7 November 2021
EMA/MB/571618/2021 Adopted
Management Board

Minutes of the 113th meeting of the Management Board

Held virtually on 7 October 2021

The Chair of the Management Board opened the meeting which was held fully virtually due to the extraordinary circumstances of the COVID-19 pandemic. 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 welcomed the new alternate for Italy, Francesco Trotta, and the new member from Luxembourg, Anna Chioti. The Chair informed the Board that the MB Topic Coordinators for the Programming document of the previous year, Nancy De Briyne, Lorraine Nolan, Rui Santos Ivo and Grzegorz Cessak had confirmed their engagement also for the 2022 EMA's Programming Document.

Draft agenda for 7 October 2021 meeting

[EMA/MB/218267/2021] The Board adopted the proposed agenda without amendments.

1. 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.4 Amendments to the existing Rules of Procedure of EMA Management Board and Scientific Committees; B.5 Amending budget 01, amending appropriations in budget 2021; B.6 a) Revision of Cooperation agreement and Key Performance Indicators for the implementation of the new Veterinary Medicines Regulation (Regulation (EU) 2019/6; B.7 c) CTIS Joint Controllership Arrangement (JCA); and B.9 Review of activities of the Working Parties of EMA: High-level recommendations for stakeholder engagement.* 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 the matter up again.

Members were asked to declare any specific interests that could not be drawn from their declaration of interests and 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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2. Minutes from the 112th meeting, held on 17 June 2021 adopted via written procedure

[EMA/MB/345297/2021] The Board noted the final minutes, adopted by written procedure on 13 August.

3. COVID-19

• EMA Status Report

The Board noted an oral update from the EMA's Executive Director on COVID-19 developments since the last Board meeting.

Most recent activities include the recommendation on 4 October for a third dose of the mRNA vaccines, Comirnaty and Spikevax in immunocompromised patients and the recommendation for a booster dose of Comirnaty for the general population approximately six months after the second dose. Several joint communications with ECDC on booster doses were published between July and September. Spikevax was authorised for children above 12 years of age on 23 July. Attention remains high on rare side effects. The risk of myocarditis and pericarditis in young males is closely monitored and all authorised vaccines have safety update reports published on a monthly basis. The Article 5(3) opinion for Vaxzevria was completed and it confirms the provisional CHMP opinion: it was not possible to identify risk factors for TTS but this rare side effect has now a decreasing fatality rate. EMA continues to work on increasing supply capacity and extending shelf lives of the authorised vaccines, through review of variations, resulting in increasing numbers of vaccine doses being made available in Europe. Five COVID-19 vaccines and three therapeutics are currently under rolling review. A marketing authorisation application for Regkirona (regdanvimab) is expected soon and three other immunomodulators are also under CHMP review. An evaluation for an extension of indication of Veklury is in progress. EMA provided an update on workload and resources across the expert network which remain an issue. Many NCAs have had to reallocate resources to support national efforts on COVID-19. The mitigation measures put in place by EMA have helped in some way, but problems remain at national level especially on recruitment and due to limited financial resources. The European Medicines Regulatory Network meetings continue on a biweekly basis and EMA now organises regular press briefings between committee meetings. Improvements to the rolling review process are being introduced. A fee waiver for scientific advice for COVID-19 products has been extended until the legal proposal for the extension of EMA mandate is adopted. The Agency is preparing to resume face to face meetings. Clinical data on all authorised COVID-19 vaccines has been published.

Members asked EMA to elaborate on the collaboration with ECDC in providing joint advice to Member States on effectiveness of COVID-19 vaccines. EMA explained that communication with ECDC has intensified and independent safety and effectiveness studies are being jointly contracted by the two agencies, with EMA being responsible for safety and ECDC for effectiveness studies. Discussions are ongoing on how EMA can further assist ECDC with collection of effectiveness data. The representative of DG SANTE called on all Member States to support EU agencies with collection of effectiveness data and stressed the importance of independent studies in order to combat vaccine hesitancy.

• Feedback on lessons learned

EMA provided a status update on the ongoing lessons learned review, building on the previous presentation at the MB meeting in June. The Agency is working with HMA to discuss challenges that COVID-19 presented for the European Medicines Regulatory Network (EMRN). The focus is on

identifying the most effective solutions that have been put in place during the pandemic, what remains to be addressed and what should be kept beyond COVID-19. Top 10 areas where learnings are currently being considered include the following: 1) support for rapid research and development activities in COVID-19 response; 2) rapid conclusion of authorisation procedures for COVID-19 products; 3) close safety and effectiveness monitoring of COVID-19 products post-authorisation; 4) ensuring and maximising the supply of products; 5) need to address issues that go beyond EMA's formal mandate; 6) increased transparency and proactive communication on COVID-19 related matters; 7) support for harmonised regulatory outcomes globally; 8) increased workload and resourcing of the EMRN; 9) coordination and reaching of a harmonised position within EMRN on COVID-19 related matters; 10) internal processes at EMA. In order to further develop this review, two workshops will be organised in Q4 of 2021 with NCAs and CHMP, PRAC and ETF representatives in order to focus on topics where more discussion is needed, i.e. on sustainability and resourcing of the EMRN including optimisation of processes and on interactions/communication with institutions and stakeholders outside the EMRN.

