12 June 2020
EMA/MB/318294/2020 Adopted
Management Board

Minutes of the 108th meeting of the Management Board

Held in Amsterdam on 11 June 2020

The Chair of the Management Board opened the meeting which was held fully in a virtual form due to the extraordinary circumstances of the COVID-19 outbreak. The Chair asked for confirmation of the number of participants and of the quorum and received this assurance from the Management Board secretariat. The Chair confirmed the validity of the meeting and proceeded to welcome Valentina Superti, the new alternate for DG GROW.

1. Draft agenda for 11 June 2020 meeting

[EMA/MB/155342/2020] The agenda was adopted without amendments.

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.5. Revised implementing rules to the Fee Regulation as of 12 June 2020, B.6. Implementation Plan - 2018 and 2019 European Medicines Agency Annual Reports on Independence, B.8.b Report of the EU Clinical Trial Regulation Coordination group and B.9.b Lessons learnt from the presence of nitrosamine impurities in sartan medicines: outcome of the targeted stakeholder consultation, impact analysis and implementation plan.* 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.

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3. Minutes from the 107th meeting, held on 19 March 2020 adopted via written procedure

[EMA/MB/152592/2020] The Management Board noted the final minutes, adopted by written procedure on 26 May 2020.

4. Update on 30 Churchill Place (in camera)

[redacted]

5. Proceedings for the nomination of the Executive Director

[EMA/MB/277313/2020] The Management Board adopted the proceedings for the nomination of the Executive Director. The Chair had considered three scenarios for the meeting to be held under the

extraordinary circumstances of the COVID-19 outbreak: holding the meeting in-person only, as a hybrid meeting with members also provided with the possibility to link in from remote, or as a virtual only meeting. After discussion of the matter with the Management Board volunteers to prepare the questions for the interviews of the candidates by the board, the proposal had been put forward to hold the meeting in the virtual-only format, in the interest of the fairness and timeliness of the procedure. The proposal also included information on the platforms to be used for the virtual meeting and the secret ballot, as well as the instructions on the voting. In a virtual secret ballot, the tellers nominated by the board to supervise the vote, Runa Hauksdottir Hvannberg (Iceland) and Audun Hågå (Norway) will fulfil a slightly different role than their usual, examining the process rather than counting the votes, as anonymous results are provided by the platform itself. A demonstration of the settings to the tellers and a training for members will be organised by the Management Board secretariat to take place before the extraordinary meeting.

Several members questioned why the shortlist of candidates proposed to the board by the European Commission contains only two candidates. The representative of DG SANTE answered that at SANTE level 5 candidates had been shortlisted, of which 2 were withheld in the final shortlist after the second step of the procedure handled by the Commission's Consultative Committee on Appointments (CCA) which avails itself also of the opinion of an independent Assessment Centre. Xavier de Cuyper, who had been the observer for the Management Board to the preselection panel of the European Commission, assured the board of the proceedings he had observed.

6. Covid-19

- **EMA Status Report**
- **Publication of all Clinical Summaries and Reports regarding Covid-19 related and authorised drugs/vaccines**

The Management Board noted the COVID-19 EMA Status Report. Since the beginning of the crisis the internal COVID-19 Task Force was set up to ensure the Agency's business continuity, provide institutional coordination in close liaison with the European Commission, and oversee the work undertaken in four areas of activities pertaining to four workstreams: therapeutic response, supply chain, business continuity and impact, and human resources related matters. As of the end of May 2020 over 300 trials for COVID-19 related products have been uploaded in EudraCT. Regrettably the majority of them is conducted in only one Member State (MS) and few in more than 5 MSs. Rapid scientific advice procedures have been set up for advanced vaccines and therapeutics of which 33 and 115 have respectively been undertaken so far, and an application for conditional Marketing Authorisation (MA) under a rolling review (RR) has started, as well as benefit/risk assessments of potential treatment options using EMA internal competences in close cooperation with ETF, PRAC and CHMP, and international cooperation with ICMRA, FDA and WHO. Under a best-case scenario the pipeline of forecasted submission for COVID-19 applications shows RR procedures for MAAs for vaccines and antivirals, as well as Extensions of Indication for Immunomodulators starting in Q3 2020 and continuing into Q1/2 2021. Up to 10 requests for Scientific Advice per month are expected. The Agency has been involved in supply chain aspects for COVID-19 medicines and asked to take on a coordinating role on shortages, even though these shortages are dealt with at the national level by National Competent Authorities (NCAs). Main activities included the establishment of the EU Executive Steering Group on shortages of medicines caused by major events (EU Exe SG), the launch of the i-SPOC system for reporting by MAHs of supply shortages for crucial medicines in the context of COVID-19, initiation of discussions on the demand/supply model focusing on medicines used in ICUs, as well as ad hoc consultations with NCAs on specific supply shortages. The unprecedented public interest has

