23 August 2021
EMA/MB/345297/2021
Management Board

Minutes of the 112th meeting of the Management Board

Held virtually on 17 June 2021

The Chair of the Management Board (MB) 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: Irene Norstedt, alternate, European Commission DG Research and Innovation (DG RTD); Paula Loekemeijer, member, Netherlands; Hugo Hurts, now alternate and attending for the last time, Netherlands; Bjorn Eriksson, member, Sweden. Ms Norstedt introduced herself to the board as the lead officer in DG RTD for research policies in the area of health and for projects in health research under the Horizon Europe programme.

1. Draft agenda for 17 June 2021 meeting

[EMA/MB/196797/2021] 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 *B.4 Revised implementing rules to the Fee Regulation as of 28 January 2022, B.6.d Approach to negotiating agreement on the Joint Controllership Arrangement for EMA to negotiate with member states and sponsors, B.7 Information Management governance review and B.10 Management Board liaison on PRAC composition – Liaison after 9 years of PRAC in 2021.* The Secretariat informed the board that all concerned members had been informed before the meeting. 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.

The Chair reminded members to keep MB documents distributed before the meeting confidential and she also invited all members to promptly update their annual Declaration of Interests.

3. Minutes from the 111th meeting, held on 11 March 2021 adopted via written procedure

[EMA/MB/153834/2021] The Management Board noted the final minutes, adopted by written procedure.

4. COVID-19

EMA Status Report

The board noted an update from EMA on the most important COVID-19 related developments since the March 2021 MB meeting.

The European Medicines Regulatory Network (EMRN) meetings continued to take place almost on a weekly basis to discuss operational aspects related to the scientific assessment of COVID-19 medicines (vaccines and therapeutics) and are appreciated by the Network as these meetings facilitate the preparedness for and implementation of the EC decisions at national level. Following agreement at the March 2021 MB meeting, short-term actions to address resourcing needs for COVID-19 applications have been implemented as of May 2021. On 3 June 2021 EMA published recommendations to facilitate forecasting demand of medicines, following adoption of a reflection paper by the EU Executive Steering Group on Shortages of Medicines Caused by Major Events. This reflection paper summarises best practices that can help develop accurate forecasting of demand for human medicinal products across the EU and at national level for emergencies. A third public meeting on the approval and roll-out of COVID-19 vaccines was held on 26 March 2021, followed by the launch in May of a pilot of regular technical press briefings organised every 2 weeks. The pilot will run until end of July 2021.

Four COVID-19 vaccines have been authorised so far, including the Janssen vaccine on 11 March, and one additional rolling review has started: rolling reviews are now ongoing for the Sinovac, Curevac, Novavax and Sputnik V vaccines. An Article 5(3) procedure on Vaxzevria and the risk of thrombosis in combination with thrombocytopenia syndrome (TTS) was launched on 14 April 2021 with interim results published on 23 April 2021. Safety updates and clinical data are being published for the authorised vaccines. Rapid scientific advice procedures for vaccines and therapeutics continue (89 completed – 15 in the pipeline). As regards COVID-19 therapeutics: CHMP Article 5(3) procedures were concluded to advise on the use of 2 monoclonal antibodies - Celltrion (Regdanvimab) and Sotrovimab - at national level before a MA is issued. A rolling review has been started for Sotrovimab, in addition to the ongoing rolling reviews for 3 monoclonal antibodies. EMA has been in discussions with developers for 194 therapeutics for COVID-19 so far.

EMA presented its initial "lessons learned" exercise on the handling of the COVID-19 pandemic, which was first presented and discussed at an ad-hoc HMA meeting on 6 May 2021. Areas being addressed in the lessons learned include: adequacy of the existing (crisis) structures and systems, adequacy of the pharmacovigilance arrangements, striving for the best evidence post-authorisation, availability of clear roles and responsibilities, interaction between EMA and the Member States' Authorities, interaction with international partners, communication related aspects and safeguarding the sustainability of the Network. More details including proposals for improvement will be presented at the October MB meeting. Discussions will also continue in parallel at HMA level. EMA emphasised the excellent work undertaken by the network under very difficult circumstances for approving COVID-19 vaccines, monitoring the authorised vaccines and quickly identifying and addressing emerging events.