Members welcomed the COVID-19 lessons learned workshops and asked for their outcomes to be presented at future Board meetings. It was underlined that the pandemic has exacerbated pre-existing challenges for National Competent Authorities (NCAs), for example on resources, and the network should use the lessons learned exercise also to become better prepared for the evaluation of future innovative products. Some members expressed caution against systematically extending the rolling review process to all innovative products, as ultimately it is not regulatory procedures that are limiting access to innovation. The planned workshop should also help define how rolling reviews can be sustainably extended after COVID-19.

B. Points for discussion

B.1 Highlights of EMA's Executive Director

The Board noted an oral update covering EMA's activities with EU institutions and agencies, international cooperation, return to the EMA building for staff and relaunch of face to face committee meetings, court cases involving the Agency, the electronic product information (ePI) project and internal organisational changes at the EMA.

EMA is an observer in the newly established European Health Emergency preparedness and Response Authority (HERA) and attended the first HERA Board meeting on 1 October. The Agency was invited to provide an update on COVID-19 vaccines and therapeutics at the informal meeting of health ministers on 12 October and EMA's Executive Director will have her annual exchange of views with the European Parliament's ENVI Committee on 30 November 2021. At international level, since the OPEN project adopted by EMA's Management Board in December 2020 has led to faster authorisations of COVID-19 medicines in some third countries, due to the international importance of AMR, EMA is exploring how to expand the scope of this project to antimicrobial products. The ICMRA Pharmaceutical Knowledge and Quality Management project and discussions on joint inspections are becoming increasingly important in order to help increase supply of medicines and share regulatory resources. EMA has been asked by the European Commission to support a project for the development of vaccine manufacturing capacity in some African countries and also to provide support for the establishment of African Medicines Agency. On 6 October the WHO recommended the deployment of a malaria vaccine for children in sub-Sahara Africa; this product had received a positive 'Article 58' opinion from the CHMP in 2015. On 1 October Martin Harvey Allchurch became the new head of EMA's International Affairs Department. EMA staff have started returning to the building for two days per week since 1 October and from 25 October 2021 EMA's scientific committees will be alternating monthly face-to-face and virtual meetings,

although delegates who cannot attend in person can still join and vote remotely in a 'hybrid' setting. The December 2021 MB meeting is currently planned on 15 and 16 December 2021 in the EMA building in Amsterdam.

As regards court proceedings, the Aplidin judgement appeal will likely be examined by the European Court of Justice in early 2022, with planned written and oral submissions by Germany, Estonia (appellants), the Netherlands and EMA (interveners). A court case against EMA regarding the negative opinion on Cabazitazel Teva was withdrawn by the applicant in early October 2021, which confirms the robustness of the CHMP's assessment of the sameness of two active substances.

EMA-HMA-EC have been working on a one-year electronic Product Information (ePI) 'set-up' project throughout 2021, which has delivered a common EU standard for ePI in Europe. A follow-on ePI project starting next year will be funded by the EU4Health programme.

B.2 Report from the European Commission

The Board noted an oral update from the representatives of DG SANTE and DG Research and Innovation (DG RTD) on its latest activities on medicines.

The representative of DG SANTE informed the Board on recent developments regarding: 1) the Health Union Package's legal proposal strengthening EMA's mandate; 2) HERA; 3) the preparation of the European Health Data Space legal proposal; 4) the implementation of the Clinical Trial Regulation, with a focus on the EC Notice on CTIS and preparation of the Implementing Regulation on Safety Coordination and related Joint Action under Eu4Health; 5) implementation activities of the Pharmaceutical Strategy; 6) preparation of the EMA Fees regulation; 7) preparation of the revision of EU legislation on blood, tissues and cells; 8) the open call launched by the Commission for Civil Society representatives in the EMA's Management Board; 9) preparation for implementation of the new EU regulation on Health Technology Assessment and launch of the EUnetHTA21 consortium; 10) preparation for the revision of the EU orphan and paediatric regulations; 11) the preparation of a Delegated Regulation banning Titanium Dioxide as food additive and its impact on medicines; 12) a status update on the implementation of the EU strategy on COVID-19 therapeutics.

The representative of DG RTD informed the Board about the preparation of new research and innovation partnerships under the Horizon Europe programme. The adoption of the Council Decision for the Innovative Health Initiative (IHI) is expected in Q4 2021 and will allow the creation of the future governance structure, which compared to IMI will also involve the medical devices sector. Regulators will be welcome to provide input into the activities of IHI via the Science and Innovation Panel, whose task, among others, will be to advise on the scientific priorities. After over 10 years of cooperation, the European and Developing Countries Clinical Trials Partnership (EDCTP3) will be transformed into a new legal entity, like IHI, and it will promote clinical trials and trainings on ethical and regulatory aspects in Sub Saharan countries; it will also support efforts by Team Europe to promote local manufacturing in that region. The Partnership for the Assessment of Risk from Chemicals (PARC), involving several Commission DGs, 3 EU agencies and 27 Member States, will also be launched under Horizon Europe. Funding calls for COVID-19 under the HERA Incubator in April 2021 are supporting clinical trials networks for COVID-19 such as VACCELERATE, EU-RESPONSE and RECOVER. A Workshop on Adaptive Platform Trials in a Pandemic Context was organised by the European Commission on 5 October 2021 to address key bottlenecks in preparing and obtaining approvals of multi-country trial protocols. In the area of Antimicrobial resistance, as part of the Pharmaceutical Strategy for Europe, a new pilot has been launched by DG RTD to test pull incentives for antimicrobials via innovative procurement practices rather than via push incentives (i.e. grants). A call for proposals was launched to this effect in June and a review of submissions is currently under way.