shown the need for the public to have access to more information than what EMA normally publishes. In the unprecedented fast track approval scenario, the public needs to be assured of the quality of the evidence behind the regulatory decisions. EMA proposes to publish a number of documents for COVID-19 products, and to resume for them the publication of clinical data, which is currently on hold due to the BCP. At its Forum for sharing best practices, the European Medicines Regulatory Network (EMRN) agreed on the need for an EMRN COVID-19 BCP to cover both CAPs and NAPs to ensure that core public and animal health regulatory activities continue to be carried out during the pandemic, irrespective of the licensing route. Among the general principles applicable, under no circumstances can COVID-19 related procedures be delayed. For the other procedures, any changes that are necessary will be applied at the level of the concerned procedure and not at a product type or procedure type level. Where delays for non-COVID-19 procedures are reported, specific arrangements apply, taking into account the specificities of the procedures for CAPs and NAPs. The EMRN COVID-19 BCP was published on 28 May 2020 and is currently being updated to include aspects relating to pharmacovigilance and inspections. Staff at EMA has been redeployed to cope with increasing workload in the areas of COVID-19 related activities like therapeutic response, supply chain aspects, business impact and human resources. In April some 66 FTEs were working on COVID-19, resulting in an impact on the implementation of the Work Programme 2020. Core activities have been maintained, but some activities which were due to start in 2020 are not being resumed at the moment while some activities have been postponed to 2021. The anticipated submission of COVID-19 related procedures and the extent to which EMA will be asked to increase its involvement in addressing shortages of medicines are expected to further influence the workload in the second half of 2020. Arrangements will have to be made to assure that the system, both at the level of the NCAs and EMA, is flexible and agile enough to cope with this challenge. Other additional implications for the Work Programme 2020 are at this timepoint difficult to predict and are dependent on the trends of the applications and further evolution of the pandemic, among other. EMA is currently working on mapping the expertise of the network for the COVID-19 related applications, identifying workload peaks for individual NCAs, identifying internal resources and expertise needed to support procedures, ensuring that the formation of MNATs is facilitated. As next steps EMA will provide support to further adjustments to the EMRN COVID-19 BCP, monitor the impact of submissions, and of COVID-19 on EMA, its activities and staff. An update on the impact on the WP2020 and the consequences for the WP 2021 will be presented to the MB at its October 2020 meeting.

A. Points for automatic adoption/endorsement

A.1 Management Board meeting dates 2021-2022

[EMA/MB/155721/2020] The Management Board adopted the meeting dates for 2021

- Thursday 11 March
- Wednesday 16 June and Thursday 17 June
- Thursday 7 October
- Wednesday 15 December and Thursday 16 December

and noted the meeting dates for 2022:

- Thursday 17 March
- Wednesday 15 June and Thursday 16 June

– Thursday 6 October

– Wednesday 14 December and Thursday 15 December

B. Points for discussion

B.1 Highlights of the Executive Director

International Activities

Due to COVID-19 nearly all previously planned international meetings have been cancelled or postponed. There has however been an increase in ICMRA meetings (held virtually) on COVID-19 related matters. EMA has co-led four technical meetings with 29 authorities and more than 100 participants on vaccines, treatments and trials and observational studies/RWE. EMA is continuing with the IPA project training candidate countries on the Acquis Communautaire over the next three years.

EU Activities

The European Parliament granted the EMA Discharge for its 2018 accounts, highlighting the unsustainable situation of EMA's former premises in the UK. The Agency was invited for an exchange with the ENVI Committee on the Agency's activities in the area of COVID-19 on 12 and on 18 May. Weekly interactions on COVID-19 have been organised by the Commissioner with DG SANTE, ECDC and EMA. The Agency has also been involved in the joint RTD/SANTE group for ERAvsCorona Action Plan.