Following the EMA presentation, several board members expressed appreciation for the coordination work carried out by the Agency and emphasised the resource challenges for the network. Some

members called for more capability building support, especially for smaller agencies, including the possibility to be able to exchange best practices and knowledge with bigger Member States with more experience in taking on rapporteur roles. It was recognised that use of the Multinational Assessment Teams (MNATs) is increasing and that many smaller agencies have been investing significantly to increase their involvement in the centralised procedure, but the process of building scientific competences takes time. The representative of DG SANTE noted that the EU4health programme is expected to support capacity building projects and that the Health Commissioner has communicated the resources constraints of regulatory agencies to the national health ministers. In relation to the lessons learned exercise, the representative of veterinarians' organisations suggested that resources could also be offered to EMA by agencies with different areas of expertise; in addition, closer alignment between MSs is needed as currently the different vaccination approaches across MSs may fuel vaccine hesitancy. Other board members stressed the need to develop more robust cooperation with National Immunisation Technical Advisory Groups (NITAGs). With reference to communication challenges, and a comment on how EMA is working to address misinformation and tackle questions also stemming from the political arena, it was noted that regular press briefings are now being piloted. Overall many members welcomed the initial findings of the lessons learned reflection and supported a more detailed discussion on proposals for improvement at the October MB meeting.

A. Points for automatic adoption/endorsement

A.1 Management Board meeting dates 2022-2023

[EMA/MB/196921/2021] The board adopted the proposed meeting dates for 2022 and noted the meeting dates for 2023.

B. Points for discussion

B.1 Highlights of the Executive Director

European Activities

Most of the EMA's European activities remain directly linked to the COVID-19 pandemic. Weekly updates with Commissioner Kyriakides and ECDC continue and EMA is participating also in the European Commission's platform on scientific advice, alongside national bodies for immunisation. Highlights of the EU activities include participation to the European Parliament's ENVI meetings and to several meetings of the EU health ministers, most recently at the EPSCO meeting on 15 June. EMA is involved in workshops and meetings organised by the European Commission for the implementation of European Pharmaceutical Strategy. On 28 April, the European Parliament granted a positive discharge on EMA's accounts for the financial year 2019. On 14 July, EMA and ECDC have been invited to the annual hearing of EU agencies at the European Parliament's Budget Committee for a discussion on their extended mandates and resources for COVID-19, in the context of the 2022 EU budget procedure.

Exceptional remuneration for NCAs for Covid-19 related activities

In order to support National Competent Authorities for the accelerated and urgent scientific assessments for COVID-19, EMA announced the proposal to provide an exceptional time-limited additional payment to national assessment teams for certain COVID-19 related assessment procedures. A detailed financial proposal will be presented to the board by written procedure based on the outcome of the ongoing discussions with the European Commission.

Communication challenges

COVID-19 response has increased media and public interest in EMA activities, with an unprecedented increase in interview requests and media queries by 600% from Q1 2020 to Q1 2021. Interviews are channelled via the press office and are recorded whenever possible. Important EMA COVID-19 communications are shared with the Network under embargo prior to publication.

Update on the EC legal proposal for extending the mandate of the EMA

Following the publication of the EC legal proposal, and in preparation of its implementation, EMA has launched an exercise to define the scope of the changes that will have to be introduced to implement the new legal mandate and to analyse the consequences of these changes. EMA has established a temporary Extended Mandate Task Force (EMTF) for this purpose, which is currently in the process of developing an implementation roadmap that will be refined to take into account the final legislative text following the Trilogue meetings among EU institutions. Depending on the progress of the legislative process, it is proposed to organise an ad-hoc Management Board meeting in Q3 for a more detailed update to the board on the proposed implementation roadmap.

International Activities

Recent highlights include the recent ICMRA/WHO statements on data transparency and vaccine confidence. International collaboration is intensifying on: virus variants with WHO; safety monitoring (TTS, Myocarditis and Pericarditis) with Israel, MHRA and FDA; GMP issues, collaboration with FDA for the Emergent site GMP issues for Janssen vaccine, with a joint inspection at the Emergent site planned with Health Canada and SAHPRA; GCP and GMP joint inspections for Sputnik vaccine with WHO. The OPEN initiative is proving successful, with WHO, Health Canada and Switzerland having used EU reviews. In particular, WHO has granted emergency use listing (EUL) for Vaxzevria based on EMA's OPEN assessment and that vaccine has been consequently authorised in more than 100 countries within 2 weeks. The UK MHRA has also used the EC Decision Reliance Procedure to recognise the EU authorisations for the Moderna and Janssen vaccines in its territory.

Update on Cyber attack

EMA continues to be confident that the intrusion of its IT system has been contained. Defensive cybersecurity capabilities have been enhanced to protect EMA from future attacks. Additional IT security measures have been and are being implemented building on the Trilateral Research outcome on EUDPR compliance, the 2020 internal audit on information security and the specialist company report following the cyber-attack. EMA is revising its Information Security Strategy and governance, putting in place a 3-year improvement road map in line with comparable organisations' best practices.

