2 October 2020
EMA/MB/519858/2020 Adopted
Management Board

Minutes of the 109th meeting of the Management Board

Held virtually on 1 October 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 Sandra Gallina, the new member for DG SANTE.

The Chair thanked Emer Cooke, who had been appointed Executive Director succeeding the mandate of Guido Rasi, for attending the meeting of the Management Board. Ms Cooke thanked the board for its confidence in her when electing her in June. She welcomed the opportunity to learn about the board's needs and expectations, which she would like to further understand by means of bilateral meetings with National Competent Authorities (NCAs) to be held at the beginning of her tenure. She confirmed that COVID-19 will remain the top priority to be addressed in the coming months and years, and will put additional strain on the stretched resources of EMA and the network. One of her first tasks in her new role will be to take stock of its impact on the Business Continuity Plan (BCP) and present to the board a revised EMA Work Programme for 2021. The accelerated development of COVID-19 medicines highlights the need to maintain trust in the quality and scientific independence of the European regulatory system. Another challenge which requires a lot of effort is the issue of shortages of medicines. The announcement by President Ursula von der Leyen in her State of the Union speech that the EMA's resources and competences to prepare for health threats will soon be reinforced is very welcome. There is no doubt that digitalisation, real world evidence and artificial intelligence will continue to play an increasingly important role in healthcare systems. The recent incident with nitrosamines and the COVID-19 pandemic have shown that the EU regulatory network needs access to the most up-to-date IT tools. A number of these priorities are already reflected in the Network's strategy to 2025, however some longer-term solution may require a revision of the legislation and are expected to be a key component of the EU pharmaceutical strategy. Ms Cooke concluded by stating that she looked forward to working very closely with the European Commission and with the network, and thanked Guido Rasi for his excellent work and leadership which, together with efforts from EMA staff, have made the Agency stronger and more resilient.

Finally the board confirmed Grzegorz Cessak, Nancy de Briyne and Lorraine Nolan and appointed Rui Santos Ivo as new topic coordinators for the budget and programming document of the Agency.

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1. Draft agenda for 1 October 2020 meeting

[EMA/MB/388242/2020] 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 *6.b. Additional safeguards (to be) put in place for securing the robustness and independence of the scientific review process for MAAs for COVID-19 treatments, B.5. Lessons learnt from the presence of nitrosamine impurities in sartan medicines: Impact Analysis and Implementation Plan and B.7. Review of activities of the Working Parties of the EMA.* 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 108th meeting, held on 11 June 2020 adopted via written procedure

[EMA/MB/318294/2020] The Management Board noted the final minutes, adopted by written procedure on 3 September 2020.

4. Minutes of the Extraordinary Management Board meeting for the nomination of the Executive Director, held on 25 June 2020 adopted via written procedure

[EMA/MB/367450/2020] The Management Board noted the final minutes, adopted by written procedure on 3 September 2020.

5. Update on 30 Churchill Place

[redacted]

[redacted]

[redacted]

6. Covid-19

a) EMA Status Report

The Management Board noted the COVID-19 EMA Status Report. Since early into the COVID-19 crisis the Agency has been liaising with pharmaceutical companies working on treatment response. Some 154 therapeutics are in discussion, and the CHMP in the context of an Article 5(3) has endorsed the use of dexamethasone in patients who require oxygen therapy. Some 38 vaccines are under discussion, with a first vaccine anticipated to start a rolling review on 1 October. One patient/consumer representative and one healthcare professional representative are joining the EMA's pandemic Task Force on COVID-19 (ETF) participating actively in meetings. In summer EMA sent letters to the EMRN highlighting the need to secure the necessary expertise to deal with COVID-19 treatments and launched a survey to obtain the most up-to date information on currently available and planned additional assessment capacity for the next 6 months period. 20 National Competent Authorities (NCAs) responded so far and more contributions are awaited. From the currently available information it appears that more than half of NCAs are planning to increase their assessment capacity for vaccines with a good distribution over different vaccine types. For Scientific Advice the situation appears to have improved since August, and there is capacity, both current and planned, for quality, non-clinical and clinical advice. A majority of NCAs plans to be involved in Multi-National Assessment Teams (MNATs) for both Marketing Authorisations and Scientific Advice. Preparation over summer for a 2nd wave of the pandemic included a survey of EMRN on anticipated shortages of ICU medicines, which showed current national measures as sufficient, and therefore no need to escalate the issue at EU level. The EU Executive Steering Group launched a pilot before finalising a draft Reflection Paper developed by its ad hoc working group, on how to better forecast demand for medicinal products in the EU/EEA. The pilot will cover a forecast for 5 medicines used in ICU setting, with EMA collecting the individual demand data from each Member State and aggregating the data at EU level. The approach to communication and transparency includes several transparency actions, including announcements and early publication of documents, as well as proactive publication of the clinical data submitted by the applicant and assessed by the CHMP. A reflection on transparency measures for post-authorisation of COVID-19 treatments has started. In terms of communication EMA is replying to an enquiry on independence and transparency for COVID-19 treatments by the European Ombudsman and is developing an information guide to be published on the development evaluation and monitoring of COVID-19 vaccines.

