12 March 2021
EMA/MB/153834/2021 Adopted
Management Board

Minutes of the 111th meeting of the Management Board

Held virtually on 11 March 2021

The Chair of the Management Board opened the meeting which was held fully in form of a videoconference 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 welcomed the new members: Roxana Stroe, member for Romania; Joakim Brandberg, member for Sweden. The Chair invited nominations for the Analysis and Assessment of the Executive Director's Annual Activity Report (AAR) 2020 to be delivered at the June meeting. Maria Jesus Lamas Diaz (Spain), Nancy De Briyne (representative of veterinarians' organisations) and Gytis Andrulionis (Lithuania) were re-appointed.

1. Draft agenda for 11 March 2021 meeting

[EMA/MB/34198/2021] 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 *4. COVID-19 EMA Status Report; B.4.2020 EMA Annual Reports on Independence; B.5.Revised implementing rules to the Fee Regulation as of 1 April 2021; B.7.Review of activities of the Working Parties of the EMA; B.10. 11th Annual Report Veterinary MUMS/limited market; B.12. a) Big Data Steering Group update b) DARWIN EU Advisory Board: mandate.* 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 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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3. Minutes from the 110th meeting, held on 16-17 December 2020 adopted via written procedure

[EMA/MB/695181/2020] The Management Board noted the final minutes, adopted by written procedure on 1 March 2021.

4. COVID-19

EMA Status Report

The Management Board noted the COVID-19 EMA Status Report and agreed the short-term actions proposed by the Agency to address the resourcing of COVID-19 applications. Since the previous Board meeting, weekly meetings of the EMRN to discuss within the Network technical aspects related to the scientific assessment of COVID-19 treatments have been held. A second public meeting on the approval and roll-out of COVID-19 vaccines was organised by EMA on 8 January 2021. Conditional Marketing Authorisations (CMAs) were granted for the Comirnaty, Moderna and AstraZeneca COVID-19 vaccines. Review of a CMA application for the Janssen vaccine and rolling reviews for the Novavax, CureVac and Sputnik V vaccines are ongoing. Safety updates as well as first sets of clinical data for the Comirnaty and Moderna vaccines have been published. Guidance for vaccine manufacturers on adapting COVID-19 vaccines to SARS-CoV-2 variants was published on 25 February. As regards COVID-19 therapeutics, article 5(3) CHMP opinions were adopted for two combinations of monoclonal antibodies, developed for the treatment of COVID-19 by Regeneron and Eli Lilly, in order to advise on their conditions of use at national level before a MA is issued. An article 5(3) CHMP opinion for the monoclonal antibody developed by Celltrion was ongoing. Rolling reviews for the monoclonal antibodies by Regeneron and Celltrion have been started. Nominations of (Co)-Rapporteurship at CHMP and for Rapporteurship at PRAC level and the identification of experts primarily in the context of Multi-National Assessment Teams (MNATs) has become more challenging in recent weeks, and need to be carefully monitored in view of the need to take any remedial action as considered necessary. Higher demand for resources currently focusses on the pre-authorisation phase but first experience with authorised vaccines indicates that a high workload will also be observed over a prolonged period as regards post-authorisation changes, e.g. to address COVID-19 variants, manufacturing capacity and safety and effectiveness monitoring. Currently the EMRN COVID-19 BCP phase 2 prioritisation methodology is applied for CHMP, which stipulates that COVID-19 procedures are always to be given priority and for non-COVID-19 procedures a decision tree for prioritisation is followed in case delays are reported. As these arrangements are no longer sufficient to address the resource difficulties, additional short-term actions have been proposed by the Agency. They have been discussed with the network in February and March 2021 and are presented to the Board for agreement. For COVID-19 procedures, the new mitigating measures foresee that the concept of an appointed peer reviewer is no longer applied in order to free-up as many resources as possible, since a peer review is being undertaken by the whole CHMP and a detailed review is also undertaken by the ETF. Secondly, EMA will facilitate the use of the MNATs concept as much as possible. If further measures are necessary, EMA will look for further experts with the necessary vaccine experience at the level of the EEA Regulatory Authorities, and in case of need, also at the level of the non-EEA Regulatory Authorities participating in COVID-19 activities in the context of the OPEN initiative. In addition, EMA will discuss with the PRAC the need for any remedial action to be taken in order to free-up resources. For non-COVID-19 procedures, the following mitigating measures are proposed on a temporary basis: i) no longer apply the concept of a peer reviewer for all applications; ii) change the current role of the Co-Rapporteur both pre- and post-authorisation so that s/he only provides a detailed critique of the Rapporteur's assessment report, as per CVMP procedures; iii) deprioritise as per decision tree for phase 2 of the EMRN BCP, iv) in case an

applicant cannot meet the agreed timetable for submission, delay submission timetable by 1-3 months. The change in role for the co-Rapporteur is excluded for first-in-class medicines. For both COVID-19 and non-COVID-19 procedures, EMA will explore how to further improve the dissemination to the EMRN of information on planned submissions, so that the national Agencies have a better oversight of the anticipated workload. EMA will also put in place a technical solution to facilitate evaluations, focusing in first instance on COVID-19 procedures.

In the discussion that followed questions were raised on the need to reach out to non-EEA experts in the OPEN initiative and members committed to further look into the capacity of their own assessment teams in view of the expected peak in post-authorisation workload, while recognising the important strain on NCAs' resources and the need to find long-term solutions. Representatives of the European Parliament, of patients' organisations and of DG SANTE praised the work done by the Agency and stressed the importance of communicating the intense efforts made within the EU regulatory network to deliver high quality scientific assessments at unprecedented speed. EMA committed to continuing to proactively communicate and explain the approval process. The board agreed with the proposed short-term mitigation actions.

5. Aplidin General Court Judgment

The board noted an update from EMA on the follow up legal actions. In January 2021 two MSs have filed independent appeals against the General Court judgement. Official notification of their actions should be published in the EU Official Journal in mid-March, and both EMA and other interested MSs could intervene in the legal proceedings within forty days of the publication of the official notice. EMA will submit an act of intervention in support of their appeal. No MSs have requested an ad interim suspension of the Court ruling so far. The representative from DG SANTE informed that the European Commission (EC) has decided not to appeal, but it is still considering whether to submit an act of intervention at a later stage. An update on the EMA actions to comply with the General Court judgement and the impact of such changes on the access to scientific experts was provided under agenda item B.4.