Members inquired about the Commission Regulation on Titanium Dioxide and its impact on veterinary medicines for food producing animals, since no MRLs have been established for such products. EMA confirmed it is looking into this aspect and will carefully consider the necessary steps after the adoption of the Commission Regulation in January 2022. Members inquired about the next steps for the EMA fees regulation following the impact assessment's targeted consultation over the summer and on the timelines for the revision of the orphan and pediatric regulations. A question was also raised on how to apply the Implementing Regulation on Safety Assessments in clinical trials, given that no transition phase is possible and no IT infrastructure will be available at the start. The representative of DG SANTE explained that the fees legal proposal is targeted for the third quarter of 2022 and the European Commission will also further discuss its preparation with the HMA Management Group; it will have to be based on the impact assessment study, but will also consider other important factors. The legal proposal on Orphans and Pediatrics is planned for publication by the end of next year, as a package with the revision of the basic pharmaceutical legislation. As regards the clinical trial Safety Assessment Regulation, the new Joint Action in this area will help Member States to build knowledge and expertise and it will also provide them with basic IT support. EMA will also further consider what can be offered to Member States in terms of IT tools.

Questions were raised about next steps on the Clinical Trials Transformation Initiative and the Chair asked the Board if there was support for the Commission to organise a workshop / group with EC, EMA and NCAs in order to advance the discussion in a small group. The representative from DG SANTE noted that the CTR Coordination Group had supported the idea of a small working group to better define the main objectives of this new initiative and prepare a more detailed proposal to be discussed at the December Management Board meeting. The Board expressed full support to the idea of developing a Clinical Trials Transformation Initiative and to the organisation of a small working group to prepare a more proposal for the December Management Board meeting.

B.3 EMA Mid-year report 2021 from the Executive Director (January – June 2021)

[EMA/MB/501841/2021, EMA/352298/2021] The Board noted the EMA mid-year report 2021 from the Executive Director.

EMA explained that this is a regular overview of the state of operations and that a final report for the full year will be presented during the regular reporting period in 2022 (annual report, annual activity report). The report is built on four components: key developments in the work programme, trends in marketing authorisation applications (MAAs), budget performance and staff indicators. The impact of COVID-19 on resources meant that EMA has not been able to fully resume all activities suspended for BCP, however EMA continued work on medicine shortages, veterinary regulation, nitrosamines, AMR, digitalisation of procedures and DARWIN EU. Increased trends in applications, such as scientific advice and in ATMP classifications, are observed. Post-authorisation applications also show an upward trend, with the corresponding increase in workload and fee revenue. As regards inspections, their volume is higher than initially forecast due to a number of reasons, including the pre-authorisation inspections required for COVID-19 products. Post-authorisation veterinary procedures are also increasing overall, while Minor Use / Minor Species (MUMS) applications are reducing, perhaps because of industry waiting for the new veterinary legislative framework due to come into force next year. As regards budget implementation, the fee revenue performance is overall positive with the forecast revenue increasing in parallel with the growing workload. An Amending Budget is therefore tabled at this Board meeting. A slightly lower-than-expected budget implementation rate takes into account the fact that the funds for EMA's extended mandate cannot be utilised until the new legislation has been adopted and the Agency is requesting the European Commission to transfer the funds to the 2022 and partially to 2023 budget

years. The Agency expects to implement annual carry overs as per targets. As regards staff indicators, the projected occupancy level for TAs is 98%, which takes into account the recruitments to fill the new mandate and the short-term temporary agent posts. Occupancy levels for CAs are set to reach 97%. Turnover rates once again show higher rates in the CA category, which results in higher knowledge loss and decreased efficiency for EMA. Several recruitment procedures are ongoing to cope with COVID-19 workload, to replace many senior managers retiring and to prepare for the new mandate. All selection procedures are proceeding at speed. In addition, a number of trainees have started at the Agency in October.

Members inquired on whether the return to the building with reduced teleworking from abroad will have any impact on staff retention levels and EMA confirmed this might have implications, including a higher turnover, which will need to be taken into account during 2022.

B.4 Amendments to the existing Rules of Procedure of EMA Management Board and Scientific Committees

[EMA/MB/439109/2021 – Rev. 2, EMA /439108/2021 – Rev.1, EMA/366005/2021, EMA/MB/439109/2021 – Rev.2, EMA/MB/115339/2004/en/Rev.8] The Board adopted amendments to the Rules of Procedure of EMA Management Board and endorsed amendments to the Rules of Procedure of the Scientific Committees in accordance with Article 61(8) of Regulation (EC) No 726/2004.

The updates to Committees' Rules of Procedure focus on the article on organisation of meetings, which has been changed to allow both in person and virtual meetings i.e. virtual meetings will now also be possible in non-emergency situations and hybrid meetings (i.e. remote participation in an in-person meeting) will also be possible, but only during emergency situations. Oral explanations or hearings with applicants will be allowed either in person or remotely. Other changes were also introduced to facilitate the functioning of the Committees and for consistency reasons. The revised rules had been adopted by the Scientific Committees in September and received a favourable opinion from the European Commission. The proposed date of entry into force is 18 October 2021, in order to allow the first PRAC face-to-face meeting the following week.