Court ruling on transparency

In January EMA obtained two favourable judgements by the Court of Justice concerning its decisions to disclose certain clinical study and toxicology reports under the Access to Documents Regulation. The Court confirmed that EMA's policies are lawful. These landmark rulings endorse the approach taken by EMA since 2011 defending transparency of its decisions and activities, in the interest of patients and public health.

Organisational changes (Future-proofing)

A half-day session during the June meeting had originally been planned but had to be cancelled due to the changed format of the meeting. COVID-19 generated a crisis which started only a few days after EMA had moved into the new building. The Agency was able to respond effectively thanks to a new seamless organisation with a short chain of command.

Future-proofing the Human Medicines Division

The new Human Medicines Division (H division) was formed in March-April, and immediately had to switch to remote working of 100% of its staff. Analysis work of all offices and processes and assessment of capacity/capability gaps had to take place in the context of the new BCP. From May to August focus is on improving support to scientific committees, aligning structure to process and to people and addressing human resources gaps. Incremental continuous improvement will start from September, unless the evolution of the COVID-19 and other issues cause delays in the implementation. The new structure has been successful in continuing to deliver core business and COVID-19 related procedures, facilitating agile redeployment of staff to the COVID crisis team and enabling synergies between task forces and the H division. Stretched resources and focus on immediate issues due to COVID may cause some reprioritisation of work with delays in recruitments and training of new staff.

Future-proofing the Information Management Division

The Information Management Division (I Division) has undertaken its transformation to respond to changing business needs and in order to be a catalyst for future innovation. The main drivers for change are the rapid advances in the scientific and technological landscape, the complex regulatory environment, the relocation to the Netherlands and the loss of staff, the Agency's custom-built legacy system requiring much maintenance, and the need to reshape synergies between the Agency and the Telematics projects. The IM vision aims at evolving the delivery and maintenance of information systems to be more customer-focused, agile, collaborative and innovative in order to better provide to all stakeholders the right information management tools, technologies and services. The new IM operating model will be underpinned by a new organisational structure, management team and roles. Expected benefits for the I Division are fostering job satisfaction and personal growth, developing multi-disciplinary teams creating end-to-end ownership of key services. For partners and stakeholder it is envisioned that investing more in a few key strategic platforms EMA staff and NCA partners will benefit from best-in-class collaboration tools. A Customer Advocacy Department will focus on strengthening the collaboration between the business and IM. A more agile and flexible division structure and operating model will improve the ability of IM to quickly respond to changing needs. Finally the Telematics and Governance Office will be integrated into the new CIO Office, streamlining and enhancing collaboration and communication with the network.

Artwork at EMA

At the end of March 2020 artwork commissioned by the project team for the EMA building from the Dutch artist Gijs Assmann and Leonard van Munster was installed in front of the building and on the terrace.

Discussion

Satisfaction was expressed on the approach taken to future-proofing, and the question was raised on how the exercise has been received by staff members. The Executive Director answered that staff appears to have largely understood the reasons, and the need to adapt the organisation to cope with future challenges. Specific organisational issues are discussed in the manager information cascade and a staff survey is being conducted. The board will be kept informed. Addressing the issue raised by a member of whether all Scientific Committees were being equally considered in the exercise to review scientific Working Parties, he added that the intention is to address the scientific needs of the whole system. Experts who contribute to Working Parties should be given by their appointing authority the necessary time and resources to motivate their work.

B.2 Report from the European Commission

COVID-19 activities

From the beginning of the COVID-19 crises the European Commission in collaboration with EMA has been monitoring shortages of medicines and medical devices and encouraging increase of their production capacity. Measures to address shortages were discussed in the EU Executive Steering Group on shortages of medicines, and in the Clearing House weekly calls with industry. Considerable time was spent on reaching out to Member States and to 3rd countries to lift or minimise export restrictions. Using a demand model the Commission has cooperated with the pharmaceutical industry in a project to match supply and demand of crucial ICU medicines. Continuity of manufacturing of medicines during the pandemic has been facilitated by clarifying regulatory flexibility in a Q&A document. The joint EC/EMA/HMA guidance on the management of clinical trials was published on April 28. The date of application of MDR (EU 2017/745) has been postponed by a year to allow NCAs and medical device manufacturers to concentrate on possible shortages during the COVID-19 crises.