The representatives of patients' and veterinarians' organisations praised the work done by the Agency and stressed the importance of transparency to dispel lack of trust in vaccines and in the outcome of

the scientific assessments. EMA will provide more information on assessment capacity at the board's December meeting, including for post-authorisation and follow-up activities.

b) Additional safeguards (to be) put in place for securing the robustness and independence of the scientific review process for MAAs for COVID-19 treatments

[EMA/MB/505166/2020; EMA/MB/506190/2020] The Management Board noted the additional arrangements put in place by EMA to ensure that the Marketing Authorisation Application (MAA) process for COVID-19 treatments and the EU vaccine purchasing procedure under the APAs are two separate procedures. In summer EMA came to the conclusion was made aware that the parallel running of licencing and purchasing activities could give rise to a perception of bias if the same experts were involved in both types of procedures. EMA took action sending letters to the EMRN identifying the need to ensure that the MAA process for COVID-19 treatments and the EU vaccine purchasing procedure are run as two separate processes, and introducing restrictions for all chairs and members of CHMP, PRAC, SAWP and ETF in case of involvement in the EU purchasing process. The new arrangements come on top of the existing arrangements on CoIs described in the EMA Policy 0044 and have been put in place for the concerned Committees/scientific fora.

In addition, the Management Board endorsed 'additional safeguards to be put in place for securing the robustness and independence of the scientific review process for MAA for COVID-19 treatments – in relation to the specific case of the consequences of State/Government funding for COVID-19 treatments' since a further issue had arisen when EMA became aware, through published information, of funding by a Government of a pharmaceutical Company developing a COVID-19 treatment. Such funding can either be direct or indirect. Direct funding occurs through direct investment in a pharmaceutical company, while indirect funding takes place when financial support is provided to the conduct of development programmes and/or an increase in the production capacity. The issue does not relate to the State/Government funding as such, but to the consequences of a possible public perception of bias if a CHMP member coming from a national governmental organisation, takes on a lead role in the scientific assessment for a product concerned by the matter. This type of situation is currently not addressed in any of EMA's policies and it should be acknowledged that similar cases are very likely to arise over the next weeks and months. In order to provide specific arrangements to be applied proactively and in a transparent way, EMA proposed an approach balancing the interests of public health, avoiding as much as possible the perception of bias versus securing the necessary high-quality scientific expertise without delaying the start of the procedure. EMA will act only on the basis of publicly available information known to the Agency at the moment of the decision-making on the (Co)-Rapporteur appointment. The measure should not be seen as introducing the notion of a 'national conflict of interest' but only as addressing a very specific situation in the context of a pandemic, and therefore not setting a precedent for the scientific review for MAAs for non-COVID-19 treatments. Any restriction will be noted in the minutes of the Committee.

In the discussion that followed members did not object to the proposed handling of direct State/government funding. The representative of DG SANTE thanked EMA for setting a framework to keep the licencing and purchasing process separate by building a firewall, a problem familiar also within the Commission. Concerning indirect funding however, questions were raised by some members on the definition of the funding itself, with the suggestion put forward to handle such cases on a case by case basis. This option was not acceptable to EMA, as the Chairs of the Committees expect clear instructions, without which no action could be taken. The board agreed that it could endorse the approach with some adjustments concerning indirect funding.

c) EMA COVID-19 BCP: Impact on the EMA Work Programme 2020 and consequences for the EMA Work Programme 2021

The Agency provided the board with a status update on the current EMA BCP status. The EMA COVID-19 BCP which is in operation since March focuses on protecting its staff, contractors and delegates, and to safeguard its core activities and ring-fence resources supporting its COVID-19 activities. EMA aims at operating as long as possible under a "business as usual" scenario whilst prioritising any COVID-19 related activity. EMA is currently in phase 2 of the EMA COVID-19 BCP which means that all activities in the 2020 Work Programme that had not yet started or re-started have been put on hold. Staff is teleworking from home, with some activities carried out on site under strict safety and physical distancing measures, all meetings of the board, Scientific Committees, Working Parties and stakeholders are held virtually at least until the end of 2020. At the same time a still considerable amount of work stemming from Brexit and the implementation of the CHMP opinion on nitrosamines in human products is added to the increased workload. There is a need to prepare for the anticipated peak in MAAs for COVID-19 treatments foreseen for Q4 2020 – Q1/Q2 2021 which will mostly affect the Human Medicines Division and the Stakeholders and Communication Division, both with insufficient resources to address the anticipated workload increase. EMA has informed the European Commission that an increase in staff is urgently needed in order to address the immediate emergency while emphasising that the longer-term workload increase post-authorisation also needs to be addressed without delay. Staff with any expertise and experience in both MAAs handling and in proactive publication of clinical data, can either be reallocated in the Divisions mentioned, or will have to be reallocated from other parts of the Agency. In any case this relocation of staff to deal with the COVID-19 pandemic consequences for the Agency will have a substantial negative impact on both the EMA Work Programme 2020 and 2021. In the current phase 2 of the EMA COVID-19 BCP some 80 Work Programme projects/activities have been temporarily reduced or suspended, however to address the important increase in workload, and in the absence of additional resources, EMA will have to temporarily reduce or suspend additional activities agreed by the board as per the EMA Work Programme 2020-2021. At the December meeting of the Management Board an in-depth analysis of the impact for the 2021 Work Programme will be presented. At this stage it can be stated that the main objective for EMA is to safeguard its core activities with absolute priority for COVID-19 treatments. The 80 Work Programme 2020 temporarily reduced or suspended projects/activities will remain on hold. Further 2020 activities may have to be reduced. There will be an impact on the handling of Access to Documents requests and on work undertaken for the handling of non-COVID-19 supply shortages as the staff relocation is driven by the expertise and experience of the staff needed to address the additional COVID-19 related workload. In addition to the EMA COVID-19 BCP, the Agency and HMA have developed the EMRN COVID-19 BCP. As the pandemic situation remains volatile, the planning of anticipated work is made as accurate as possible by means of 2 weekly updates sent to the EMRN. The workload increase post-authorisation for the yet unknown portfolio of authorised COVID-19 treatments will be considerable and also needs to be carefully addressed. As a consequence, a survey to capture the resources needed post-authorisation in the Network for COVID-19 treatments (therapeutics and vaccines) will be launched. Since the important workload increase may affect the core work performed by EMA and NCAs, a scaling up of both the EMRN and the EMA COVID-19 BCP cannot be excluded at this stage. In addition, there may be staff absences due to staff falling ill or having to take care of ill relatives, which may not be easily replaced depending on their competencies.