6. Update on 30 Churchill Place

[redacted]

7. Update on Brexit

EMA is finalising the implementation of the EU-UK Trade and Cooperation Agreement (TCA) signed at the end of 2020. Awareness and technical meetings on the end of the transition period and the implementation of the IE/NI Protocol were held with industry, EMRN and UK Authorities (MHRA/VMD) in late 2020 and discussions continued in Q1 of 2021. As of 1 January 2021, UK is to be treated like any other third country, will not participate in EMA decision making or shaping and will receive only the outcomes of EMA procedures, with some exceptions for COVID-19 related procedures. However, MHRA and VMD participate as observers in the GMDP IWG in the context of the TCA. UK will have no access or only partial access to most EMA systems and databases, but it will retain full access to the PSUR repository and Eudralink. After 31 December 2020, only 3 Brexit-affected veterinary Centrally Authorised Products (CAPs) are not compliant with EU acquis, and two of those are not marketed. For these products EMA sent a non-compliance letter to the MAH. Following publication of the EC Notice on application of the EU pharmaceutical acquis in markets historically dependent on medicines supply from Great Britain in December 2020, EMA received four requests for exemption from QC testing in the UK and advised those MAHs to contact directly the relevant NCAs for the 4 markets since all CAPs for human use are already regulatory compliant. The NCAs for the 4 markets can then decide which exemptions to grant based on the needs for supply to their markets. The Agency completed all the required changes to the EMA IT databases and systems, except for EudraGDMP for which further changes required in the context of the TCA are being implemented following clarifications recently received from the EC. All other communication activities and guidance on the changes to EMA IT databases/systems and internal processes have also been completed.

A. Points for automatic adoption/endorsement

A.1 Management Board decision – amendment to Commission decision on transfer of pension rights

[EMA/MB/46155/2021, EXT/644244/2020,EXT/644221/2020, EMA/MB/44358/2021] The Management Board adopted a decision adopting by analogy Commission decision C(2020) 4818 final amending Decision C(2011) 1278 of 3.03.2011 on the general implementing provisions for Articles 11 and 12 of Annex VIII to the Staff Regulations on the transfer of pension rights. The decision aims to update the methods to calculate the years of pensionable service taking into account updated actuarial parameters published by EUROSTAT, such as the interest rate, mortality and invalidity coefficients.

B. Points for discussion

B.1 Highlights of the Executive Director

European Activities

EMA has weekly calls with Commissioner Kyriakides, DG SANTE and ECDC's Director Andrea Ammon to provide updates on COVID-19 vaccines and treatments developments and on the status of shortage monitoring. Commission President Von der Leyen has invited EMA to join meetings with the CEOs of the COVID-19 vaccine producers, as part of the implementation of the HERA Incubator, which is tasked to identify and address production bottlenecks, help increase supplies and support the manufacturing of additional vaccines addressing new variants. EMA participated in informal meetings of the EU health ministers on 13 January and on 1 March to give an update on COVID-19 vaccine approvals. As regards the European Parliament, on 7 January EMA participated in a hearing at the Budgetary Control

committee to discuss the discharge of its 2019 financial accounts; on 26 January EMA appeared in front of the Committee on the Environment, Public Health and Food Safety for an update on COVID-19 and on 28 January EMA participated in a public hearing on access to medicines at the EP's Special Committee on Beating Cancer.

International Activities

COVID-19 is the main driver of international activities and ICMRA remains very active on several aspects, with a focus on safety monitoring of vaccines, SARS-CoV-2 variants, pregnant and breastfeeding women. An ICMRA statement on transparency and data integrity was recently finalised and will be published soon. EMA and EC have signed a confidentiality agreement with Brazil (ANVISA), which will be important for inspections and APIs. EMA are in close contact with the European External Action Service (EEAS) office in Moscow to facilitate the GMP inspection of the Sputnik vaccine production sites and are working with WHO on sustainable regulatory agilities, based on best practices and lessons learned from COVID-19.

Organisational changes

Pierre Pradal was introduced to the board as the new Head of Audit and EMA informed of the retirement of Hans-Georg Eichler at the end of April 2021 after many years as the Agency's Senior Medical Officer. The board and EMA thanked Prof Eichler for his significant contribution and thought leadership in shaping Europe's position in Regulatory Science on a global stage.

Update on Cyber Attack

Following the cyber-attack in November, the Agency swiftly launched a full investigation, in close cooperation with law enforcement and other relevant entities such as the Dutch Cyber Unit, Europol and the Computer Emergency Response Team for the EU institutions, agencies and bodies (CERT-EU). EMA has enhanced its IT security operations also with advice from a specialised third party company. EMA continues to support the criminal investigation led by the Dutch authorities. EMA has worked with the EDPS to agree an approach for assessment of personal data at risk as well as with OLAF and with its insurance company. Media interest in the attack has been high in part due to information leaked by the attacker on the web. EMA has informed all companies and all NCAs as well as NCAs' staff an EMA staff where their data was compromised. The Agency held a meeting with companies whose data have been subject to unauthorised access, with participation also of EFPIA and Vaccines Europe. The Agency has remained operational and the cyber attack has not affected timelines for scientific procedures.

Emails from public to EMA Management Board members with regards COVID-19 vaccines

Board members were invited to redirect all public correspondence on COVID-19 assessments sent to them towards the Agency where all queries are centralised and answered by a dedicated team of professional writers using validated information.

COVID-19 third public stakeholder meetings

To date, EMA has held two public stakeholder meetings on 11 December and 8 January to update the public on COVID-19 vaccines. A third public meeting will be organised on 26 March to inform EU citizens about the continued assessment, approval and safety monitoring of COVID-19 vaccines, as well as their expected impact at community level.

Update on electronic Product Information

Following publication of EMA/EC/HMA key principles on electronic product information (ePI) in 2020, EMA has begun work on a one-year 'set-up' project on ePI for EU medicines in collaboration with the EC and the HMA 'Support for Better Use of Medicines' group. Funding for a one-year project has been exceptionally made available by EMA. The one-year ePI set-up project in 2021 will deliver: common standards for ePI, a prototype to perform a feasibility study generating ePI from PI and a roadmap towards future piloting and implementation of ePI into business. EU4Health funding has been secured for the subsequent follow-up project.