The changes to the Management Board's Rules of Procedure are similar to the ones for Committees and had also received a favourable opinion from the European Commission.

B.5 Amending budget 01, amending appropriations in budget 2021

[EMA/MB/457635/2021, EMA/MB/458302/2021] The Board adopted the EMA Amending Budget 01 amending appropriation for the 2021 budget.

The Agency explained that the Amending Budget is due to changes in revenue and expenditure. As regards revenue the Amending Budget recognises the additional fees, shift of revenue for the Extended Mandate Union funding from 2021 budget year to 2022, and some technical aspects. As regard expenditure, the Amending Budget primarily recognises the corresponding extra workload and remuneration to National Competent Authorities, the expected increase in cost of translations, the investments to strengthen cyber security and the cost of interim staff to manage workload, among other items.

B.6 Cooperation agreement and Key Performance Indicators

[EMA/MB/472842/2021, Rev.1, EMA/MB/339083/2021] The Board adopted a revision of the Cooperation Agreement and of its Annex on Key Performance Indicators as required for the implementation of the New Veterinary Regulation.

a) Revision of Cooperation agreement and Key Performance Indicators for the implementation of the new Veterinary Medicines Regulation (Regulation (EU) 2019/6

[EMA/MB/504321/2021] The Board adopted Addendum 6 to the Cooperation Agreement between EMA and NCAs, including annexes.

EMA explained the changes focus on three areas. First to align the Cooperation Agreement to the new terminology of regulatory procedures under the New Veterinary Regulation. Secondly to delete references in the Annex on Key Performance Indicators (KPIs) to a pilot on KPIs that was started in 2010 and became normal reporting practice since 2012. Finally, to reflect in the Cooperation Agreement the fact that the derogation on the Irish language will expire in 2022. Following adoption by the Board, the Addendum 6 to the revised Cooperation Agreement will be circulated for signature by all Member States.

b) Annual report 2020 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use

[EMA/MB/400732/2021, EMA/MB/399014/2021] The Board endorsed the Annual Report 2020 on Key Performance Indicators for the evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use.

EMA explained there are no major changes or deviations in multi-annual trends compared to 2018 and 2019, however the 2020 report underlines the impact of COVID-19 on some aspects of the performance of EMA. A detailed document was circulated to members showing how individual national agencies performed. As regards changes to procedural timetables for COVID-19, the report shows that the adjustments made by EMA to cope with COVID-19 workload in general allowed compliance with legal deadlines, although for several variations they went over the legal requirements as per the exceptional flexibilities agreed by the European Commission. Overall, 2020 was a quite a successful year and the metrics will provide an important evidence base for the ongoing COVID-19 lessons learned.

B.7 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/458573/2021] The Board noted an oral update by EMA and the Coordination Group on the Clinical Trials Information System (CTIS) project for the implementation of the Clinical Trial Regulation.

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

[EMA/MB/458574/2021, EMA/MB/473854/2021] The Board noted an update on the Clinical Trials Information System (CTIS) project.

The publication of the CTIS Go Live Plan is planned in early October and it will provide: an overview of the final preparatory activities for the operation of CTIS, including the creation of a dedicated EMA CTIS service desk; a description of the initial scope for safety reporting and monitoring in clinical trials; a list of CTIS trainings and other change management activities; and a description of activities to address the functional and non-functional areas for Go Live.

As regards the status of CTIS implementation, the focus continues to be on delivering a stable system for Go Live meeting stakeholders' expectations. During the extended testing in June by Member States and sponsors, several blocking bugs were identified and are planned to be fixed prior to Go Live. The developer confirmed capacity to deliver the Go Live items and fixes from the projected findings also from the user testing of October 2021. Further testing by Member States and sponsors is currently ongoing and shows the system can handle a large workload from multiple users concurrently. Organisation models are being developed in collaboration with Member States to prepare Member States users to work with CTIS. Access to a virtual training environment (sandbox) will be granted to Member State Master Trainers from 15 October 2021 and will be available a month later to Sponsor Master Trainers. Remaining IT implementation will focus on: finalising the remaining technical scope for Go Live, resolving blocker findings from user testing activities and fixing remaining regression issues. A communication plan for the CTIS Go Live is being prepared and will be shared with the Management Board at the December meeting. At the request of the Commission, the Coordination Group endorsed a process for a harmonised handling of queries on CTR/CTIS, which will be piloted from now until January. On 27 September the Coordination Group also endorsed the mandate for a drafting group which will develop high level business requirements for the information management systems supporting the coordination of safety assessments in clinical trials, as required by draft Commission Implementing Regulation on safety assessments. Until such IT systems are in place, EMA will provide technical and administrative support to Member States to complement the EudraVigilance dashboard for Serious Unexpected Suspected Adverse Reactions (SUSARs) and SharePoint for exchanging documents.

As regards next steps for CTIS, the focus of EMA remains on ensuring quality and stability of the system for successful Go Live, on delivering essential technical support for safety monitoring and on change management and communication. Priorities for further system development include stability of the system; ability to deliver key milestones, for example submission of an application and decisions on trials; and data integrity. All users should be prepared to define internal functions and processes embedding CTIS, to define forms of Member States organisations and to select and train staff to work with CTIS, including by using the CTIS sandbox when available.

b) Report of the EU Clinical Trial Regulation Coordination group

[EXT/553140/2021] The Board noted a status report from the Chair of the EU CTR Coordination Group.