7. Update on Brexit

Brexit preparedness activities have carried on at EMA as the Agency continues to track and monitor all Brexit-affected Centrally Authorised Products (CAPs). It appears that regulatory compliance will be

achieved after 31 December 2020 as most MAHs have made the necessary changes an all MAH transfers have been submitted. There are a number of CAPs for which changes to the QPPV, PSMF or manufacturing sites are still pending, but these do not need to be implemented before the end of the transition period. Concerning inspections, in 2019 the GMDP IWG developed and agreed a risk-based approach guidance allowing for GMP certificates for sites located in the UK and issued by UK authorities after the transition period, to be used under specific conditions. Due to the COVID-19 pandemic and the restrictions to travel, the IWG is considering the extension of the approach to sites located in 3rd countries that have been inspected by UK authorities. The impact of the implementation of the IE/NI Protocol on EMA IT systems and databases is currently being analysed. While there are no problems in continuing to provide full access or entirely withdraw access for the UK to EU databases, it is technically more challenging to provide partial access to the UK/Northern Ireland as this entity will have a new status and will require adjustments and changes that will impact on processes and systems. Further information will be provided to the board at the December meeting.

A. Points for automatic adoption/endorsement

A.1 Management Board Decision - Amendment to rules on leave

[EMA/MB/458533/2020; EXT/12715/2014; EMA/MB/156327/2020] The Management Board adopted the Decision on application by analogy of Commission Decision of 16 March 2020 amending Decision C(2013) 9051 of 16 December 2013 on leave to include the scenario where a staff member may become a parent by way of surrogacy.

A.2 Revision of rules on handling declared interests of staff and candidates before recruitment

[EMA/MB/458456/2020; EMA/371831/2020; EMA/259494/2016, Rev. 4*] The Management Board adopted the Decision of EMA on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment to align it to all other policies by updating the definition of pharmaceutical company.

B. Points for discussion

B.1 Highlights of the Executive Director

Nomination of Emer Cooke as Executive Director of EMA

After nomination by the board on 25.06.2020, all steps necessary for Emer Cooke's formal appointment have taken place: she was heard at the European Parliament on 13.07.2020 and a recommendation for her appointment was endorsed by the Parliament's Conference of Presidents on 22.07.2020. Her contract was then signed by her and the Chair of the Management Board on 15.09.2020 and the contract can now start on 16.11.2020. The Executive Director expressed satisfaction for the nomination of an dynamic and competent former staff member of the Agency, and wished her luck in her new position.

IM Future-proofing

The Head of the Information Management Division presented current efforts of rethinking the Agency's operating model. Supporting the Network mission, striving for excellence in everything, including security and quality standards, and leveraging best in class capabilities, are among the guiding principles reshaping the way EMA tries to anticipate developments in its environment, evolving despite demanding times. EMA had to select new managers, and transform its IM to modernise its infrastructure and underpin and support the forwards-looking Task Forces charged with digitalisation and data. A IM Roadmap 2021-2023 in being drafted, to guide the implementation of a portfolio of projects in the areas of Regulatory optimisation, digitalisation of Admin, data & analytics, workplace digitalisation and business continuity.

International Activities

International collaboration continues with high priority on COVID-19 through ICMRA. More than 30 meetings were held so far on vaccines, medicines and trials. Priority is on convergence of regulatory requirements and exchange of information with other ICMRA members. Health Canada participated in the remdesivir rolling review and CHMP CMA review (as expert peer-reviewer) and this allowed Canada to expedite their review in 3 weeks. Other interactions on COVID-19 took place with EDQM, and through direct country-to-country with e.g. Brazil, Israel. A first webinar was held with Accessing and Candidate countries (Instrument for Pre-Accession IPA) to build capacity on the Acquis Communautaire. In the meantime collaboration and exchange of information continue on nitrosamines in the Nitrosamines International Strategic Group.