Virtual visit of the King of the Netherlands

His Majesty Willem-Alexander, the King of the Netherlands, paid a digital visit to the Agency on 19 February. The King welcomed EMA to the Netherlands and was interested to learn more about the Agency's role in public health in Europe, the Agency's relocation to the Netherlands, its contribution to the COVID-19 response and its vision for the future.

A representative of patients' organisations praised EMA's engagement with the public on COVID-19 and the support to the board in dealing with external correspondence. Questions were raised on the long-term response to the cyber-attack and how the Agency would continue to guarantee the highest levels of protection of patients' personal data. EMA explained the potential impact on patient data was the top priority of the investigation and was thoroughly discussed with the EDPS who confirmed risk of re-identification of patient data is very low. Even before the cyber-attack EMA had IT security high on its agenda, but will now be using this experience and the investigation to build a stronger system and will invest heavily in this area in the coming months.

B.2 Report from the European Commission

[EXT/146060/2021, EXT/147893/2021, EXT/147894/2021]

Pharmaceutical strategy for Europe

The Strategy includes a total of 55 actions to be implemented in the coming four years, many of which are ongoing, and many are related to EMA. Of high relevance for the EMA is the revision of the basic pharmaceutical acts. A roadmap for such revision will be published soon and a legislative proposal is planned by the end of 2022. Discussions are intensifying in the Pharmaceutical Committee to define options for changing the legislation. A public consultation on such policy options will be organised in Q3 2021 for 12 weeks. It will provide inputs for an external study which will inform the impact assessment of the future legislative proposal. At the same time work is progressing on the revision of the orphan and paediatric regulations, for which a legislative proposal is expected in early 2022. Discussions on the HTA regulation have progressed in the Council and the EC hopes to start trilogues soon.

Health Emergency Preparedness and Response Authority (HERA)

The legal proposal for the establishment of HERA will be presented in late 2021. On 17 February the Commission presented a new EU bio-defence preparedness plan against COVID-19 variants, called HERA Incubator, which aims to boost preparedness, develop vaccines for the variants and increase industrial production. It will serve as a blueprint for the EU's long-term preparedness for health emergencies and as a test phase for the full-fledged Authority. As part of the Incubator, on 11 March the Commission adopted changes to the Variations regulation to accelerate the approval of changes to

the MA of COVID-19 vaccines to adapt to new SARS-CoV-2 variants; the proposal will shortly be submitted to the European Parliament and Council for scrutiny.

EU4Health programme

The largest funding programme on health of the EU, EU4Health, worth 5.1 billion for the period 2021-2027, was adopted by the European Parliament on 9 March 2021. It provides opportunities for MSs to obtain funding to collaborate on: shortages of medicines and production capacity, repurposed medicines, tackling AMR, international convergence, innovative clinical trials, sharing best practices on pricing and reimbursement and protecting the environment. A work programme will be published in April and the Commission foresees funding for three joint actions in the pharmaceutical sector, namely on shortages, innovative clinical trials and GMP inspections.

The representative of veterinarians' organisations asked if a one health approach will be adopted for HERA as zoonoses are important health threats and the current pandemic is leading to more use of antibiotics, increasing AMR. Questions were raised if the sustainability issues of the network will be addressed by the Commission and if HERA incubator will also support production of ancillary substances, vials, old antibiotics and generics for which production issues are encountered. The representative of DG SANTE explained the preparatory phase of HERA after 2021 might include pilots on AMR and zoonoses, while the HERA incubator is only limited to COVID-19 variants due to the current urgency. Vials and other ancillary substances for vaccines are likely to be included in the HERA Incubator programme. Funding for MSs to increase production capacity and reduce dependency on third countries will arrive from the Recovery and Resilience Facility and to date at least 8-9 MSs have announced investments in their biotech industry.

B.3 EMA Annual Report 2020

[EMA/MB/74231/2021, EMA/706919/2020] The board noted an update on the preparation of the EMA Annual Report 2020. Due to the current heavy workload in the communications team at EMA due to COVID-19 related activities, preparation of the annual report this year has been delayed slightly. As such, the report will not be presented to the March Management Board as usual, but it will be shared with the board for a written procedure starting on 12 April. It will then be enriched with visuals and design and published as a digital report. It will include key figures, description of strategic priorities, of the handling of the pandemic and a timeline of the main initiatives. The 'major activities' chapter will focus on the highlights from the authorisation and monitoring of medicines, public health response including the fight against AMR, Brexit and relocation, EMA's first 25 years and preparing for the future (EMANS to 2020 and Health Union proposal). The PDF version will include many annexes with detailed statistics. The Annual Report 2020 will still be published and sent to EU institutions by the legal deadline of 15 June.

B.4 2020 EMA Annual Report on Independence

[EMA/MB/116532/2021, EMA/34780/2021] The board endorsed the 2020 EMA Annual Report on Independence.

The report was originally requested in 2015 by the EC to increase transparency on the state of implementation of the three independence policies at the Agency. Three annual reviews have been presented to the Management Board in 2016, 2018 and 2020. All three EMA independence policies were last revised in June 2020 to include the definition of financial interests of stock warrants, a definition of partner and of references to the GDPR legislation. The revised Policy 0044 for scientific committees' members and experts became effective on 1 January 2021 and also includes new

obligations for experts to declare their personal involvement, or the involvement of their organisation, in the repurposing of a medicinal product. CAT members and alternates also have to declare interests in the biotechnology and the medical device sectors (activities linked to ATMPs). Restrictions have been introduced for inspectors declaring close family interests and grants, i.e. they are not allowed to perform inspections in the declared company(ies), to align with current practice in the majority of EU member states and at FDA. In 2020, 6 delegates mentioned an intention to become an employee in a pharmaceutical company, but none of these cases constituted a conflict for any ongoing procedures. EMA did not initiate any breach of trust procedure in 2020. EMA performs a preventive control of the e-DoI of each new expert, checking it against their CV before involvement in scientific procedures (ex-ante controls): 617 such checks were done in 2020 with 22 errors (3.6%) noted in the e-DoI, all clarified prior to involvement. The ex post controls, i.e. checks after involvement in EMA activities, focussed on SAG/AHEG and WP participants who declared direct or indirect interests. 40 experts were randomly selected. No major problems were detected.