A pharmaceutical strategy for Europe

The draft pharmaceutical strategy rests on four pillars: ensuring access and availability, ensuring affordability of medicines for patients and health systems sustainability, enabling sustainable innovation and succeeding on the global level. Initial lessons learned from the COVID-19 crises, such as on how to deal with shortages and APIs, will be incorporated in the strategy. Following the publication of the roadmap on 2 June an online consultation was launched until September. The strategy, including a list of actions, is planned to be adopted in Q4.

EMA Fees

Consultations with EMA and NCAs for an external study supporting the impact assessment will take place in Q1 2021. Given the highly technical nature of the exercise, instead of a public consultation only targeted consultations with NCAs, EMA, industry and other relevant stakeholders will be held. The study team is building a model to match the fee system and to estimate the impacts.

Medical device legislation

Work on the implementation of the Medical Device Regulation and In Vitro Diagnostic Regulation is progressing with collaboration between COM, NCAs and other relevant stakeholders, following the adoption of the Joint Implementation Plan of March 2020. The EU Medical Devices Database (EUDAMED) collates and processes information regarding devices on the EU market. Expert panels to provide scientific, technical and clinical assistance will be established in September 2020. A number of guidance documents endorsed to facilitate implementation were published on DG SANTE website.

HTA update

Negotiations on the HTA proposal have been delayed due to the COVID-19 crisis, but will resume under the German Presidency. The EUnetHTA remains very active and its board has decided to prioritise COVID-19 related work for its remaining 12 months of activity.

Discussion

A member expressed the feeling that since the Inception Impact Assessment on the EMA Fees there had been less information provided on the process, and NCAs had no notion of what funding models could be expected. The representative of DG SANTE admitted that there had been delays, but work was resuming with the circulation of a survey by the contractor. The representative of veterinarians' organisations suggested that Lessons Learned on COVID-19 should take into account the need to improve the One Health response, as the origin of the pandemic was zoonotic, and enquired about the impact of COVID-19 on AMR. According to the European Commission, the response will be found in the EU for Health programme. In the Lessons Learnt Exercise (LLE) in October possible proposals for legislation will be included. A member pointed out that some of the problems arising in the crises were originated in Medical Devices in health service delivery capabilities. Efforts are needed to partner medicines and medical devices networks.

B.3 Assessment of the Executive Director’s Annual Activity Report (AAR) 2019

[EMA/MB/265843/2020; EMA/33568/2020; EMA/220995/2020] The Management Board noted the Annual Activity Report (AAR) and adopted the Assessment of the Executive Director’s AAR 2019 which had been prepared by the Topic Coordinators María Jesús Lamas Diaz, Nancy de Briyne and Gytis Andrulionis. As part of the review the Topic Coordinators have discussed the Agency’s accounts with the Accounting Officer. The Discharge for the 2018 budget has been granted. A review of the effectiveness of the internal control system and control standards was carried out at the Agency with positive results. The Executive Director was therefore able to provide reasonable assurance that the

resources assigned to the activities described in the report had been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions. The attention of the board was called on the Emphasis of Matter, which the Executive Director had issued for the third year in a row to highlight the consequences of imposed reduction of 10% of the Agency's establishment plan since 2014, during the same period that fee-related workload has grown significantly and new tasks have been granted. This, combined with the permanent loss of short term contract staff following the relocation to the Netherlands, could result in risks to delivering on future public health and legislative responsibilities, and put at risk the Agency's ability to re-introduce the activities currently reduced or suspended. A second Emphasis of Matter concerned the long-term liability and responsibility for the former premises of the Agency in London, which is incompatible with EMA's public health role.

