas Reichhart *(alternate)*
Poland	Grzegorz Cessak *(member)*
Portugal	Rui Santos Ivo *(member)* Maria Morais *(observer)*
Romania	Roxana Stroe *(alternate)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Momir Radulović *(member)* [1]
Finland	Eija Pelkonen *(member)*
Sweden	Catarina Andersson Forsman *(member)* Asa Kumlin Howell *(alternate)*

[1] Competing interest declared resulting in no participation in decision with respect to agenda points B.6, B.7.a, B.8.b, B.10, B.13.b, B.15 and B.17. .

European Parliament	*Apology received from Matthias Groote* Tonio Borg
European Commission	Andrzej Rys (DG SANTE) Carlo Pettinelli (DG GROW) Aude L'hirondel DG SANTE (*observer*) Kristof Bonnarens DG SANTE (*observer*) Sylvain Giraud DG SANTE (*observer*)
Representatives of patients' organisations	Ioannis Natsis Marco Greco
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdottir Hvannberg (Iceland) Vlasta Zavadova (Liechtenstein) Audun Hågå (Norway) Karen-Marie Ulshagen (Norway)

European Medicines Agency	Guido Rasi Noël Wathion Nerimantas Steikūnas Agnes Saint-Raymond Alexis Nolte Fergus Sweeney Zaide Frias Hilmar Hamann Ivo Claassen Melanie Carr Anthony Humphreys Peter Arlett Edit Weidlich Stefano Marino Mario Benetti Anabela Marcal Marie-Agnes Heine Rebecca Harding Hilde Boone Frances Nuttall Silvia Fabiani Apolline Lambert Sophia Albuquerque