EMA took immediate minimum measures to implement the judgment for both the Aplidin application and for ongoing and planned regulatory procedures as from November 2020. For SAGs and AHEGs, experts that are employed by universities or university hospitals performing development or manufacturing activities on any medicinal products actually or potentially competing with the (candidate) product for the indication under review, are not allowed to be involved in the procedure. The adverse impact of the judgment on EMA's operations, but also on the NCAs, is considered very significant in terms of finding the best specialist expertise, a trend that has already been observed and which may lead to decreasing the robustness of the scientific assessment and possible important delays in the assessment of MAAs. In practice EMA is no longer able to use disease-specific experts and has to use generalists. In addition, in 7 scientific meetings organised following the ruling, despite targeting generalists for 40 experts contacted, 15 had to be excluded based on prior exposure.

As regards the revised Policy 0058 for Management Board Members, which became effective on 1 July 2020, ex ante controls on DoIs of all MB members' DoIs are done prior to each meeting. No ex post controls were carried out in 2020 due to the EMA BCP, but EMA is considering how to resume.

Rules for EMA staff became effective on 1 October 2020. A DoI is requested from all candidates on appointment and for all staff annually. Ex post controls in 2020 were performed on 50% of staff DoIs with interest level 2 and 3. 53% of the DoIs evaluations contained 1-3 minor errors (wrong form), which will require some training of reporting officers in assigning risk levels. None of the findings had an impact on the participation of the staff members in their EMA activities. A yearly ex post control to ensure compliance with the rules will be performed as of 2021. As regards Joint Committee procedures (article 16 of Staff Regulations), in 2020 36 applications were made, 8 with restrictions, 28 with no restrictions, for SNE cases no restrictions were applied. Examples of restrictions for staff leaving EMA include a distance clause whereby the former staff member may not contact individual Agency staff for a period of time, e.g. 6-12 months; all decisions include a reminder of the binding obligation of confidentiality after leaving and a requirement that opinions given in public presentations must be stated to be the former staff member's own and not linked to their former employment at EMA. EMA decisions on senior staff leaving EMA are available, as of 18 December 2020, in a register on the EMA corporate website.

As regards implementation of the additional safeguards for COVID-19 MAAs endorsed by the board on 1 October 2020, requests to declare involvement in case of State/Government funding for COVID-19 treatments or involvement in Advance Purchase Agreements were sent. If no reply was received by 28 January 2021, it was considered that there was no involvement in APAs. 1 CHMP member and 3 alternates were restricted, no restrictions were needed for PRAC nor for ETF. For assessment team members, 349 declarations were received, with nobody declaring involvement in APAs. In one situation state funding was identified and resulted in agreed restrictions being implemented (no rapporteurship

role). Implementation of the recommendations in the 2020 report on independence will have to take into account EMA's workload and available resources, including EMA's capacity to act on any IT implementation.

B.5 Revised implementing rules to the Fee Regulation as of 1 April 2021

[EMA/MB/506725/2020, EMA/MB/316533/2020] The board adopted a revision of the Fee Implementing Rules coming into force as of 1 April 2021.

The revision includes the following changes: 1) a fee exemption for pandemic human influenza vaccines, taking account of the public health need to maintain the authorisations for pandemic preparedness vaccines; 2) 50% reduction in post-authorisation fees for human vaccines authorised under exceptional circumstances for preparedness in the context of bioterrorism; 3) clarification that fees for EMA consultations on medical devices are charged to the medical devices manufacturer, as original requester and beneficiary of the conformity assessment, even though EMA's consultation is triggered by the Notified Body; 4) decision to postpone the annual adjustment of fees to inflation until 2022, taking into account the low rate of inflation in 2020.

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

[EMA/MB/44296/2021] The Management Board noted the Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation.

a) Summary Report from 23 February 2021 meeting

[EMA/MB/118548/2021] The first independent Audit visit by KPMG took place in November-December to test the EU Portal and Database as required by the clinical trial Regulation and the preliminary audit findings were received by EMA at the end of 2020. A contradictory procedure between EMA and KPMG ensued and in February 2021 EMA prepared an implementation plan to rectify the challenges identified in the first audit visit. Both the first audit visit findings and the EMA implementation plan were presented at the ad hoc Management Board meeting on 23 February 2021. KPMG will measure the implementation of that action plan during a second audit visit at EMA starting on 15 March 2021. KPMG will provide its final audit report and a review of the project release plan proposed by the EMA by 14 April. The final audit report will be discussed by the board at a preparatory meeting on 16 April, then by the CTR Coordination Group (CG) on 19 April and finally at an extra-ordinary meeting of the Management Board on 21 April 2021, when the board should decide on the outcome of the audit and adopt a communication to the European Commission in accordance with Article 82 of the clinical trial Regulation.

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

[EMA/MB/44297/2021] EMA presented the CTIS delivery plan until go-live in January 2022. The plan prioritises essential technical developments, legal requirements and priorities business requirements, while further technical and functional development will take place after go-live. During the testing period in the coming months the addition of new requirements should be avoided. In March-April the project team will focus on fixing the audit findings and analysing the legal and business requirements. Between May and September, it will implement these requirements and test the system with end users. Between September and January 2022 all development will freeze and the project team will

focus on addressing the remaining issues and essential technical features. Between the Go-live on 31 January until July 2022, the "hyper care" period will be dedicated to fixing issues from production use and related to IT security, performance and scalability that have been agreed to be addressed in that period. After July 2022 an enhancement period will start for delivery of new functionality as of October 2022. The EMA project team will consist of a business team interacting with MSs and sponsors for testing, a change management team dedicated to training and user support and a service desk for first line technical support. The maintenance support will be provided by the external contractor, Everis. An overview of functionalities that will be available at go-live and which will be developed after go-live was presented. The training programme will include a master training programme for the MSs. Sponsor training is intensifying and sessions with pharmaceutical industry and CROs will be organised in Q2, webinars for SME and academia were held in Q1 and for international stakeholders will be organised as of May. More trainings will start in the last part of the year, as many users as possible need to be trained and understand how to use the system.

c) Update on planning for go-live and post-go-live, planned go-live date and update from EU Clinical Trials Coordination Group