European Activities

Most of our European activities of the past months have been directly linked to the COVID-19 pandemic as EMA has weekly calls with Commissioner Kyriakides, Sandra Gallina, John Ryan and ECDC's Director Andrea Ammon where the latest updates on the status of vaccines and treatment developments and on the status of shortage monitoring are provided. EMA has been supporting DG SANTE in the implementation of the EU Vaccines Strategy by developing regulatory and labelling flexibility for vaccines. The Agency is having discussions with DG SANTE on the urgent need for funding to be able to set up large scale post-authorisation studies to monitor the effectiveness and safety of vaccines, jointly with ECDC, immediately after they start to be rolled out in the MSs. The Agency has also been invited to debates and public hearings on COVID-19 in the European Parliament

9 years with the EMA Management Board

The Executive Director shared with the board his regret for not being able to say goodbye and thank the Management Board in person. Having had the privilege to sit on both sides of the board, starting as a member representing Italy in October 2008, he had witnessed the progress, achievements and challenges that the Agency and its Board had had to overcome. He recalled the main events which had taken place in the last 9 years and had shaped his tenure and his legacy. He concluded acknowledging the fact that his departure takes place at a time when the pandemic crisis is still ongoing, but the recognition of EMA's strength and its successes are taking the form of a renewed mandate, bringing new responsibilities to the Agency. He thanked all the friends and colleagues he had made along the way. The Chair thanked Guido Rasi for his time at the Agency, and for the energy, enthusiasm and competence with which he had led it through good times and difficult times. In particular his ability to maintain clarity of vision in the face of extraordinary and challenging events had set an example for the Agency's staff creating a climate of confidence in the ability of the EMA

management to steer the Agency through difficult times. The board joined the Chair in wishing Guido Rasi all the best for the next phase of his life.

B.2 Report from the European Commission

COVID-19 activities

In the period since last June, DG SANTE has been actively fostering procurement of ICU medicines for 10 Members States, EEA and other countries, covering 21 medicines in 6 areas. An evaluation of the offers is being finalised. A joint procurement for remdesivir is about to be launched. After its authorisation on 3 July 2020 a contract with its MAH was signed on 28 July, securing treatment doses for Member States and for the UK. The European Commission has funded the purchase of plasmapheresis machines and supported training for the collection of convalescent plasma as well as made funds available to support clinical testing of repurposed medicines to treat COVID-19 patients. The Commission continues to work closely with EMA and the NCAs in the EU Executive Steering Group to monitor shortages of medicines and medical devices. Concerning its strategy on vaccines supply, the Commission has so far concluded an agreement on behalf of EU Member States for the purchase of 300 million doses of vaccine and is in exploratory talks with four other pharmaceutical Companies who have a vaccine at an advanced stage of development.

Pharmaceutical strategy

The consultation on the Pharmaceutical Strategy Roadmap, which was run until July, has generated a total of 232 items of feedback from a variety of stakeholders. An analysis of the answers provided information on the frequency of the themes identified in the replies. Supply of medicines and accessibility are as the most discussed themes, while simplification and incentives appear to have a lower priority.

Strengthening of EMA

In her State of the Union speech on 16 September 2020, the President of the European Commission Ursula von der Leyen set out her priorities for the Union. In her vision for health, she stated that the mandate of EMA will be extended to reach the objectives of faster authorisation of medicines and of monitoring of shortages. Good cooperation by all will be crucial to achieve these goals. In the discussion on health competences for the EU, the issue of horizon scanning should be tackled, as there is a need for structured handling of crisis and health threats.

Evaluation of the Orphan/Paediatric regulation

The Evaluation of the medicines for rare diseases and children legislation has been published on 11 August and was conducted in line with the Commission's Better Regulation Guidelines. The resulting Commission Staff Working Document will be part of the implementation of the Pharmaceutical Strategy.

Following the presentation, some members of the board were interested in further details from the Commission. The representatives of patients' organisations enquired on the lack of transparency on contracts for the COVID-19 Vaccines. The Commission replied that the confidentiality of contracts has been imposed by the pharmaceutical companies. The Commission would itself favour greater transparency, but can understand why too early publicity on the contracts may not be desirable. The contracts have all been drafted on the basis of a single template to keep conditions as similar as possible for all. The representative of Doctors' organisations wondered what would happen to the

procurement should remdesivir turn out not to be widely used. The Commission explained that at the current moment it is important to secure the quantities that are required, as it will be available only in December and might be needed in case of a 2nd wave. A constant monitoring is in place, and if there would be a need to make adaptations to the marketing authorisation, the Commission will act.