The topic coordinators provided a general overview over the Work Programme 2019, the Business Continuity Planning and Future-proofing at EMA. They highlighted the continued high interest in the PRIME initiative and good performance of the Scientific Advice, which had been given to nearly 60% of applicants receiving a positive opinion. 66 medicines, of which 30 had a new active substance, were recommended for marketing authorisation, and the CAT experienced a rise compared to 2018 by 27% of requests for ATMP classification and 56% in recommendations. For Paediatric medicines, PDCO agreed to 94 initial PIPs, the highest number in 5 years. Other activities at the Agency to be noted were work on the scientific and technical recommendation for the European Commission within the new veterinary regulation, guidance issued on AMR, the launch of the EU SPOC system by the HMA-EMA taskforce to improve information sharing on shortages of medicines with the Network, and the 30% increase in veterinary ADRs. The regulatory science strategy had been finalised after extensive consultation and will be a key element of the next European Medicines Agencies Network Strategy to 2025. Collaboration with non-EU regulators remains strong. The Topic Coordinators agreed that 2019 had not been an easy year for the EMA. The EU Telematics implementation roadmap 2015-2017 had been extended to the end of 2019 to guide the ongoing developments. Although CTIS has not yet been completed, there were significant steps undertaken, and much work was done also for the implementation of the veterinary applications that need to be up and running in 2020. It was recommended to continue to work towards a feasible strategy in 2025, with an operational plan on what to achieve given the available resources. The future-proofing initiative is very promising in this regard. For the veterinary Union Database the project seems on track, but it is important to ensure appropriate resources for the future development.

B.4 Preparation for written procedure on Amending Budget

[EMA/MB/237984/2020] The Management Board noted the ongoing focus of the Agency on the monitoring of revenue and expenditure under the current COVID-19 related circumstances. The Agency will assess the overall revenue and expenditure situation in July 2020 and decide whether an amending budget is required to manage the budgetary outturn at year end. Consequently, it may request the Management Board's approval by written procedure for an amending budget to be adopted before the October meeting.

B.5 Revised implementing rules to the Fee Regulation as of 12 June 2020

[EMA/MB/238468/2020 Rev. 1; EMA/MB/238467/2020 Rev. 1] The Management Board adopted the revised implementing rules to the Fee Regulation. A new fee was introduced for the 'rolling review' whereby in the context of the current COVID-19 pandemic situation a potential marketing

authorisation application (MAA) is evaluated in parallel to the development of the product before actual submission of the formal MAA for the product. As the service provided for the 'rolling review' is also part of the evaluation activity for any subsequent MAA, the amount charged is then deducted from the amount that is to be charged upon submission of a valid MAA for that product. In case of multiple rolling review cycles, the flat fee is charged only once. 50% of the fee will be paid to the NCAs.

B.6 Implementation Plan - 2018 and 2019 European Medicines Agency Annual Reports on Independence

[EMA/MB/226425/2020; EMA/176567/2020; EMA/89351/2020; EMA/89374/2020; EMA/259494/2016 Rev 3] The Management Board adopted the implementation plan of actions in 2020 and those planned for 2021, the revised Policy 0044 on the handling of competing interests of scientific committee members and experts, the revised Policy 0058 on the handling of competing interests of Management Board members and the revised MB Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the EMA and candidates before recruitment. At the March meeting the board had endorsed the Annual Reports on Independence 2018-2019 including recommendations for improvement. The implementation will take place with a step-wise approach with most actions to be implemented in 2020 and the remainder in 2021. New provisions applicable to three policies are the inclusion in the definition of financial interests of stock warrants, i.e. type of stock option, introduction of a definition of partner, i.e. registered partnership certifying a stable non-marital partnership, and inclusion of reference to the new EU GDPR legislation. For Policy 0044 new provisions concern the introduction of a definition of biotechnology and medical device sectors for CAT members and alternates, changes to include repurposing of a medicinal product regarding patient representatives, as well as restrictions for inspectors declaring close family interests and grants/funding to align with current practice in the majority of EU member states and at FDA. The implementation of changes to the e-DOI form for experts will take place in two phases, in June and in Q1 2021. Following the consultation with the European Commission an additional change to policy 0044 was suggested in relation to the definition of a pharmaceutical company.