Update on Aplidin court proceedings

The Court of Justice have combined the appeals by Germany and Estonia against the Judgment of the General Court in Case T-549/18, Pharma Mar v Commission (Aplidin). EMA has submitted its application for leave to intervene in support of both Member States in the appellate court proceedings. The Agency is now waiting to be notified by the Court of Justice as to whether the requested leave to intervene has been granted. The European Commission's Legal Service has decided not to submit a written response to the Court.

Delivering the Network Strategy to 2025: proposal for an EC-HMA-EMA co-led European clinical trials transformation initiative

The board was informed about the proposal to establish an EC-HMA-EMA co-led European clinical trials transformation initiative to deliver the recommendations of the European Medicines Agencies Network Strategy to 2025 to drive innovation in clinical trials. The proposed programme aims to: make the EU

competitive for the conduct of clinical trials by reducing the administrative burden and increasing the set-up speed especially for large multistate clinical trials; enable clinical trials to be impactful based on excellent methodological advice; leverage data and information for public health benefit; strengthen the EU leadership and coordination. The programme will be delivered within the current legal framework and include, amongst many, a number of assessor trainings for the network, the establishment of a multi-stakeholder platform, development and implementation of guidelines (on clinical trials design and conduct) and support to safety monitoring.

EMA Annual report 2020

The EMA Annual Report 2020 was published on 14 June on the EMA website, following its written adoption by the Board in April. It highlights the key outcomes of the work that EMA and the regulatory network have achieved last year, including the rapid response to COVID-19 and core regulatory activities to protect public and animal health in the EU. The publication also consists of an enhanced timeline of EMA's main activities in 2020 with additional audio-visual materials, infographics, videos and documents. The report is available not only in a traditional print-ready PDF version, including all figures and trends illustrating EMA's activities in the regulation of medicines, but also in an interactive digital version that can be accessed quickly and easily through the EMA website.

Succession planning/arrangements

The Board was informed that a recruitment procedure for the role of Chief Medical Officer will be launched shortly. The Deputy Executive Director (DED) Noël Wathion will retire as of 30 June 2021. The DED Office tasks will be re-distributed across the Agency. Ivo Claassen, Head of Veterinary Division, will be assigned Deputy Executive Director responsibilities in addition to his current role, and he will also take over IT security oversight from the current DED. Melanie Carr will take on ad-interim duties related to crisis and emergency management, in addition to her current role. A new department on institutional liaison and policy will be created as an Advisory function and Hilde Boone will take up the position ad interim. Facilities Management will move to Administration. Fergus Sweeney, Head of Clinical Studies and Manufacturing Task Force (TCS) will retire in May 2022. To facilitate handover, the Clinical Trials Information System (CTIS) team will move ('lift and shift') to the Data Analytics and Methods Task Force (TDA), and will report to Peter Arlett, as of 1 July 2021. Agnès Saint Raymond will retire in September 2021 and a new Head of International Affairs is in the process of being recruited.

Following EMA's presentation, members commented that there was a need for closer collaboration with NITAGs to share up-to-date information on the EMA's latest scientific assessments and coordinate for external communication. It was noted that EMA is already engaging in biweekly meetings with NITAGs. The proposed exceptional financial support from EMA to NCAs for COVID-19 activities was welcomed by several national agencies. The board was informed that a letter would be sent by HMA to the Portuguese Minister of Health to inform the Council of the recent HMA discussions on the lessons learned and the challenges faced by the regulatory network during the pandemic. Appreciation was expressed for the clinical trials transformation initiative which is also supported by HMA and will be further discussed by the HMA Management Group. A representative of patients' associations thanked the EMA for the clarifications on IP issues and asked EMA for an update on the number of adverse drug reactions registered for COVID-19 vaccines. The Agency replied that the current pharmacovigilance system is delivering despite high volumes of information being received and has allowed the EMA to be the first region in the world to identify and react on the TTS signal. The Agency called on all Member States to continue promptly reporting in EudraVigilance and noted that some suggestions to further improve the efficiency and adequacy of pharmacovigilance arrangements will be presented to the board in October as part of the reflection on lessons learned from the pandemic.