[EXT/143080/2021] The Coordination Group noted that at its ad hoc meeting on 23 February 2021, the EMA Management Board was updated on the outcome of the first audit visit. The Board asked EMA to provide more details on the impact of the proposed reprioritisation in the technical items, to provide a concrete overview of the functionalities that will be delivered at the moment of go-live and subsequent releases after go-live, and a detailed planning (including user testing) for the different periods (pre-freeze, freeze). The CG met on 4 March 2021 and reviewed the detailed plan for go-live. The plans were considered detailed and able to deliver CTIS for go-live on 31 January 2022. The CG also heard that this plan will deliver all the functionality that were developed for the audit version, as well as the agreed additional functionality (MVP) for go-live. The deferral of some technical items until post go-live, whilst having impact on performance, service levels and requiring close security monitoring, will not result in functionality currently agreed being deferred to after go-live. The deferred technical items can be addressed in the first six months of hypercare post go-live. The trade-off will be in quality, response times and security. The information presented provides elements of assurance towards the delivery in the above-mentioned deadline. The first delivery of additional functionality post go-live will take place towards the end of 2022. There will be further budget for development of additional functionality as well as maintenance during 2023 so more releases can take place. The CG also noted the extensive training now being undertaken and asked for the Board to be updated on this. The CG agreed that the planned go-live date of 31 January 2022 should be announced in the Management Board highlights of 11 March 2021. The public highlights should nevertheless clarify that this go-live date is the aspiration of the Board, being without prejudice to verification of the final audit outcome and full functionality of CTIS by the Management Board in accordance with Article 82 of the clinical trial Regulation.

B.7 Review of activities of the Working Parties of the EMA

[EMA/125403/2021, Rev.1, EMA/MB/125024/2021, Rev.1, EMA/MB/134823/2021] The Management Board endorsed the revised high-level implementation plan.

Following the discussion at the December 2020 Management Board meeting, further work was requested on the high level implementation plan in order to provide more precise information on the Operational Expert Groups (OEGs), temporary Drafting Groups (tDG) and Special Interest Communities (SIC) with particular emphasis on how these allow all Member States to engage with the system and to ensure the plan would deliver on expectations across the different Domains. To this end, the

implementation plan was adapted to introduce these elements as well as conducting a dedicated HMA satellite meeting on 2nd March 2021 to review the operation of these structures in more depth. The review and its effort to rationalise the structure of working parties has led to the proposed introduction of the concept of five Domains of quality, non-clinical safety, methodology, clinical and veterinary. The Domains were endorsed by the board in March 2020 and they are new strategic oversight bodies populated by chairs of the relevant Working Parties and chairs and/or vice-chairs of CHMP/SAWP/CVMP and SAG chairs, as appropriate. Four other organisational entities report to the Domains: European Specialised Expert Communities (ESEC, formerly proposed as Special Interest Communities), temporary Drafting Groups (tDGs), Operational Expert Groups (OEGs) and standing Working Parties (WPs). The Domains should perform STORES (Strategic, Tactical, Operational, Reactive, Educational, Stakeholder) functions in order to implement the Network and RSS Strategies to 2025 in a dynamic way, including by generating 3-year rolling strategic plans linked to these Strategies. Domains are also expected to coordinate activities within the European Specialised Expert Communities and oversee their activation within other organisational entities (tDGs, OEGs, WPs). ESECs are proposed to be a community of experts with special knowledge and interest in a given topic area. ESECs should be the source of expertise when constituting tDGs, OEGS and WPs which will deliver the various work elements and be as inclusive as possible. It should be possible for the same assessors to be in more than one ESEC depending on their expertise. Once established, ESECs can also further specialise as needs evolve. Temporary Drafting Groups (tDGs) are designed as lean structures, between 3-5 members volunteering from relevant ESEC(s), primarily constituted for the purposes of drafting guidelines. Up to 200 potential guidelines have been identified to be developed or revised in the next 2-3 years and the Domains will need to establish priority in such guidelines development, having consulted with stakeholders. Operational Expert Groups (OEGs) deliver input on live assessments, providing advice to CHMP and PRAC. Advice on products can be provided by standing Working Parties or by OEGs depending on topic and product. Standing Working Parties (WPs) will continue to perform certain tasks associated with the drawing up of scientific opinions or the work of the Committees. Their expertise is proportional to expected workload but can be modulated accordingly. The benefits of the new model are the potential to deliver strategic priorities, being adaptable to future needs, being able to reach out to stakeholders, show strategic leadership and ultimately make the EU a more competitive region in global drug development. Other benefits of the new model are to redistribute expertise in a more agile structure such as Operational Expert Groups (OEGs) and Temporary Drafting Groups (tDG) and consequent reduction in number and membership of standing working parties. ESECs in particular will introduce efficiency and consistency by providing information flow to the network, training development and source of expertise. ESECs will also enhance the involvement of network experts and foster the concept of MNATs. Experts may choose the level of activity, from listening to topics to becoming major contributors, in agreement with their nominating Head of Agency. The issue of funding NCAs' contributions in expertise to the network should be addressed in the ongoing fee regulation revision, to ensure sustainability. As regards next steps, the endorsement of the high-level implementation plan will trigger human and veterinary implementation. However EMA will only initiate implementation of the review after the COVID-19 peak is past, possibly in Q2 or Q3 of 2021, to be decided by the chairs of the Committees. A formal review will be presented to the Management Board two years after the go-live of the new model, in order to take stock and identify possible readjustments.

Following the presentation from EMA, requests were made for the veterinary domain to be detailed in the implementation plan in the same way as for the human Domains and for WPs to have a good balance and repartition across NCAs whereby, when several candidates are available, the criterion of representativeness should be taken into account. During the implementation phase EMA is committed to guaranteeing diversification and representativeness of the new system. The Management Board

Review Group will continue to oversee the implementation process in accordance with its extended mandate and provide periodic reports to Management Board at significant timepoints.

B.8 Update on Commission legal proposal for extending the mandate of the European Medicines Agency

The representative of DG SANTE provided an update on the discussion of the EC legislative proposal in the Council and European Parliament. The examination of the three proposals in the Health Union package started in the European Parliament on 25 February with an introduction from the Commission and the Parliament plans to finalise its position by July. In Council the examination started on 5 March and the subsequent meeting is planned on 23 March. The extra budget for EMA and ECDC was already allocated and adopted at the end of 2020 and is now available to the agencies for the new tasks.