Progress is being made and the Coordination Group is receiving high quality reports from the development team. National agencies and ethics committees need to ensure that their staff and procedures are ready for the Clinical Trials Regulation and the CTIS Go Live date on 31 January 2022. The Coordination Group is pleased that the Go Live functionalities have been delivered and the system is now undergoing stabilisation and further user testing. Member States must adapt their processes to the capabilities of the CTIS. The CTIS training environment (sandbox) will soon be available and Member States should support the use of the CTIS sandbox to train their staff. Master Trainers and Mentors from the Member States are ready to train users and the helpdesk at EMA will also be ready to

assist. Common messaging to sponsors and other stakeholders is important in order to facilitate a gradual entry of CTIS into daily operations of sponsors while Member States gain their first experience with the system in real life.

Members asked how prepared the Agency is in order to implement the IT requirements of the Implementing Regulation on Safety Assessments and if a Plan B is needed. The Agency confirmed that the essential elements will be ready, such as a dashboard from EudraVigilance for SUSARS, a shared workspace and an allocation of roles, however some of the work will remain manual. As the Annual Safety Reports will not be an immediate requirement, the network will have more time to get equipped for them. In mid-October the drafting group on technical IT requirements for safety reporting will be re-convened and this will help clarify what will be needed in the medium term.

c) CTIS Joint Controllership Arrangement (JCA)

[EMA/MB/422912/2020] The Board endorsed the Clinical Trials Information System (CTIS) Joint Controllership Arrangement (JCA).

EMA scheduled four dedicated meetings between July and September with Member States and the European Commission to review the draft JCA for CTIS users, and to review and take into account all the comments and inputs received. In parallel EMA scheduled review meetings with representatives of sponsors, including industry associations, clinical research organisations, academia and the Co-Chairs of the Health Care Professionals Working Party (HCPWP), which unites scientific learned societies. After discussing all outstanding points, the text was endorsed by the sponsor representatives on 23 September 2021. The final text was endorsed by the European Commission, EMA and Member States representatives on 24 September 2021.

The JCA includes a definition of the legal framework applicable to the parties of the Arrangement, describes the processing operations of personal data in and out of scope of CTIS and of the Arrangement; defines roles, relationships and responsibilities towards data subjects including data breach handling and notification timelines. It also outlines joint liability towards data subjects in case of non-compliance and establishes an internal partitioning of responsibilities. In Annex it includes a Privacy Statement for users and data subjects, and a list of all the Member States' contact points. CTIS users appointed by the parties will have to electronically confirm acknowledgement of the Arrangement at time of first log-in and this acknowledgement will be logged in the system.

B.8 Update on preparation for implementation of Veterinary Medicinal Products Regulation

The Board noted an oral update from the DG SANTE representative on the implementation of the Regulation on veterinary medicinal products.

The focus continues to be on the Acts which need to be adopted before or by 28 January 2022. So far ten Implementing or Delegated Acts have been published in the Official Journal and one is to be published soon. After a lot of discussion in the European Parliament, the draft objections to the Delegated Regulation on the criteria for the designation of veterinary antimicrobials to be reserved for human use were not endorsed by the European Parliament plenary. These criteria have consequences on the Delegated Act on imports of animals and products of animal origin from third countries, which is still at a drafting stage and remains a very sensitive issue from a foreign trade perspective. Work is also ongoing on the Implementing Act on the online logo and on the Implementing Act on the format for collection of data on antimicrobials; the latter is undergoing a second written procedure and will be published for an open consultation soon. The feasibility study under Article 156 for an active-

substance-based review/monographs system and possible alternatives for the environmental risk assessment of veterinary medicinal products is due to be published by the end of October.

EMA provided an update on the activities for the implementation of the Veterinary Medicinal Products Regulation (VMP-Reg). Two scientific advices to the European Commission are in preparation. The advice on a list of antimicrobials to be reserved for human use has been delayed due to the objection raised during the scrutiny procedure in the European Parliament on the Delegated Act for the criteria and as a consequence of the questions raised some re-drafting of the list of reserve antimicrobials has been requested to EMA by the European Commission. The final advice is therefore now expected by January 2022; the same delay will apply to the advice on the cascade as they are interlinked. Development is ongoing on the Manufacturer and Wholesale Distributors Database; specifications are being drafted for the Antimicrobial Sales and Use Database, which is due by end 2022. The Union Product Database (UPD) release 3 is live and it allows NCAs to submit their legacy data which is essential to enable pharmacovigilance signal detection and management activities and a number of post authorisation activities, such as recording availability, marketing authorisation status and submission of sales volumes. Development of the Union Pharmacovigilance Database is progressing and is on track to be ready by 28 January 2022. As regards legacy data submission into UPD, Reference Member States have time to submit a common data set for MRP/DCP/SRP products until November 2021, then Concerned Member States will need to start completing their national data sets for the already entered products. Data for NAPs can be submitted at any point in time until Go Live. Legacy data submission has started with 27 products created in UPD however a large majority of products still have to be entered in the production environment. EMA is doing everything possible to allow the system to go live on time. Many change management activities are ongoing: additional mapping support was offered to NCAs for substances and organisations and webinars for NCAs are ongoing and available in the EU Network Training Centre. The priority for trainings keeps being on supporting NCAs in the upload of legacy data. A first webinar for MAHs on UPD functionality was held in September. EMA has also started to work with the UK's VMD so that Northern Ireland data can be entered in UPD and the legacy data upload is progressing on track.