B.3 EMA Mid-year report 2020 from the Executive Director (January – June 2020)

[EMA/MB/476052/2020; EMA/386447/2020] The Management Board noted the mid-year report 2020 from the Executive Director. The Agency had planned to gradually resume its full scale of operations within the limits of available resources in 2020. Following the outbreak of the COVID-19 pandemic in Q1 2020 the Agency invoked business continuity in order to protect staff, delegates' and contractors' health while delivering on its mandate. A BCP agreed with the whole EU regulatory network defined the guiding principles for the prioritisation of COVID-19 related work and of regulatory procedures. The Agency established an ad hoc BCP governance structure led by the COVID-19 Task Force. The Agency categorised its activities into 3 levels of priority (category 1 highest priority related to core and COVID-19 related activities, category 2 strategic activities and other core activities, category 3 lowest priority non-strategic activities) based on their impact on public health and on the ability of the Agency to function. Through these measures the Agency was able to mobilise circa 40 FTE to face the challenges originating from the pandemic. Out of 151 activities included in the work programme 2020 64 had to be suspended while 16 continued at a reduced volume and pace. Only 71 activities could be maintained at full scope. Among the key developments and achievements in 2020 the Agency submitted five different recommendations in support to the delegated and implementing acts of the European Commission, contributed to the CHMP assessment of remdesivir in the framework of emergency use of medicines in case of a public health emergency, worked on dialogue with the Commission on COVID-19 vaccines, established the EU Executive Steering Group on shortages caused by major events, continued the review of nitrosamines impurities in medical products and published the report on the lessons learned in the sartans review in June. The Agency's Regulatory Science Strategy was adopted. Following the HMA-EMA Joint Big Data Task Force's final report, the Big Data Steering Group was established. Trends on innovation show positive results, as seen in trends of classification of ATMPs, prime eligibility, scientific advice and initial evaluation applications. The positive application trends in conjunction with the COVID-19 emergency and the last consequences of Brexit have created a surge in workload which has not been met by an increase in staff. COVID-19 has had an impact on inspections, which were suspended given the inability to travel, but led to more complex desk-work and reliance on international partners. Veterinary procedures show healthy trends with increases in variation applications and requests for MUMS/limited market. Project implementation is largely on track and the data integration programme can resume its activities by Q3 2020 after resources had been redirected under the New Veterinary Legislation programme in the first half of 2020. Budget implementation as of the first semester 2020 has further improved in comparison to 2019 and can be considered as very satisfactory. Staff occupancy for Temporary Agents (TA) shows a 0.3% vacancy rate, while Contract Agent (CA) positions are covered only to 89.0% due to their less attractive contractual conditions and insufficient resources for selection procedures. Staff turnover has slowed down for TA and CA alike, as extraordinary provisions for teleworking linked to the relocation from London come to an end by the end of the year.

B.4 Revision of Internal Audit Charter of the Audit Capability (AF-Audit) of EMA

[EMA/MB/404190/2020; EMA/209787/2017 Rev.1] The Management Board adopted the revised Internal Audit Charter of the Audit Capability (Advisory Function-Audit) of the European Medicines Agency. The revision ensures alignment with the revised IIA Standards, Agency's Financial Regulation and Data Protection Regulation.

B.5 Lessons learnt (LLE) from the presence of nitrosamine impurities in sartan medicines: Impact Analysis and Implementation Plan

[EMA/MB/469318/2020; EMA/INS/GMP/473118/2020; EMA/INS/GMP/473117/2020] The Management Board endorsed the Executive Summary Lessons learnt from presence of *N*-nitrosamine impurities in sartan medicines Impact Assessment and Implementation Plan and the Lessons learnt from presence of *N*-nitrosamine impurities in sartan medicines. After the report and High Level impact assessment and Executive Summary had been endorsed by HMA and the Management Board in March 2020, the board and HMA endorsed the final report Lessons learnt from presence of N-nitrosamine impurities in sartan medicines in June, after a targeted consultation on the report recommendations had taken place in May 2020. The report on lessons learnt was published on 23 June 2020. The sartan LLE (Lessons Learnt Exercise) group has finalised the impact assessment and implementation plan which will be submitted for final endorsement to the HMA after endorsement by the board. Progress with the implementation of the plan will be periodically reported to HMA and the Management Board. The 40 recommendations of the LLE were assessed individually and allocated to several individual actions. A lead party and an indication of expected involved parties have been assigned to each recommendation/action. Each individual recommendation/action was assessed in terms of general impact and categorised by criticality, timeline for implementation, regulatory network investment needed. The Leads will be informed after the endorsement of impact assessment and implementation plan so that they can proceed with planning, prioritisation and implementation. A simplified table indicating the LLE recommendations, the Lead/involved parties and timeline will be published. The leads will also be asked to develop a more detailed cost (FTE or financial investment) assessment as part of the detailed project planning of the individual actions.

B.6 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/472757/2020, Rev.1; EMA/464240/2020; EMA/276356/2020, Rev.1; EXT/505221/2020] The Management Board noted the Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation, the Revised Full Functionality Document and the report of the EU Clinical Trial Regulation Coordination group.