The board paid tribute to the EMA Deputy Executive Director ahead of his retirement at the end of June. The board warmly thanked Noel Wathion for his key contribution to the work of the Agency over

25 years and for his relentless commitment to the protection of public and animal health in the EU. The board also expressed its gratitude to the EMA Head of International Affairs, Agnes Saint-Raymond, who was also attending her last MB meeting, for her important contribution to the protection of public health in the EU and globally.

B.2 Report from the European Commission

The representative from DG SANTE informed the board that a 'General Approach' on the EMA extended mandate's legal proposal was reached in Council on 15 June and the European Parliament is expected to adopt its position on 21 June in the ENVI committee and in early July in plenary. Trilogue negotiations between the co-legislators will then follow. As regards the Pharmaceutical Strategy, the implementation is channeled through the Pharmaceutical Committee as the main forum for discussion with Member States. Four ad-hoc workshops of this Committee on specific topics have already been held and the fifth one is scheduled on 18 June. A joint meeting of the Pharmaceutical Committee with the Directors responsible for pharmaceutical policy will be organised under the Slovenian Presidency on 8-9 July. The Commission has direct interaction with EMA and its scientific committees on specific aspects of the strategy and further contacts will take place in the coming months. As regards EMA fees, for the study supporting the impact assessment a targeted consultation of MSs, EMA and other stakeholders was launched on 14 June and some follow-up interviews will take place in July. Based on that feedback, the financial model by the contractor will be adjusted and delivered to the Commission by Q4 2021. As regards the EU4health programme, the work plan for 2021 will be adopted by end June and in the following years EU4health will fund the following actions of relevance to the EMA's board: (1) an action to support capacity building on coordinated safety assessment in clinical trials, including an expert exchange program and funding for an administrative secretariat; (2) support for the coordinated and expedited assessment of clinical trials for COVID-19 therapeutics (included in the EU COVID-19 therapeutic strategy); (3) a Joint Action to enhance cooperation between Member States and share best practices in the area of shortages of medicines; (4) actions to support oversight on the quality of medicines (joined audits, trainings and GMP/GDP inspections) and to support the implementation of the Pharmaceutical Strategy. The European Commission will adopt before the Go-Live date of CTIS an Implementing Regulation pursuant to Article 44.2 of the Clinical Trials Regulation to facilitate the cooperation in the assessments of annual safety reports (ASR) and suspected and unexpected safety adverse reactions (SUSARs) in clinical trials. Following an EFSA scientific opinion on E171 published on 6 May 2021, DG SANTE has requested EMA to provide by 23 July an interim analysis of the impact on medicines of the potential removal of titanium dioxide from the list of food additives authorised in the EU. The ban is expected to be decided for the food sector in September.

The representative of DG Research and Innovation presented on the health workstream (cluster) of the Horizon Europe programme, which will have a total budget of €8,2 billion. Its first bi-annual work programme (2021-22) was published on 16 June 2021 and includes one topic relevant for medicines regulators, i.e. a call for research projects on 'New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment'. A broad portfolio of actions in response to COVID -19 has been deployed using all possible funding instruments for a total investment of over €1 billion so far. Investments arrived from the European Research Council, collaborative research (Horizon 2020), the EU research infrastructures, and the EU Innovation Council which also supported CureVac and BioNTech. Other initiatives include the projects: COVID-19 data platform, EU-RESPONSE project, RECoVER, VACCELERATE, and the European Virus Archive. Funding has also been allocated for the development of diagnostics, therapies, and vaccines and also for cohort studies investigating the long term effectiveness of vaccination (e.g. ORCHESTRA project). Three emergency calls for proposals under the HERA incubator have been launched since January 2021 and are currently under examination. Under Horizon Europe, several Partnerships will be developed,

such as: the Innovative Health Initiative (IHI) Joint Undertaking, which is being negotiated with the Council and will also involve the med tech industry; the Global Health Partnership EDCTP3 Joint Undertaking, which focuses on research in neglected diseases involving 16 countries in sub-Saharan Africa; the Pandemic Preparedness Research; the European Research Area for Health; and a research partnerships on Rare Diseases. The Cancer Mission under Horizon Europe will also contribute to support Europe's Beating Cancer Plan.

A Member State representative inquired about the Implementing Act on safety assessment in clinical trials and suggested to consider introducing a transition period allowing more time for CTIS and EudraVigilance to reach optimal functionalities for Member States to take up the new obligations. The representative of DG SANTE noted that the Commission is looking into the Implementing Act and the supporting Joint Action at the same time. Noting the reality of IT infrastructure and limited experience in the network, he offered to look into the idea of a transition period. HMA and the board will be further consulted. On the topic of the additional exceptional remuneration for scientific services on COVID-19, the Commission fully supports the EMA initiative but noted that some details still need to be further looked into before the MB written procedure can be launched.