The Board noted a proposal from EMA to establish an Advisory Group for the prioritisation of upgrades in the IT systems for the VMP-Reg. The mandate of the Advisory Group would be to discuss and prioritise new functionalities to developed for all veterinary IT systems. It should be composed by 6-10 Member State representatives, 4 representatives from industry, 2 representatives from veterinarians' associations, and representatives of EMA and EC. It will feed back to the Network Portfolio Advisory Group to align on next development priorities and review the VMP-Reg IT development plan for the following 24 months. The Agency will draft a mandate for this Group in consultation with the VMP-Reg Coordination Group and will submit it to the Board for adoption at the December meeting. The mandate will also be shared with HMA-V for information. Once established, the new Advisory Board would replace the current VMP-Reg Coordination Group upon closure of the ongoing development programme.

A Joint Controllership Arrangement (JCA) for UPD is being drafted in consultation with Member States and based on the CTIS JCA. Once agreed, it will be circulated to Management Board for endorsement at the December meeting.

The Chair asked for more details on the creation of the Advisory Group and if Member States will have to nominate contact points also for the UPD JCA. EMA clarified that a call for nominations to the Advisory Group will be launched in January after endorsement of the mandate by the Management Board and confirmed that Member States have to appoint contact points for the JCA. The representative from veterinarians' organisations thanked EMA for the VMP-Reg implementation newsletter and noted that substantial progress has been achieved, but still a lot of work remains to be done. In addition, there is a high risk on the submission of legacy data. She expressed full support to

the new Advisory Group and then asked the Commission if veterinarians could be consulted on the Delegated Act on the list of reserve antimicrobials, as important products for their profession are likely to be included on that list and then be banned for animals in Europe. The representative from DG SANTE noted that the Commission is sensitive to the needs of veterinarians and will explore how to best to consult them on this matter.

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

- **High-level recommendations for stakeholder engagement**
- **Update from the Implementation Task Force**

[EMA/MB/525082/2021, EMA/377662/2021] The Board endorsed high level recommendation for stakeholder engagement of the Working Parties and noted an oral update from the Implementation Task Force for the Review of the Activities of the Working Parties of the EMA.

High-level principles and proposals for the review of the activities of the Working Parties have been endorsed by the Board in March 2020 and Recommendations on the guideline generation process were endorsed in October 2020. This final set of recommendations addresses the engagement and relations of EMA's Domain and Working Parties with relevant European and international stakeholders' organisations. At the EU level, it is proposed to continue to organise meetings/workshops with EU bodies and Agencies throughout the year, as required and agreed in the 3-year rolling strategic plan. At the international level, the recommendations propose to realign the cluster meetings with international regulators to match the new operational model, in particular the revised Standing Working Party structures, and to reinforce cooperation with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) including by using their training materials more widely. Secondly it is proposed to create an ICH (Human) Steering Group to make sure the four Domains together with CHMP chair/vice-chair and EMA secretariat are more closely involved in what is prioritised and achieved at ICH level.

Following the endorsement of the revised High-Level Implementation Plan at the March 2021 Management Board meeting, due to the COVID-19 crisis the preparation for the implementation phase started only in Q3-2021 and a Project Implementation Task Force has been activated in September. Transitional governance for the five Domains has been established and it will exercise oversight on the Implementation Plan of the Working Parties with a focus on priority activities. The following activities are ongoing: developing an operating model/support architecture at the Domain level in cooperation with the Chairs of the current Working Parties and relevant Committees; constitution of Working Parties, Drafting Groups, Operational Expert Groups and European Specialised Expert Communities (ESECs); and definition of a timetable of activities and tasks needed to implement the new operational model. On 17 September the Steering Committee agreed the activation sequence of the human Domains, whose kick-off meetings are planned in October. As next step, the Implementation Task Force will decide the prioritised portfolio of activities in relation to the available secretarial support. The Task Force is also revisiting the Working Parties Implementation Roadmap which foresees building all the new structures by mid-2022 and then starting the implementation of the new operational model shortly thereafter. Further updates will be provided at the next Board meeting.

B.10 Big Data Steering Group update and progress report on the use of Real World Evidence in EMA committee decision-making (including DARWIN EU)

[EMA/512714/2021] The Board noted a progress update on the implementation of the work plan of the Big Data Steering Group (BDSG) and on the use of real world evidence (RWE) to support the EMA's committees, including via the DARWIN EU project.

The representative from DG Research presented a recently published study on real world evidence funded by the European Commission. The study shows that real world evidence is increasingly used in regulatory decisions and it recommends the development of harmonised data standards and data models for RWE. It also suggests the development of a methodological framework for the collection and analysis of healthcare data. A Horizon Europe call for proposals for research projects on methods and data collection tools for the effective use of RWE in regulatory decision-making or health technology assessment opened on 6 October. It has an available budget of 35 million Euros and the call will close on 21 April 2022.