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

Following Sprint 23 the implementation appears to be on track for the audit, with only four technical items pending to be completed in Sprint 24 which is now ongoing. According to the action plan presented by the developer at the end of Sprint 18, the delivery team is focused on delivering the remaining audit scope and recovering the undelivered and regression gap at the end of Release 14. From an audit analysis readiness heatmap a small number of technical items remain to be resolved. In the meantime the auditable version is providing a wide range of functionalities. The CTIS governance

in June-July agreed on the final scope of the audit version of CTIS. Following a public procurement procedure the contract for conduct of the independent audit was awarded to KPMG Germany. Audit initiation and audit kick-off meetings with KPMG, EMA and appointed technical experts from Member States took place in September and the first wave of audit documentation was shared with KPMG. Following the Board's June meeting The Go-Live and post Go-Live Prioritisation group was set up, the methodology was agreed and almost 1800 existing issues were prioritised in order of importance and sequence of development with an aim to finalise in October 2020. The Go-Live plan will be presented to the board at the December 2020 meeting. The validation of Release 13 was the first which took place under the new user testing strategy. Regression testing has shown fixing of regression items progressing well, and only 15 items remaining to be fixed for the audit. Extended testing of the full test suite will be performed during Sprint 24 to secure a stable version for the audit. Online learning is central for the CTIS knowledge transfer. Seven learning modules out of 21 have been developed to date. Materials are available to authorities in a restricted website and will become opened up to all user groups through the EMA website. It is essential that the network continues to be engaged in the training process and contributes with input and validation of training materials. The network of Member States Master Trainers is nearly established and onboarding will start in October 2020. A preliminary evaluation of the audit results should be available for mailing to the CTIS governance on 18 February 2021. An ad hoc teleconference should take place on 23 February to brief the board ahead of its meeting of 11 March 2021. The preliminary evaluation of audit results is scheduled to be mailed to the CTIS governance on 8 April 2021. On 14 April the Final Audit Report and the Report on the review of the Agency's project plan should be sent to the CTIS governance and to the Management Board. A provisional date for a preparatory meeting of the Management Board has been set for 16 April 2021, so that the board can take a decision in an extraordinary meeting on 21 April 2021.

b) Report of the EU Clinical Trial Regulation Coordination group

The EU CTR CG reported that substantial progress on the CTIS project has been made during the last couple of months. The first field work of the audit will take place on the auditable release on 16 November 2020, therefore making the Go-Live of the Clinical Trial Regulation by end of 2021 possible. The next months will be crucial, and frequent interactions will be needed with the Coordination Group and the other governance groups. A detailed planning for the go-live and post-go-live will be delivered to the Management Board at the December meeting. All involved were commended for their ongoing hard work and commitment.

B.7 Review of activities of the Working Parties (WP) of the EMA

[EMA/MB/492845/2020; EMA/491249/2020] The Management Board endorsed the High-level recommendations for guideline lifecycle process. Following the adoption of the high-level principles and proposals for the review of the activities of the Working Parties at the March Management Board meeting, the Review Group has continued to prepare and deliver their implementation by establishing a domain model and activating a cross Agency project team. In parallel, the CVMP has progressed with preparatory steps and initiated implementation. A data gathering request was sent to all Chairs of WP and Scientific Committees during summer and collected a wide response which is currently being fed into the workplans by the Domains. Feedback received is captured under the perspective of STORES: Strategic, Tactical, Operational, Reactive, Educational, and Stakeholder. To deliver STORES the new expertise model finds support by a majority committed to turnover. All WP consider that they are needed and that their work is essential to continue. Following the experience with COVID-19 the virtual meeting format is broadly supported. Chairs identified new expertise needs in the areas of real-

world evidence, AI, digital therapeutics, medical devices, hepatology and pharmacoepidemiology. A high level implementation plan is currently being prepared with the aim to have it finalised for endorsement at the EMA Management Board meeting in December and to go-live in March 2021. It is important to note that the launch may be impacted by a COVID-19 workload peak in Q4-2020 to Q1-2021. The Review Group has continued its discussions to address additional strategic areas, namely the guideline generation process, and has proposed some high-level recommendations on the different phases of the guideline lifecycle process for endorsement, including: (1) strategic planning, (2) initiating guidelines, (3) guideline development, (4) dissemination of the guideline and (5) training.

B.8 Progress report on the European Medicines Regulatory Network (EMRN) Strategy to 2025

The board noted the progress report on the drafting paper of the Network Strategy to 2025. A 2-month public consultation took place from July to September to promote transparency and stimulate visibility and awareness. Feedback was collected through an on-line form and grouped in clusters according to stakeholder types. In total 177 comments were received, with a good response by all. The overall impression of the joint strategy was positive, as three quarter of responders declared themselves highly satisfied/satisfied with comparable distribution among all the clusters. A comparison among the stakeholders was also done on what they considered as priorities, with all attributing very high priority to most topics in the strategy. Asked about whether there were significant elements missing in the strategy, a number of suggestions were provided. All stakeholders provided feedback for each of the themes. Overall, the consultation received a broad range of feedback with no stakeholder group predominant and focussing on a few specific themes. The experience with COVID-19 needs to be reviewed in order to include learnings and strengthen EU co-ordination and response to public health emergencies, including crisis communication. The strategy will now be updated taking into consideration the feedback received. Collaboration with the European Commission will continue to align the strategy with the pharma strategy and with IT colleagues working on the telematics roadmap. Appropriate actions will be identified and translated into the relevant work programmes/implementation plans which need to be finalised by end of 2020. The final strategy document and the summary report of the pubic consultation will be submitted for adoption by written procedure to the Management Board and HMA on 30 October with a deadline of 13 November 2020. The board was asked to note a placeholder on 17 November for a possible virtual meeting with HMA to finalise the network strategy should there be any outstanding issues. Publication of the strategy is expected by beginning of December 2020.