B.3 Assessment of the Executive Director's Annual Activity Report (AAR) 2020

[EMA/MB/277559/2021; Rev.1, EMA/81758/2021; Rev.1; EMA/233043/2021] The board noted the Executive Director's Annual Activity Report (AAR) 2020 and adopted the assessment report on the AAR.

EMA presented the AAR which provides information on the management and control systems of EMA and on the work programme implementation. It is prepared in accordance to article 48 of the EU financial regulation and forms part of the next discharge process. The AAR describes the contribution of the Agency to tackle the COVID-19 pandemic and EMA's adjustments to a new working environment. It provides detailed data on the EMA's 2020 budget, which registered a positive outturn of 1.08%, and carryovers by title. Payments against appropriations carried forward from 2019 to 2020 reached 95.49% which is on target. In 2020 the agency revised the guidance on commitments and payments in line with that of the Commission which influences carryovers. The 2020 occupancy rate amongst temporary agent staff was 100%. 18 external selection procedures were run in 2020 and 2,628 candidates applied. The performance indicator to run selection procedures in maximum 3 months between the publication of the vacancy notice and the establishment of the reserve list has been achieved and has contributed to the high occupancy rate. EMA has a comprehensive control system and had a number of internal audits (on Information Security management, IT outsourcing and PRIME) as well as external audits, with only three very important recommendations stemming from internal audits carried out before 2020 remaining open. Ex ante and ex post controls and self-assessment of implementation of control standards were carried out. The Executive Director has signed the declaration of assurance with no reservations. Two points were included in the Emphasis of matter: the adequacy of staffing and resources available to the Agency, and the lease agreement for EMA's previous premises in London requiring political resolution.

The member from Lithuania and from the veterinarians' organisations, as MB topic coordinators, presented the highlights of the proposed board's assessment. The board expressed a positive assessment on the implementation of the work programme 2020, despite the Business Continuity Policy and COVID-19, welcoming the rapid deployment of ad hoc structures to address the impact of the pandemic and the successful completion of the Agency's relocation to its permanent office in Amsterdam Zuidas. As regards core business, highlights include 97 medicines recommended for marketing authorisation in 2020 of which 39 with a new active substance, the digitalisation of scientific

advice procedures and the actions to avoid/mitigate risk of presence of nitrosamine impurities in medicines. On the veterinary side, significant progress has been achieved to implement the new veterinary regulation with six scientific recommendations to EC for delegated/implementing acts and IT development initiated for its three databases (Union Product, Pharmacovigilance, and Antimicrobials Sale and Use Databases) in 2020. Important achievements were accomplished in the areas of AMR, of availability of medicines, regulatory science and network strategy to 2025, as well as on the CTIS, ePI and Digital Application Dataset Integration (DADI) projects. The coordinators stressed the importance of extending the Agency and network expertise on vaccines and antivirals to strengthen the handling and assessment of COVID 19 related medicinal products. They recommended the adoption of the board's Assessment of the Annual Activity Report 2020.

B.4 Revised implementing rules to the Fee Regulation as of 28 January 2022

[EMA/MB/64673/2021; EMA/MB/52454/2021] The board adopted the revised implementing rules to the EMA's Fee Regulation, applicable as of 28 January 2022.

EMA explained that the ongoing revision of the EMA Fee Regulation (Council Regulation (EC) No 297/95) will not be completed by the time the new veterinary regulation comes into force in 2022. Therefore, to safeguard the financing of the activities and the remuneration of National Competent Authorities to take account of the new Veterinary Medicines Regulation (Regulation 2019/6), a revision of the current Implementing Rules as per Art.11(2) of the EMA Fee Regulation is required to establish 'transitional fees'. The proposed revision of the Implementing Rules has had a favourable opinion by DG SANTE. In order to prepare the transitional fees, the Agency mapped the existing procedures and activities for veterinary medicines and, using the current fee levels and assuming average volumes of applications, matched them to the future procedures and activities envisaged in the new veterinary medicines regulation. Where a procedure is new, a benchmark to an existing procedure in terms of process/complexity was used. As a result of the application of the proposed transitional fees, the Agency will face a revenue reduction for veterinary products due to the following: Type IAs equivalent variations not requiring assessment will not generate income; renewal procedures no longer will be required; new approach to sharing of income for Type IBs-equivalent variations requiring assessment. The Agency estimated its income loss of around 2.9 Mio EUR and expects to cover this shortfall during the transition period with no change to the allocated EU contribution. The shortfall will be accounted in the 2022/2023 programming document. The proposed transitional fees should have no effect on the network, provided the volumes of applications remains similar to the average experienced in the past years. NCAs may see a 1 Mio EUR increase in revenue due to remuneration for Type IBs equivalent variations requiring assessment. The revision is a transitional proposal until the new EMA Fee Regulation enters into force, which is expected by 2023.