EMA provided an update on the preparation for implementation which has already started in light of the requirement for the Agency to start implementing the new tasks soon after entry into force of the new legislation. EMA launched an internal exercise to assess the scope of changes required to existing business processes, aiming to define a plan for implementation to be presented to the Board at the next meeting in June. Challenges identified in the current phase are: a moving target as legislation is still under discussion, need to efficiently address an important increase in the reporting volume on shortages from MAHs (i-SPOC) and MSs (EU SPOC), the lack of expertise in the medical devices field, the need to ensure compatibility between the system of expert panels developed by the EC's Joint Research Centre and EMA's procedures for organising scientific committees. The strengthening of EMA's role in crisis preparedness and management should demonstrate added value for patients, HCPs and other stakeholders. If the final legal provisions for extending the current EMA mandate cannot include a longer deadline to allow for adequate implementation, then only minimum deliverables are possible at the implementation date, largely building on what EMA has put in place since the COVID-19 pandemic started. Even these minimum deliverables should allow for a future proofed operation in terms of objectives, processes and tools. If considered necessary, an ad hoc meeting of the Management Board may have to be considered closer to the June meeting.

In the following discussion, questions were raised if the proposal should cover the veterinary sector. Support was shown to the idea of a more detailed presentation by EMA at the next board meeting to clarify the background of what already exists and the proposed implementation of the new requirements, as this might also have a significant impact on NCAs. The representative of DG SANTE explained the proposal was built on the experience in the human sector during the first part of the crisis, including on the need for expertise in medical devices. Comments on widening the scope to the veterinary field were also expressed by both co-legislators, but it should be considered that the focus of the veterinary agencies is currently on the intense preparation for the new veterinary legislation. It was also noted that the EC will revise again the EMA mandate in 2022 when the basic pharmaceutical legislation will be recast under the Pharmaceutical Strategy, which will provide an opportunity to carefully reflect on more long-term solutions and consider all options. EMA offered to dedicate part of the Management Board meeting in June to the implementation of the new EMA mandate.

B.9 Update on preparation for implementation of Veterinary Medicinal Products Regulation

The board noted an update from the European Commission and from EMA.

The representative of DG SANTE noted the continued focus on the first and second package (12 acts) which need to be adopted before or by 28 January 2022. Within these packages, most acts are on schedule except for the restructuring of Annex II. Concerning the feasibility study under Article 156

(active-substance-based review system or other potential alternatives for the environmental risk assessment of VMPs), the final study report is due by end of September 2021. Overall, the work is progressing on time. The Commission maintains its ambition for timely implementation and relies on the commitment of EMA and of all Member States for the implementation of the Union Product Database (UPD). The Commission is aware of the resource issues for NCAs and will try to further raise the awareness at the political level.

As regards the EMA's implementation, work is ongoing on scientific advices to the EC on the list of antimicrobials to be reserved for human use and the list of substances not to be used or used subject to certain conditions under the so-called 'cascade'. Both are dependent on finalisation by the EC of the Delegated Act on criteria for reserving antimicrobials for human use. The VMP reg programme refers to IT systems to support the new veterinary regulation and consists of four projects: the Antimicrobial Sales and Use (ASU), the Manufacturers and Wholesale Distributors (MWD), the Union Product Database (UPD), and the veterinary pharmacovigilance database (EVV). Delivery of legislative requirements and of a MVP for all these systems by 2022 is on track. Key risks are due to COVID-19, which prevents face to face meetings, and timely upload of legacy data for UPD by NCAs, which also puts the benefits of EVV at risk. UPD work started in January 2020, while work on ASU database and MWD started in 2021. The ASU will continue after 2022 and once completed will take over from ESVAC. Change management will continue after early 2022. The VMP-Reg Coordination Group agreed that availability status reporting by MAHs should be reported at package level. It also agreed a simplified implementation of variations not requiring assessment, e.g. by approving/rejecting directly in UPD, and a phased submission for legacy data on MRP/DCP products, whereby the RMS submits 'common data' and the CMSs add only 'national' specific data subsequently. Upload of NAP and CAP data in UPD will start in July 2021 and from November onwards the CMSs can complete the dataset for these types of products. Submission of information on parallel trade can be done after product data have been uploaded. A change management programme is ongoing and EMA called on missing MSs to join it. A newsletter was published in January 2021 and webinars have also started and are available in the EU NTC. As regards NCA tracking progress in NCAs' preparations a traffic lights system as developed by the HMA TF CIVR. An EU Veterinary Implementation Guide for UPD was published for consultation and it provides the basis for NCA preparations of legacy data and their own systems, as necessary. An UPD Access Policy has also been published. The EVV Access Policy has also been published for consultation. The EMA recalled the consequences of not submitting legacy data in UPD are that the risk that variations not requiring assessment cannot be submitted/handled in UPD for products not recorded and that adverse event reports will not be captured by signal detection and management activities in EVV. A Big Data Veterinary Stakeholder forum will be organised on 1-2 June as the first in a series of workshops. It is organised as the new veterinary regulation prescribes an increased use of digital sales data and in order to build on the EMA/HMA Big Data Task Force recommendations.

The representative of the veterinarians' organisations thanked EMA for the newsletter and webinars and asked if all the 12 priority acts will be all adopted by January 2022, as some are still at a very preliminary stage, while the most critical acts for veterinarians, i.e. reserve and cascade and oral medication, still have to be designed. Concerns were also expressed that national implementation of the new veterinary medicines and medicated feed legislation might still allow some divergences across Europe, despite both acts being regulations. MSs were also invited to engage more in dialogue with their veterinarians' organisations. Concerns were expressed on the legacy data, due to the difficulties in adapting national databases to the UPD, to the short timelines, the lack of resources at national level and the impact of COVID-19, which all call for the development of a contingency plan. EMA noted discussion are ongoing as regards prioritisation of legacy products to be uploaded, so as to mitigate the NCAs' difficulties, but a contingency plan is not available as the legal deadline is very prescriptive and the transition from the Directive to the Regulation will be instantaneous. The representative of DG

SANTE confirmed the Delegated Acts are on track and informed that the Commission is in contact with the US for the conclusion of a MRA on inspections.

From this point onwards, the Chair was temporarily replaced by the board member from Belgium, as the most senior member in absence of the Vice-Chair as per the rules of procedure, due to the need to attend an urgent meeting at national level on COVID-19 vaccines.

B.10 11th Annual Report Veterinary MUMS/limited market

[EMA/MB/83320/2021, Rev.1, EMA/553359/2020, Rev.1] The board endorsed the 11th annual report on the operation of the Minor Use Minor Species (MUMS)/limited market scheme for veterinary medicines.