B.9 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. Focus is now on the 13 acts from the 1st and 2nd work packages which need to be adopted before or by January 2022. In order to achieve the implementation of the new Veterinary Medicinal Products Regulation, the work packages have been prioritised on the basis of their legal obligation, the acts in the 3rd and 4th packages do therefore have less stringent or no mandatory deadline. Concerning the feasibility study under Article 156 (active-substance-based review system or other potential alternatives for the environmental risk assessment of VMP) the tendering process has been completed and a kick-off meeting is due shortly with the winning contractor. Delays to the legal deadline of 28 January however cannot be excluded in view of the current situation. The European Commission continues to aim for a timely adoption.

EMA reported on good progress with four advices submitted and ongoing work on two advices proceeding on schedule. The staffing of the five additional posts allocated to the Veterinary Division in the 2020 budget has almost been completed. The VMP-Reg governance endorsed at the October 2019 meeting is fully established and the pre-inception for additional required projects is ongoing and will apply the same governance model. The VMP-Reg Coordination Group adopted a Change Management strategy in March and has drafted and discussed a plan with the HMA TF on Coordination of Implementation of the Veterinary Regulation. A quarterly newsletter was launched in 2020 and will become bi-monthly in 2021. Programme delivery is on track for EVVet3 while development work on the Union Product Database can continue on firmer ground now that the implementing act has been adopted. Although mitigations have been put in place, COVID-19 related circumstances can have repercussions on the programme and project delivery if key resources are impacted. To ensure delivery, it is necessary that budget allocations for 2021 and beyond must be secured to ensure delivery. Delivery of a minimum viable product is dependent on careful scope management and should not be endangered by repeated discussion of elements that are not within scope.

B.10 Introduction to the Union Product Database (UPD) Access Policy under the Veterinary Medicinal Products Regulation (VMP-Reg)

[EMA/MB/391703/2020; EMA/198149/2020] The Management Board noted the Union Product Database (UPD) Access Policy. The UPD Access Policy is required by Regulation (EU) 2019/6 and the draft implementing act on the specifications for the UPD. It defines the access rights of different stakeholder groups to the data contained in the database with a similar approach to those of the EVVet and the EVHuman access policies. 3 access levels (regulatory authorities, industry and the public) are defined in the document, while its annex defines accesses on field level. Product data elements accessible are established by stakeholder group along with the access enabled (read, create, update, delete). The Access Policy was endorsed by the UPD Project Group and the VMP-Reg Coordination Group for release for consultation and the board informed accordingly. The document was published for consultation from mid-July 2020 until mid-September and is now being revised by the UPD Project Group in light of the comments received. Following endorsement by the VMP-Reg Coordination group in early December 2020, the document will be submitted to the board for adoption during the December meeting, and subsequently published on the EMA website

The board discussed the updates provided on the implementation of the Veterinary Medicinal Products Regulation and of the UPD. The representative of veterinarians' organisations welcomed the progress made, and enquired specifically about the issue of exportation to third countries. The representative of DG SANTE acknowledged the difficulty of the discussion, which is also closely linked to the 'Farm to fork' policy. Some members stressed the importance for NCAs to be able to know as soon as possible the requirements on which to build their own national databases.

B.11 Update on Big Data Steering Group (BDSG) and DARWIN (Data Analytics and Real World Interrogation Network)

Following publication of the HMA-EMA joint Big Data Task Force report in January 2020, The Big Data Steering Group was established and it's workplan was published in September 2020. The workplan acknowledges that the COVID-19 pandemic may have an impact on implementation, and the milestones may need to be amended depending on circumstances. The presentation then focussed down on DARWIN EU. The mandate for DARWIN EU stems from the recognition that the EU has a rich and diverse healthcare data landscape but with limited access to data scattered across different partners. The vision of DARWIN EU is therefore to establish and maintain a secure EU data network

that supports EMA and the Member States for better decision-making throughout the product lifecycle with reliable evidence from real world healthcare (real-world data (RWD) and real-world evidence (RWE)). DARWIN EU will be a distributed network for fast access and analysis, with federated data access (data stay local with only results shared) and a third-party coordination centre. Principal benefits relate to the regulation of medicines throughout the product lifecycle delivering safe and effective medicines for patients, but additional benefits will be for the European Commission, as it delivers on European Health Data Space (EHDS), for national governments who can support health policy and delivery of healthcare systems, for HTA bodies and payers to support better quality decisions, and ultimately for EU patients who will have faster access to innovative and safe medicines. In the future DARWIN EU can act as a central pillar for health crisis planning and response, by understanding the natural history of the disease to support drug development, and by monitoring the safety and effectiveness of vaccines and treatments on the market. DARWIN EU should be anchored in the EHDS and be a pathfinder initiative of the EHDS demonstrating concrete health benefits for EU citizens. Funding of the project for the period 2021-2023 should come from the EU4Health programme and Horizon Europe starting 2021. From 2023 onward maintenance and evolution of DARWIN EU should ideally be financially covered by the revised EMA fee regulation.
More detailed discussions will continue at the December meeting of the board.