The representative of veterinarians' organisations commented that in the veterinary area there are more and more non-fee generating activities, such as the AMR scientific advices, which are crucial for public and animal health. This should be reflected in the future fee regulation so that EMA and NCAs can have the required resources for such activities. A member expressed disappointment with the revised Implementing Rules proposal since it does not present a global reform of veterinary fees to account for the impact on the NCAs of the new veterinary regulation. He indicated that the proposal does not remunerate all the work to advise the EC for the delegated acts and to develop new IT systems. Concern was also expressed as regards the negative impact on the EMA budget. For the Union Product Database (UPD) many NCAs are asked to do a lot of manual work and they cannot wait for two more years for additional financial support. The member further noted that veterinary agencies are currently underrepresented in the board and this should be further considered. Another member stressed there is a risk to national income as less products will likely pass by MRP/DCP when the

optional scope of the centralised procedure is opened to all products after the date of application of the new veterinary regulation. EMA confirmed that the proposal is an interim measure which aims to provide continuity and it does not aim to pre-empt the discussion on the new fee revision which is currently the object of extensive consultations with NCAs and other stakeholders.

B.5 Annual report of internal audit and advisory activities at the European Medicines Agency 2020

[EMA/MB/237754/2021; EMA/50919/2021; Ares (2021)1134437] The board noted the annual report for 2020 on the internal audit and advisory activities at the EMA.

The EMA Head of Audit explained the annual report is presented to fulfil the obligations of the Financial Regulations and International Professional Practice Framework Standards, which require the Head of Audit to report annually to the Management Board on the internal audit activities. The Head of Audit confirmed that in 2020 the full organisational independence necessary to effectively carry out the responsibilities of the internal audit activity was preserved, in particular through the dual reporting relationship to the Management Board and Executive Director and through direct and unrestricted access to senior management and the Executive Board. The internal audit work in EMA was free from interference in determining the scope of internal auditing, performing work and communicating results; and there was no impairment to individual objectivity, in particular through conflict of interest, scope limitations, restrictions on access to records, personnel, and properties, or resource limitations. In 2020 three audit engagements were conducted by the internal audit function: on Information Security, on management of IT outsourcing and on the PRIME scheme. The physical security management audit was postponed until 2021 but has now been performed. The three internal audits in 2020 resulted in 21 major recommendations and 3 major recommendations remain under implementation: one is mostly due to a reassessment of priorities in allocation of resources in relation to the Business Continuity Plan. The other two are relatively complex actions related to pharmacovigilance, with therefore a long implementation plan. The new Head of Audit confirmed that the internal control systems put in place by the Agency in the period subsequent to the move of the Agency from London to Amsterdam, and marked by the COVID-19 crisis, provide reasonable assurance regarding the achievement of the business objectives in line with BCP arrangements. Based on audit findings in 2020, EMA has prepared improvement action plans and continues to monitor their implementation.

One member commented positively on the work of the internal audit service of EMA. He inquired about the findings of the information security management audit and asked if this is what led to reinforced measures on cybersecurity. It was clarified that reinforced efforts and investments on information security are being implemented, driven by the 2020 audit, the study commissioned last year from "Trilateral Research" and by the internal and a consultant's review following the cyber-attack.

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

[EMA/MB/255108/2021, Rev.1]

a) Minutes from the Extraordinary Management Board meeting of 21 April 2021 adopted via written procedure

[EMA/MB/243718/2021] The board noted the minutes from the Extraordinary Management Board meeting of 21 April 2021 adopted via written procedure.

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

[EMA/MB/255110/2021] The board noted an update from EMA on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation.