The report provides information on the products/indications classified/reclassified under this policy and details of the types of products for which support was provided between 1 January and 31 December 2020. The number of requests for classification in 2020 appears to be more or less consistent year on year with a total of 32 MUMS requests reviewed in this reporting period. The number of MUMS centrally authorised, 3 in 2020, has been stable during the last 4 years. Overall, the policy has been successful in terms of incentivising the submission of requests for classification of products as MUMS/ limited market, resulting in newly authorised products becoming available for MUMS/limited markets. EMA's MUMS/limited market policy will cease to apply once the Veterinary Medicines Regulation (Regulation (EU) 2019/6) becomes applicable in January 2022, as the Regulation contains new legal provisions on veterinary medicines intended for limited markets. New guidance on limited markets was adopted by CVMP and published for consultation until May 2021: members were invited to review the draft guideline as it represents a significant change to current practice, both in terms of conditions for limited market classification and of the reduced data requirements.

B.11 Information Management governance review

[EMA/143069/2021] The board noted a mid-term update on the preparation of the Information Management (IM) governance review.

The IM governance review started in December 2020 and will be finalised in June 2021 with a proposal for endorsement by the board. The review is due to the many new requirements on the regulatory IM systems, which increasingly have to do more with the same, and to the overall drive for digital transformation, which calls for improved IM delivery and maintenance. The scope of the review is both NCA/telematics projects and EMA-only IM projects. To start the review EMA sought an external perspective and engaged a third party who conducted 35 interviews of NCAs and industry stakeholders. At a high level, interview outcomes identified challenges across five areas: 1) governance, 2) role management, 3) accountability, 4) benefit management, and 5) budgeting. As regards governance, stakeholders perceived lack of clarity on how strategy translates into project deliverables, how projects are managed, budgets allocated, and decisions made on the types of technology to be used. As regards role management, there is a tendency to create new governance bodies for each new requirement/project which results in overlapping roles and decision-making structures. In terms of accountability, a lack of shared accountability between EMA and NCAs and between IT and Business divisions was reported, with some lack of clarity around the role of the Accountable Executive of the project. Concerning benefit management, difficulties in deciding when to stop a project were reported as were challenges in tracking benefits and demonstrating value. As regards allocating budgets and adjusting budgets during delivery, this process is not considered robust and leads to excessive scope creep and difficulties in accounting for value.

Based on these findings a new governance framework based on the Agile delivery model is being developed to enable more stability and improved planning. Its design principles will include: 1) strategic alignment, i.e. business drives project portfolio; 2) simplicity, minimal number of boards and of documentation; 3) informed decision-making, based on a facilitator, e.g. an agile portfolio office, and improved communication for transparency on what is decided; 4) proper composition and autonomy, with right experts at the table; 5) co-ownership, both at the strategic and execution level; 6) focus on value for budgeting; 7) agility, whereby governance facilitate agile development. These principles will be translated in practice in several ways. Firstly, EMA will revise existing governance structures which have grown organically in recent years in order to simplify. Secondly, EMA will ensure there is greater transparency for the Management Board on technology development and key choices. Thirdly, a portfolio management approach will be introduced. Greater transparency will be put on decision-making, on understanding the impact of new technology and on the need for interoperability with Member States. Co-ownership will be considered in order to move away from a customer-supplier relationship as regards Telematics. Clearer rules of engagement as regards working with industry associations and pharmaceutical companies on technology development will also be introduced. Options to balance the corporate needs of EMA with the needs of the Network will also be explored. EMA will continue to work with EUTMB and a detailed presentation of the proposal will be presented in June for endorsement.

B.12 Big Data Steering Group update

[EMA/MB/84860/2021, Rev.1] The Board noted the report on the activities of the Big Data Steering Group in 2020 and adopted the mandate of the DARWIN EU Advisory Board.

a) Big Data Steering Group 2020 activities report

[EMA/48625/2021] In January 2020 the EMA/HMA Big Data Task Force's final report was published and proposed 10 major recommendations. The Big Data Steering Group (BDSG) was established in May 2020 to oversee implementation of those recommendations. In September 2020 its workplan was published. A multi-stakeholder event with high participation was organised in December. In terms of progress on the recommendations achieved in 2020, DARWIN EU was established as a project, with the ambition that by end 2021 a network centre is established and it can engage in a first pilot with the EC on real world evidence (RWE). In terms of data quality, a study to provide a common language and framework for RWE in medicine regulation was agreed. On findability/discoverability of data, a study to establish 'meta-data for real world data (RWD)' was initiated, which should allow initiating a catalogue of RWE in 2021. As regards training on data science, RWE and biostatistics curricula were developed. A PRAC RWE analysis pilot was progressed and a CHMP review of RWE in MA submissions initiated. A software for RWD analytics was selected and a pre-pilot of raw clinical data analysis was initiated at CHMP. In the context of the revision of WPs at EMA, the methodology expertise was aggregated in the methods Domain and it is planned that this Domain will start work in 2021. A series of workshops with stakeholders to navigate RWE respecting data protection was organised in 2020 and a Q&A in that area will be published by EMA by end 2021, pending a review by EDPS. By end 2021 a roadmap for collaboration on RWE with international regulators should be agreed. A first veterinary as well as a second human stakeholder meeting on big data are planned in 2021.

b) DARWIN EU Advisory Board: mandate

[EMA/87192/2021] The concept of an Advisory Board was presented to the Management Board in December 2020. It will advise on the establishment of DARWIN EU, ensure alignment and create synergies with other EU initiatives on data, such as the European Health Data Space (EHDS), and it will create a two-way communication between the network and other stakeholders, including the national

authorities in the Joint Action on the EHDS (TEHDAS). Membership of the Advisory Board will include representatives from the European Commission, selected NCAs, payer and HTA bodies, data permit authorities, the TEHDAS and, following HMA consultation, representatives from ECDC, patients' and healthcare professionals organisations. The pharmaceutical industry will be added as an observer, so to be kept informed. In future the project could evolve like the FDA Sentinel programme, which is for public authorities to operate, but the infrastructure could be leveraged by industry. The Advisory Board will be co-chaired by EMA and HMA.