The representative of DG SANTE supported the financing model of the project in its set-up phase stating that the Commission would support it. She welcomed the suggestion for possible funding for its maintenance from a revised EMA fee regulation. She pointed out that in order to establish fees, the legislator needs to receive information on foreseeable costs. These should be based on a stabilised business case and contain adequate description of operational costs. Once the annual cost estimates are available and synergies and economies of scale have been demonstrated, work on setting up fees can begin. She reminded the board that work by the contractor for the financial aspects of the impact assessment will start soon, and for DARWIN EU to be included in the legislation on fees, data would need to be available on costs. When proposing the fee system, also provisions for flexibility for later changes will be considered, but it is most important to observe the right sequencing. The BDSG co-chairs replied that DARWIN EU is a new and better way of supporting national and European regulatory decision-making as a complement to clinical trials and that costing data will be provided to the European Commission services for their impact assessment work for the fee regulation. Assurance was given to a board member that DARWIN EU is not a database, but a network of data holders to support regulators leveraging data and initiatives at a national level. Several members congratulated the Task Force for the promising progress.

List of written procedures finalised during the period from 27 May 2020 to 15 September 2020

- Consultation no 12/2020 on the appointment of Blanca Garcia-Ochoa as CHMP alternate as proposed by Spain ended on 11 June 2020. The mandate of the nominee commenced on 12 June 2020.
- Consultation no 13/2020 on the appointment of Karin Janssen van Doorn as CHMP alternate as proposed by Belgium ended on 22 July 2020. The mandate of the nominee commenced on 23 July 2020.
- Consultation no 14/2020 on the appointment Kim Boerkamp as CVMP alternate as proposed by The Netherlands ended on 11 August 2020. The mandate of the nominee commenced on 1 September 2020.
- Consultation no 15/2020 on the appointment of Armando Genazzani as CHMP member as proposed by Italy ended on 3 September 2020. The mandate of the nominee commenced on 4 September 2020.
- Consultation no 16/2020 on the appointment of Nicola Magrini as CHMP alternate as proposed by Italy ended on 3 September 2020. The mandate of the nominee commenced on 4 September 2020.
- Consultation no 17/2020 on the appointment of Amalia Papadaki as CVMP alternate as proposed by Greece ended on 15 September 2020. The mandate of the nominee commenced on 16 September 2020.
- Consultation procedure for the adoption of the Agency's Final Accounts 2019 ended on 29 June 2020. The procedure was endorsed.
- Consultation procedure for the endorsement of the draft European Medicines Agencies Network Strategy to 2025 ended on 29 June 2020. The procedure was endorsed.
- Consultation procedure for the draft minutes of the 108th Management Board meeting ended on 3 September 2020. The procedure was adopted.
- Consultation procedure for the Extraordinary Management Board meeting minutes ended on 3 September 2020. The procedure was adopted.

Documents for information

- [EMA/MB/396798/2020; EMA/396803/2020] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/474257/2020] Outcome of written procedures finalised during the period from 27 May 2020 to 15 September 2020
- [EMA/MB/447191/2020] Summary of transfers of appropriations in budget 2020
- [EMA/MB/484473/2020; EMA/484474/2020] Tenth six-monthly report on ex ante and ex post evaluation of projects for the period 1 January to 30 June 2020

List of participants at the 109th meeting of the Management Board, held virtually on 1 October 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)* Nikolai Brun *(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	*Apology received*
Cyprus	*Apology received*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gytis Andrulionis (member)
Luxembourg	*Apology received*
Hungary	Mátyás Szentiványi *(member)* [1] Beatrix Horvath *(alternate)*
Malta	Anthony Serracino-Inglott *(member)*
Netherlands	Hugo Hurts *(member)* Michiel Hendrix *(observer)*
Austria	Thomas Reichhart *(alternate)*
Poland	Grzegorz Cessak *(member)*
Portugal	Rui Santos Ivo *(member)*
Romania	Romica Andrei Baciu *(member)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Momir Radulović *(member)* [1]
Finland	Eija Pelkonen *(member)*
Sweden	Asa Kumlin Howell *(alternate)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points 6.b, B.5 and B.7.*

European Parliament	Matthias Groote Tonio Borg
European Commission	Sandra Gallina (DG SANTE) *Apology from Kerstin Jorna (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 Emer Cooke *(Executive Director designate)* Noël Wathion Nerimantas Steikūnas Fergus Sweeney Hilmar Hamann Ivo Claassen Melanie Carr Anthony Humphreys Zaide Frias Alexis Nolte Agnes Saint-Raymond Edit Weidlich Stefano Marino Peter Arlett Maria Alves Hilde Boone Monica Dias Riccardo Mezassalma Marie-Agnes Heine Frances Nuttall Silvia Fabiani Sophia Albuquerque Rebecca Harding Apolline Lambert Sara Giorgi