The HMA Co-chair of the Big Data Steering Group (BDSG) provided an overview of the developments since the June update and on key activities planned in 2022 across the 11 priority recommendations of the BDSG work plan. A data standardisation strategy is being prepared in order to define what should be accepted in regulatory decision-making and will be presented for adoption at the December Management Board meeting.

The EMA Co-chair of the BDSG presented an analysis of the sources of demand and supply of real world evidence in the EU regulatory network. Sources of demand for RWE include drug development support, marketing authorisation applications and post-authorisation studies from the EMA's scientific committees. RWE is supplied by pharmaceutical companies, public scientific literature, and independent studies such as those sponsored by NCAs and EMA. The Scientific Committees can get support and advise on RWE from EMA as regards methodological questions from companies and on how to identify appropriate data sources, including registries to be consulted to inform committee decisions. To this end, a catalogue of data sources is currently being updated building on the ENCePP Resources Databases and should be available by the end of 2022. Committees can also benefit from an improved catalogue of observational studies based on the EU PAS register, which is planned to be updated by the end of next year. EMA can provide real world evidence to the committees via in-house accessible datasets derived from primary care sources and by procuring external studies through the EMA's framework contracts. As of 2022, studies with real world evidence will also be delivered through the federated network of the DARWIN EU project. A tender for the DARWIN EU Coordinating Centre is in progress and three candidates have been invited to submit a detailed offer. The appointment of the Coordinating Centre is planned for early 2022. EMA is also collaborating with the European Commission and participating in a pilot project to test use cases for the European Health Data Space. Due to the timeline for the DARWIN EU tender, the 2021 budget for that project has been transferred to 2022 via an Amending Budget. Proof of Concepts and pilots are being discussed with the Committees so that in-house studies, EMA commissioned external studies and studies via DARWIN EU can be rolled out more routinely in support of regulatory decisions over the coming months and years. Such observational studies in support of the committees should become routine practice from 2023 onwards and will become a valuable tool in response to future health crises. EMA is evaluating the impact of RWE in its decision-making processes and in order to discuss and compile best practices in this area a workshop, the Big Data Learning Initiative, is being planned for the 30 November.

The representative of DG SANTE asked if any collaboration is taking place between the Agency and the EU eHealth Network, which is performing important work on Electronic Health Records, as well as with

RWE-related IMI projects. EMA confirmed that several types of cooperation are ongoing, including with the Joint Action for the European Health Data Space (TEHDAS). The Agency is working with the French Data Hub to organise a pilot testing use cases for the European Health Data Space and it is waiting for the finalisation of the DARWIN EU tender before intensifying collaboration with more external consortia. There is however a need for the Network to prioritise and focus its limited resources where it can add most value and where the work will benefit medicines regulation. Members of the Board praised the good progress implementing the BDSG work programme and asked whether the EMA's analysis of the use of real world evidence in regulatory decisions had already been publicly disseminated. EMA clarified that the analysis results will be presented to the public for the first time at the workshop on 30 November. Overall, around 50% of the analysed submissions contain some RWE, but the importance of such data for regulatory decisions, particularly compared to clinical trials, merits further evaluation.

B.11 Information Management (IM) Agile governance reporting

[EMA/512714/2021] The Board noted a progress update on the implementation of the new Agile governance framework for Information Management projects.

The Agile methodology for the IT Portfolio was adopted by the Board at its June meeting together with a pilot to test the Agile ways of working on a subset of IT projects (i.e. DADI, ePI, PMS). The objective of the transition to Agile is to move towards a management approach with closer involvement of the Management Board and of HMA in the IT Portfolio, a closer alignment of IT projects with the strategic goals of the Network and a discontinuation of the separation between Telematics and non-Telematics projects. Work is ongoing to implement the new IM governance structure: the Network Portfolio Advisory Group (NPAG) had its first meeting on 29 September and the Network ICT Advisory Committee (NICTAC) will have its first meeting on 14 October. The Agile pilot has started and currently EMA is mapping the existing teams for DADI, ePI, PMS to Agile roles and establishing a calendar of Agile ceremonies, such as System Demos, sprint planning, etc. EMA is also aligning the backlog of these three projects to optimise delivery and overall business outcomes. A meeting with IT Directors dedicated to the IM governance revision and Agile methodology will be organised on 22 October and a further meeting is planned in Paris in April 2022. The Telematics website will be regularly updated on achieved progress during the transition phase. On 25 October a meeting with senior representatives from industry associations will be organised to provide more information on the new governance model and the Agile ways of working. First lessons learned from the Pilot include the recognition that the implementation of the Agile ways of working is a steep learning curve, that System Demos are critical for receiving constructive feedback from stakeholders and that the Agile methodology is a highly controlled process which focuses on optimising the system as a whole over optimising its individual components, and so it might result more complex than expected at the beginning. The Agile governance also entails a cultural change and requires increased delegation of decision-making to value stream owners and other teams at the execution level.

Further to the EMA's presentation, the Chair clarified that according to the European Commission civil society members of the Board can participate in the Agile governance structures until the end of their current mandate on 14 June 2022. A member of the Board asked how large IT projects, such as CTIS and the databases for the New Veterinary Regulation, will be transitioned to an Agile way of working. EMA noted that CTIS has been implemented as an Agile project since 2018 and this has helped to identify problems along the way more quickly, however large IT projects to implement legislation often come with tight deadlines, so they are likely to remain difficult. The Agile Pilot is mostly about testing governance structures: each project will have two Product Owners, one from the Agency and one from

NCAs. Product Owners would ask themselves how many decisions steps are needed and how to better focus the implementation. Although there is not a straightforward solution to improve the delivery of major and complex IT projects, the Agile Pilot is expected to provide useful inputs on how to further optimise them in the future.