B.7 Annual report of internal audit and advisory activities at the European Medicines Agency 2019

[EMA/MB/237105/2020; EMA/143243/2020] The Management Board noted the Annual Report of internal audit and advisory activities at the European Medicines Agency 2019 which the head of Audit is required to provide to the Management Board as set out in the Financial Regulation, and the 2019 confirmation of independence of the Internal Audit Capability of EMA (AF-Audit) to the Management Board of the Agency. The 2019 report provided information on 7 audit and consultancy engagements out of 10 planned for 2019. Out of these, 2 audits were performed by external auditors; 2 audits were conducted respectively by IAS and ECA, while AF-AUD completed 3 engagements (One internal audit and two consultancy engagements). 2 engagements (One external audit on clinical trials and one consultancy on security management was postponed, whilst a second consultancy was cancelled. The status of the implementation of improvement action plans shows that in 2019 several value added recommendations were implemented, among which were the creation of sub-policies and procedures to support the Agency Security Policy, training courses for staff and EU network on handling of confidential information, new practices and controls and the establishment of the requirement for an annual review of the security baselines. Based on the results of past and ongoing audits, follow-ups, consultancy activities and analysis, the Head of Audit confirmed that the internal control systems put in

place by the Agency provide reasonable assurance regarding the achievement of the business objectives in line with BCP arrangements.

B.8 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/202071/2020 Rev. 1; EMA/201952/2020, EXT/267687/2020; EMA/160943/2020; EMA/193987/2020;] The Management Board endorsed the Report on the EU Clinical Trial Regulation Coordination Group and the proposal for the go-live readiness plan, and decided to continue the monitoring of the performance of the IT supplier by the Monitoring Subgroup.

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

The report on the development from March to May highlights that Release 12 was validated by the Product Owners (POs). Two sprints of the following release were delivered, but results were found to be lower than expected, due to a high number of complex issues in the scope. The supplier has prepared an improvement plan with additional developers and testers. For the assessment of audit readiness operational assessment 2 (OA2) was completed in April and OA3 was conducted in May. An action plan, including further prioritisation, has been prepared to agree on a final scope for audit and has been shared with MS POs. In line with the audit readiness plan agreed by the Management Board in December 2019, the final confirmation of detailed functionalities that are ready for audit needs to be finalised by the end of June. The CTIS Go-Live readiness plan foresees that the go-live date is mainly driven by the need to implement the Clinical Trial Regulation as soon as possible. Functional specifications will be met, but not all functionalities defined in the Product Vision and the Requirements for go-live will be delivered at that time. Their order of implementation pre- or post go-live will be the subject of a prioritisation exercise. Six months before go-live functionality will be frozen in order to stabilize the system. Functionality developed after this point will be released in 2022 after go-live during the subsequent three releases to be implemented in 2022. Based on this premise, the go-live date is set as a working assumption to enable planning, to December 2021. The go-live and post go-live scope will be prioritised by the Prioritisation Group starting in June and confirmed by the CTIS governance in December 2020. In the area of training, development of material is ongoing, and network expert input is needed to form a network of member states Master Trainers to be established by September 2020. Contractual arrangements for the independent auditor are based on a framework contract of the European Commission, and it is expected that the contract will be signed by the end of July 2020. The contract with the current IT supplier has been extended for a year and a new tender has been launched on 7 May, allowing for the replacement of the current framework contract to be in place by the end of 2020.

b) Report of the EU Clinical Trial Regulation Coordination group (EU CTR CG)

The EU CTF CG reported that it had reviewed the go-live readiness plan and agreed to fix the go-live date of CTIS as a working assumption to December 2021, which means that the final audit report needs to be available in April 2021 at the latest. The prioritisation exercise is based on two elements: capacity available and number of items to be developed. The Prioritisation Group is responsible for delivering a detailed prioritisation of all outstanding issues to the CTIS governance. Further adaptations and adjustments will be required when the necessity arises. In March 2020 the Monitoring Subgroup introduced a revised set of KPIs of which two specifically designed to follow-up audit

readiness. Concrete results are visible, as the quality of the system has improved together with the user satisfaction. The increase of throughput should however be continuously monitored as some agreed remediation actions still need to show their effect. It was therefore proposed to continue the monitoring at least until after the CTIS audit. Following the endorsement of the User Testing Strategy proposed by EMA, Member States not yet engaged in testing activities as well as stakeholders such as industry and academia are invited to nominate testers and participate actively.