EMA reminded the board of the benefits of CTIS, in particular to facilitate multi-state clinical trials. Implementation of the agreed Go-Live scope is progressing with close monitoring from the CTR-Coordination Group (CG). Implementation of the MVP (Minimum Viable Product) scope and findings of Readiness Confirmation 15 are progressing as planned. Focus is on quality of development. Extended user testing will commence on 21 June, executing additional test cases defined by Product Owners. Scope of work is strictly managed to keep the focus on issues blocking day to day operations at day 1 of Go-live of the regulation for Sponsors or Member States. A new specific contract for CTIS covering development to Go-Live and a 6-month Hyper-Care period will be signed at the end of June 2021 to cover until July 2022. A review of the draft text of the Implementation Regulation on cooperation in assessment of safety between Member States is ongoing. Evaluation of the minimal information system support possible at the time of Go-Live is being done in cooperation with the Member States and the Commission. In order to assure the Go-Live of CTIS, it will not be possible to make additional changes to CTIS per se but to rather use EVDAS, business intelligence and other tools to support these activities. The High-level Go-Live delivery plan was presented. As of September EMA will no longer develop any new functionality and will focus only on stabilisation. Current contract includes hyper care and technical post Go-live enhancement. The training programme continues and will be ramped up before Go-Live. Seventy percent of the online materials have been developed and published. More than 50% of the Member States Master Trainers programme has been completed and national dissemination has started. Coordinated access to a virtual training environment ("Sandbox") is planned for October/November 2021. Each MS will choose how to organise internally for each CTIS role and a CTIS Training expert panel will be established in June 2021. A CTIS training helpdesk will be set up at EMA in October/November 2021. EMA has reached out to sponsors (industry and academia) and will produce a sponsor handbook, whose first version is to be published on EMA corporate website over the summer. An extensive online programme and a sponsor Master Trainer programme are ongoing. On 29 July 2021 a public event on CTIS will be organised. EMA called for all MSs to nominate their CTIS Administrators, who will cascade all the actions to internal national teams. The board reviewed the MB highlights extract on CTIS and the representative of DG SANTE confirmed that the EC is on track with the publication of the Official Notice on 31 July 2021.

An NCA representative inquired about the training material prepared by EMA, including Q&As and sandbox, and asked if they could be delivered before Q4 of this year. EMA explained this will require diverting IT support which needs to be focussed on Go-Live. Since code-freeze is planned in September, to avoid problems for stability EMA will only be able to start sandbox in the final quarter of the year. The representative of DG SANTE asked for more details on how EMA will manage the Q&A preparation. EMA explained that work with CTFG chair and EC is ongoing to streamline the processing of questions from sponsors since many questions are expected. Some questions will be on national approaches to the interpretation of regulation and some will be technical queries on CTIS. CTIS team will group similar questions together and will refine how questions will be registered and tracked, likely via the JIRA application. The representative of DG SANTE and the Chair of the Coordination Group (CG) noted that a single centralised system for retrieving questions and providing answers will be crucial.

c) Joint Controllership Arrangement (regarding personal data protection) for CTIS

[EMA/MB/422912/2020, EXT/160261/2019] The board noted a presentation by EMA on the Joint Controllership Arrangement regarding personal data protection for CTIS.

CTIS provides multiple functionalities that enable the processing of personal data in line with the agreed functional specifications e.g. personal data of registered users, contact persons, sponsor and NCA/EMA/EC staff, investigators. According to Regulation (EU) No 536/2014, personal data should only be processed to the extent necessary for the cooperation between CTIS users in accordance with the Union data protection rules. Personal data are accessible via the secure domains of sponsors/MAHs/European Commission/Member States/EMA. Personal data are captured in CTIS and some are published in accordance with the agreed disclosure rules. In July 2018, EMA consulted the European Data Protection Supervisor (EDPS) as regards the clarification of the "controllership" of CTIS. In November 2018, the EDPS clarified that from a data protection perspective EMA, the Commission, the Member States (including National Competent Authorities and Ethics Committees) and clinical trial sponsors are "joint controllers". In accordance with Article 28 of the GDPR/Article 26 of EUDPR, the respective responsibilities for compliance with the joint controllers' data protection obligations need to be formalised in a Joint Controllership Arrangement (JCA). A draft JCA has been developed following a data protection impact assessment and includes a description of processing operations of personal data of parties involved as part of CTIS and of processing operations out of scope of CTIS. The JCA defines roles, relationship and responsibilities towards data subjects, including data breach handling and notification timelines of Parties involved, the cooperation between Parties and the liability for non-compliance. The JCA must be accepted electronically by CTIS users at time of first log-in in CTIS and acceptance will be logged in the system.

d) Approach to negotiating agreement on the Joint Controllership Arrangement for EMA to negotiate with member states and sponsors

[EMA/MB/297428/2021] The board endorsed the proposed approach for EMA to consult and negotiate the draft Joint Controllership Arrangement (JCA) with Member States and sponsors.