Following the presentation, the representative of DG SANTE expressed support for the Advisory Board and welcomed its role in further enhancing cooperation between EMA, MSs and the EC in preparation for the development of the EHDS. He also asked how DARWIN EU will help with safety monitoring of medicines. EMA noted the project will significantly facilitate access to a much wider pool of data used to investigate safety signals and improve regulatory decision-making on risk minimisation measures. Initiatives are already being progressed to investigate adverse reactions from COVID-19 vaccines, for example by establishing background rates of side effects before and after vaccination, and further studies will be feasible when the DARWIN EU network centre is in place.

At this point, the Chair re-joined the meeting and resumed chairing.

B.13 Revision of the EMA Anti-Fraud Strategy and related Action Plan for the next 3-year period (2021-2023)

[EMA/MB/108779/2021 rev.1, EMA/111152/2021, EMA/128273/2021] The Board adopted the revised Anti-Fraud Strategy and related action plan 2021-2023.

At its December 2020 meeting, the Management Board decided to postpone the approval of a revised Anti-Fraud Strategy (AFS) for the years 2021-2023 at its next meeting in order to allow more time to the new Executive Director to review the actions. Three strategic objectives are proposed: 1) maintain and enhance an anti-fraud culture underpinned by high levels of awareness, integrity, impartiality and transparency within EMA and also among non-staff members; 2) strengthen measures for detection of suspicious behaviours, including through maintaining an efficient system for internal reporting and handling of suspected irregularities; 3) implement all actions necessary for fraud risk mitigation, also identified through internal and external audits.

The action plan will include four specific actions with a set deadline, such as updating the compulsory anti-fraud e-learning training course in line with recent fraud trends and best practices in other EU institutions and Agencies, strengthening staff's awareness of internal reporting and whistleblowing procedures, preventing cybersecurity fraud and evaluating the need for specific fraud risk assessments in respect of possible conflict of interest of scientific experts. Actions on a need-be basis relate to administrative enquiries based on continuous monitoring of ethical behaviours and on the annual fraud risk assessment. Permanent actions will include: regular communication to all staff on anti-fraud related matters, reporting on the Anti-Fraud Strategy in the Annual Activity Reports and other strategic documents, targeted awareness raising sessions, annual fraud-specific risk assessments and audits with the aim to identify areas of vulnerability to fraud, assessments of the adequacy and effectiveness of the associated systems of internal controls, also through monitoring and audit activities. At present no additional resources are budgeted to implement the AFS action plan for 2021-2023. Progress reports on the implementation of the actions will be provided to the Executive Director and the Management Board on a regular basis. The next revision of the AFS will take place in 3 years, to be adopted by the Management Board in December 2023.

B.14 Preparation for the written procedure on revision of budget remarks

[EMA/MB/136279/2021] The Board noted the upcoming written procedure before the June meeting in order to update the EMA's budget nomenclature for IT budget lines.

The Agency is implementing a new operating model for ICT external technical assistance and services, aiming to rationalise interaction between development and maintenance activities. Separate contracts for application development and maintenance will no longer be used, as the Agency is moving to contracts 'per platform'. The corresponding funds for IT maintenance and IT development will be brought together. A written procedure to clarify this approach in the budget nomenclature will be launched before the June meeting and the corresponding appropriations will be adjusted among the relevant budget lines. These changes will have no implications on the agreed budget.

List of written procedures finalised during the period from 26 November 2020 to 12 February 2021

- Consultation no 23/2020 on the appointment Velislava Todorova as CHMP alternate as proposed by Bulgaria ended on 7 December 2020. The mandate of the nominee commenced on 8 December 2020.
- Consultation no 24/2020 on the appointment of Helena Panayiotopoulou as CHMP member as proposed by Cyprus ended on 23 December 2020. The mandate of the nominee commenced on 24 December 2020.
- Consultation no 01/2021 on the appointment of Minna Leppänen as CVMP member as proposed by Finland ended on 15 January 2021. The mandate of the nominee commenced on 1 February 2021.
- Consultation procedure for the adoption of the minutes of the 109th Management Board meeting, held on 1 October 2020. The procedure was adopted.
- Consultation procedure for the adoption of the endorsement of the revised agreement for EMA's former building in London (30 Churchill Place). The procedure was endorsed.

Documents for information

- [EMA/MB/27703/2021, EMA/27657/2021] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/80733/2021, EMA/620104/2020] 2020 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2020
- [EMA/MB/58488/2021, EMA/58487/2021] 11th six-monthly report on ex ante and retroactive evaluation of projects for the period 1 July to 31 December 2020
- [EMA/MB/53054/2021] Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2020
- [EMA/MB/81947/2021] Outcome of written procedures finalised during the period from 26 November 2020 to 12 February 2021
- [EMA/MB/76157/2021] Summary of transfers of appropriations in budget 2020

List of participants at the 111th meeting of the Management Board, held virtually on 11 March 2021

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier de Cuyper *(member)*
Bulgaria	Bogdan Kirilov *(member)*
Czech Republic	Irena Storová *(member)*
Croatia	*Apology received (alternate)*
Denmark	Mette Hansen *(alternate)* Nikolas Jørgensen *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Rita Purcell *(alternate)*
Greece	Eleftherios Pallis *(member)*
Spain	María Jesús Lamas Diaz *(member)* César Hernández *(alternate)* Maria Alcaraz *(observer)*
France	Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Nicola Magrini *(member)* Pietro Erba *(observer)*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	*Apology received (member)*
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	Roxana Stroe *(member)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Momir Radulović *(member)* [1]
Finland	Eija Pelkonen *(member)*
Sweden	Joakim Brandberg *(member)* Asa Kumlin Howell *(alternate)* Hannes Eintrei *(observer)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points 4, B.4, B.5, B.7, B.10, B.12.b*

European Parliament	Matthias Groote Tonio Borg
European Commission	Andrzej Rys *(alternate)* (DG SANTE) *Apology received* (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) *Apology received* (Liechtenstein) Audun Hågå (Norway)

European Medicines Agency	Emer Cooke Noël Wathion Nerimantas Steikūnas Fergus Sweeney Hilmar Hamann Ivo Claassen Melanie Carr Anthony Humphreys Zaide Frias Alexis Nolte Agnes Saint-Raymond Pierre Pradal Stefano Marino Peter Arlett Maria Alves Hilde Boone Monica Dias Riccardo Mezzasalma Marie-Agnes Heine Frances Nuttall Silvia Fabiani Sophia Albuquerque Rebecca Harding Apolline Lambert