B.9 Update on the presence of nitrosamine impurities in medicines

a) Follow-up to and implementation of the Art 5(3) CHMP scientific review of the presence of nitrosamine impurities in human medicines

On 10 September 2019 the Executive Director triggered an Art 5(3) scientific review on the presence of nitrosamine impurities in human medicines, asking CHMP to provide considerations on the identification of possible presence of nitrosamine impurities in these medicines and taking into account ongoing work for the lessons learnt on the sartans review, to evaluate all scientific knowledge and consider if the current scope should be broadened to other medicinal products, and to advise Regulatory Authorities on the actions to be taken. After the launch on 19 September of a call for review to MAHs in a stepwise manner, the board at its December 2019 meeting agreed on an EMRN short-term and temporary approach for the handling of new information on nitrosamine presence in medicines. A finalisation by CHMP of the Art 5(3) review could be expected at its June 2020 meeting, but preparatory work for the implementation of the CHMP opinion has already started. Once the CHMP opinion will be provided to the EMA Executive Director, agreement needs to be reached within the EMRN on how to implement it across the network for both CAPs and NAPs, and on the content and timing of the communication. Key success factors in the implementation of the Art 5(3) opinion across the network will be based on greatest possible simplicity, avoiding multiple follow-up discussions in various fora; greatest possible efficiency making best use of the available network and resources; alignment with EMRN in order to achieve a consistent approach for both CAPs and NAPs whilst acknowledging the specificities of their procedures; and finally a dedicated transparency and communication strategy. Engagement at senior level within the EMRN is necessary to agree on common implementation principles. In parallel discussions with the EU Industry Associations will continue to ensure engagement within industry. EMA will organise a meeting of the EMRN once the CHMP has concluded its review, inviting the European Commission, HMA, CHMP Chair/Vice-Chair, CMDh Chair/Vice-Chair and EDQM with the aim of agreeing on both common implementation principles and working methodology.

b) Lessons learnt from the presence of nitrosamine impurities in sartan medicines: outcome of the targeted stakeholder consultation, impact analysis and implementation plan

[EMA/MB/306023/2020; EMA/307799/2020; EMA/INS/GMP/307955/2020; EMA/303870/2020] The Management Board noted the overview of external stakeholder comments to the sartan report and the press release that will accompany the report publication and endorsed the final report Lessons learnt from presence of *N*-nitrosamine impurities in sartan medicines.

The report and High Level impact assessment and Executive Summary had been endorsed by HMA and the Management Board in March 2020. Targeted consultation on report recommendations with

industry, HCP and patient and consumer organisations were finalised on 26 May 2020. The full report will be published in the second half of June 2020. A draft High level impact assessment prepared by EMA had been shared with HMA and the board in March 2020. Work is ongoing with the LLE group to discuss and further refine the impact assessment and assign leads and involved parties for each action. The impact assessment will be provided to the board for endorsement by written procedure if necessary.

B.10 Annual report 2019 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use

[EMA/MB/235475/2020; EMA/223363/2020] The Management Board endorsed the annual report 2019 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use. The report presented no major deviations from previous years and no significant impact on timelines due to the redistribution of the UK portfolios of products was noticed.

B.11 Progress report on the drafting paper of the European Medicines Agencies Network Strategy to 2025

The board noted the progress report on the drafting paper of the Network Strategy to 2025. In a meeting of the EMA/HMA Drafting Group on 10 June the current draft strategy was reviewed to sharpen the focus and incorporate recent experience with the COVID-19 crisis. The decision was taken to maintain the current timeline. After endorsement by written procedure by Management Board and HMA, to be launched on 15 June, the strategy will be released for a 2 month public consultation on the strategy between 6 July and 4 September. The representative of DG SANTE reminded the board of the importance of maintaining alignment on priorities of the Network Strategy and the Pharmaceutical Strategy as the overarching strategy for medicines in Europe.

B.12 Update on preparation for implementation of Veterinary Medicinal Products Regulation

The representative of DG SANTE provided an update on the implementation of the Veterinary Medicinal Products Regulation. Overall the implementation work is progressing according to deadlines, although the current crisis situation may have knock-on effects on the process further down the line. Concerning the feasibility study under Article 156 (active-substance-based review system or other potential alternatives for the environmental risk assessment of VMP) the legal deadline of 28 January 2022 may be affected because of the time required to award the contract to conduct the feasibility study and prepare the report.