Before closing the meeting, the Chair paid tribute to a staff member of the Management Board secretariat, Sophia Albuquerque, who will move to another role within the Agency from November 2021. Ms Albuquerque joined the Management Board secretariat in June 2011 and has since then organised under two Executive Directors more than 45 Management Board meetings, including ad hoc and extraordinary meetings also in different locations from the EMA's headquarters, such as in Rome and in Lisbon. Board members thanked Ms Albuquerque for her high-quality support to the Board and wished her well in her new role.

List of written procedures finalised during the period from 26 May 2021 to 13 September 2021

During the period from 26 May 2021 to 13 September 2021, the Board was consulted seven times via written procedure, as listed below:

- Consultation no 02/2021 on the appointment of Grzegorz Cessak as CHMP member as proposed by Poland ended on 10 August 2021. The mandate of the nominee commenced on 11 August 2021.
- Consultation no 03/2021 on the appointment of Inês Flor Dias as CVMP alternate as proposed by Portugal ended on 31 August 2021. The mandate of the nominee commenced on 1 September 2021.
- Consultation no 04/2021 on the appointment of Caroline Coner as CVMP alternate as proposed by Luxembourg ended on 10 September 2021. The mandate of the nominee commenced on 11 September 2021.
- Consultation procedure for the adoption the opinion on the Agency's final accounts for the financial year 2020. The procedure was adopted.
- Consultation procedure for the adoption of the Management Board Decision on the establishment of an exceptional flat-rate amount payable for the provision of specific assessment services during the current COVID-19 pandemic. The procedure was adopted.
- Consultation procedure for the adoption of the Management Board Decision on the transfer of appropriations in budget 2021, transfer No. 09-2021. The procedure was adopted.
- Consultation procedure for the adoption of the minutes of the 112th Management Board meeting, held on 17 June 2021. The procedure was adopted.

Documents for information

- [EMA/MB/518862/2021,EMA/518667/2021] Report on EU Telematics
- [EXT/553703/2021] Feedback from the Heads of Medicines Agencies
- [EMA/MB/520127/2021] Outcome of written procedures finalised during the period from 26 May 2021 to 13 September 2021
- [EMA/MB/457657/2021] Summary of transfers of appropriations in budget 2021
- [EMA/MB/481513/2021, EMA/481514/2021] Twelfth six-monthly report on ex ante and ex post evaluation of projects for the period 1 January to 30 June 2021

List of participants at the 113th meeting of the Management Board, held virtually on 7 October 2021

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier de Cuyper *(member)*
Bulgaria	Bogdan Kirilov *(member)*
Czech Republic	Irena Storová *(member)*
Croatia	*Apology received from Siniša Tomić (alternate)*
Denmark	Lars Bo Nielsen *(member)* Mette Hansen *(alternate)* Nikolas Jørgensen *(observer)* Jesper Kjær *(Co-presenter point B.10)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Alar Irs *(alternate)*
Ireland	Lorraine Nolan *(member)*
Greece	Eleftherios Pallis *(member)*
Spain	María Jesús Lamas Diaz *(member)* María Jesús Alcaraz Tomas *(observer)*
France	Christelle Ratignier-Carbonneil *(member)* Miguel Bley *(observer)*
Italy	Francesco Trotta *(alternate)* Agnese Cangini *(observer)*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Jānis Zvejnieks *(alternate)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti (member) Marcin Wisniewski (alternate)
Hungary	Mátyás Szentiványi *(member)* [1] Beatrix Horvath *(alternate)*
Malta	Anthony Serracino-Inglott *(member)* John-Joseph Borg *(alternate)*
Netherlands	Paula Loekemeijer *(member)* Michiel Hendrix *(observer)*
Austria	Thomas Reichhart *(alternate)*
Poland	Grzegorz Cessak *(member)*
Portugal	Rui Santos Ivo *(member)*
Romania	Robert Ancuceanu *(member)*
Slovakia	*Zuzana Baťová (member)*
Slovenia	*Apology received Momir Radulović*
Finland	Eija Pelkonen *(member)*
Sweden	Björn Eriksson *(member)* Asa Kumlin Howell *(alternate)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points B.4 B.5, B.6.a ,B.7.c and B.9*

European Parliament	*Apology received from Matthias Groote* Tonio Borg
European Commission	Andrzej Rys (DG SANTE) *(alternate)* Irene Norstedt (DG RTD) *(alternate)* Kristof Bonnarens (DG SANTE) (*observer*) Fergal Donnelly (DG RTD) (*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	Emer Cooke Ivo Claassen Fergus Sweeney Nerimantas Steikūnas Zaide Frias Melanie Carr Anthony Humphreys Hilmar Hamann Alexis Nolte Peter Arlett Pierre Pradal Stefano Marino Martin Harvey Maria Alves Hilde Boone Riccardo Mezzasalma Luc van Santvliet Monica Dias Marie-Agnes Heine Rebecca Harding Salvador Ruiz Marco Capellino Apolline Lambert Sophia Albuquerque