EMA also reported on good general progress thanks to excellent collaboration with the European Commission and commitment by all stakeholders. All pieces of advice have so far been delivered on time, with the latest two on pharmacovigilance submitted to the Commission at the end of May. The work on further six advices is ongoing and on schedule, with the possible exception of the advice on the list of antimicrobials to be reserved for human use due to the need to consult human experts which are currently occupied with COVID-19 related activities. In the 2020 budget five additional posts were allocated for the V Division and recruitments have almost been completed. The VMP-Reg governance which was endorsed at the October meeting has been fully established with minor changes to

mandates and composition and has already adopted two very important documents, its Programme Vision and Definition and its Change Management Strategy. Work on the delivery of EVVet3 the Union Product Database (UPD) is continuing on track for 2020, but a discussion on the budget for 2021 is needed, as well as a contingency plan for the UPD, should problems in delivery arise during the development. At the present time the risks that could affect the VMP-Reg programme are the COVID-19 crisis if key resources were affected and the fact that the development of both UPD and EVVet3 continues to take place against a moving target, as further requirements might arise from the discussions of implementing acts. Careful scope management is needed to ensure that delivery of a minimum viable product is possible in January 2022 and is not endangered by repeated discussion within the governance of elements that are not in scope.

B.13 Report on the establishment of the Big Data Steering Group

[EMA/MB/249685/2020; EMA/251096/2020; EMA/251092/2020] The board noted the Report on the establishment of the HMA-EMA joint Big Data Steering Group. Following the discussion at the December meeting of the board, the mandate of the HMA-EMA joint Big Data Steering Group (BDSG) mandate was endorsed by HMA and the board in February 2020 and the Steering Group is now fully formed and operational.

List of written procedures finalised during the period from 21 February 2020 to 26 May 2020

- Consultation no 07/2020 on the appointment of Peter Zsolt Fekete as CVMP alternate as proposed by Iceland ended on 3 March 2020. The mandate of the nominee commenced on 4 March 2020.
- Consultation no 08/2020 on the appointment of Annelin Bjelland as CVMP alternate as proposed by Norway ended on 3 March 2020. The mandate of the nominee commenced on 4 March 2020.
- Consultation no 09/2020 on the appointment of Edward Laane as CHMP alternate as proposed by Estonia ended on 24 March 2020. The mandate of the nominee commenced on 25 March 2020.
- Consultation no 10/2020 on the appointment of Kirstine Moll Harboe as CHMP alternate as proposed by Denmark ended on 14 May 2020. The mandate of the nominee is intended to start on 1 June 2020
- Consultation no 11/2020 on the appointment of Dorota Distlerova as CHMP alternate as proposed by Slovakia ended on 20 May 2020. The mandate of the nominee commenced on 21 May 2020.
- Consultation procedure for the draft minutes of the 106th Management Board meeting ended on 2 March 2020. The procedure was adopted.
- Consultation procedure for the draft minutes of the 107th Management Board meeting ended on 25 May 2020. The procedure was adopted.

Documents for information

- [EMA/MB/225113/2020; EMA/225114/2020] Report on EU Telematics
- [EXT/312654/2020] Feedback from the Heads of Medicines Agencies
- [EMA/MB/283295/2020] Outcome of written procedures finalised during the period from 21 February 2020 to 26 May 2020
- [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/201079/2020] Summary of transfers of appropriations
- [EMA/MB/483727/2019] Summary of implementation of assigned revenue budget

List of participants at the 108th meeting of the Management Board, held in Amsterdam, 11 June 2020

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier de Cuyper (member)
Bulgaria	Bogdan Kirilov (member)[1]
Czech Republic	Irena Storová (member)
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)* Mette Hansen *(alternate)* Nikolas Jørgensen *(observer)*
Germany	Karl Broich (member)
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)*
France	Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Nicola Magrini *(member)*
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	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.5, B.6, B.8.b, B.9.b. .

European Parliament	Matthias Groote Tonio Borg
European Commission	Anne Bucher (DG SANTE) Valentina Superti (DG GROW) Kristof Bonnarens 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)

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