EMA explained that the JCA text has to be negotiated and agreed by all CTIS users. The Agency plans to consult industry via the EU industry associations; for academia, EMA will use its Academia liaison office and/or Healthcare Professionals Working Party. A small EMA team will consult the parties and a mandate for it to interact with these user representatives is being asked to the board. EMA asked Member States representatives of the board to provide via a functional mailbox their contact points by 4 July. The appointed contact points should have knowledge of CTIS and of GDPR. Negotiations with the Member States contact points will take place between 19 July and 30 September 2021. An agreed JCA will be presented at the October MB meeting for endorsement. The Chair asked what type of contact details for contact points are required and EMA clarified that no CV but only email and phone details are necessary.

B.7 Information Management governance review

[EMA/MB/273382/2021; EMA/250013/2021] The board endorsed a pilot to implement the Agile way of working for a subset of the current IM project portfolio in 2021-2022 and a revised Information Management (IM) governance system replacing the current Telematics governance.

EMA presented a summary of the IM governance review process started in late 2020. The progress in science and technology has made the landscape more complex and IT projects need to be implemented in a faster way. The EU Medicines Agencies Network Strategy to 2025 calls for transparency in IM governance and prioritisation. EMA explained the benefits of the Agile way of

working. Agile gives a more resilient structure which allows to rapidly reprioritise backlog. CTIS, IRIS and UPD have already adopted agile ways of working at the execution level. EMA presented a case study on how Agile working was used for CTIS. The Agile change is also a business change, not just an IT change. It has been observed that IM governance structures have grown organically over the years and there is a lot of redundancy with many topics being discussed in multiple different groups. EMA presented the core principles of the proposed new IM governance: a portfolio management approach built on value streams; one portfolio, one Network and so the differentiation between Telematics and non-Telematics will become redundant; closer involvement of MB and HMA representatives in the Portfolio office; portfolio is aligned with strategic goals via value streams reflecting the network strategy priorities; the Management Board, Executive Board and the EMA Portfolio Board remain the main decision-making bodies for strategic/portfolio topics; Agile product teams led by MS/EMA product owners will be empowered to deliver at the execution level.

A new Network Portfolio Advisory Group (NPAG) will represent the EMA Management Board and the Heads of Medicines Agencies and will interreact with the EMA Portfolio Board. NPAG will be comprised of six EMA MB/HMA members nominated by the EMA MB and meet on a quarterly basis with the EMA Portfolio Board. A NPAG member can be designated to follow a specific value stream or topic. They will provide input into strategic and portfolio objectives as well as budget preparation, will monitor the delivery of the agreed portfolio during the year and can engage with industry representatives at industry stakeholder meetings. The EMA Enterprise Architecture Board (EAB) will advise the EMA Portfolio Board on the technical aspects, i.e. if projects are cost effective and not duplicating technology unnecessarily. The Network ICT Advisory Committee (NICTAC) will gather a subset of the IT Directors and EMA staff and advise both the EMA EAB and the Portfolio Board on topics including technology needs, priorities, and policies from NCA and/or Industry, technology implementation choices across the Network, interoperability requirements across the Network, input and advice on data standards, data model design and implementation and advice on dependencies (system and resource) across Network initiatives.

The Network ICT Advisory Committee will regularly connect with the IT Directors group to share best practices, as it is currently the case e.g. on cyber security. The EMA Portfolio will be divided in value streams comprised of multiple products managed by product teams. DADI and UPD projects can be considered products and will have their own Agile product teams. The EU Network Data Board is maintained as the forum to discuss data governance issues e.g. on ISO standards, ICH. A calendar of structured engagement opportunities will connect the execution level with the portfolio and strategic decision-making structures. Industry will provide input into strategic level discussions through the HMA and via continued interactions with the EMA MB (NPAG) at defined times during the year. Industry will have interactions with the NICTAC to discuss technical questions on system interoperability and industry representatives will continue to contribute at the execution level as technical subject matter experts invited into Agile product teams. Finally, industry representatives would be invited to the quarterly strategic portfolio review meetings and system demo meetings. The board was requested to endorse a pilot with the ePI, DADI and PMS project (25% of the existing Telematics portfolio, all dealing with product data and being mutually interdependent) starting from Summer 2021 in order to test ways of working and feed lessons learned into the Agile adoption process. EMA will establish success criteria and report on efficiencies gained at the December 2021 MB meeting. During the pilot the NPAG and NICTAC will be established and the existing governance structures will be restructured accordingly. Existing Telematics bodies - i.e. the IT Directors Executive Committee (ITDEC), the EU Telematics MB (EUTMB) and the Telematics Enterprise Architecture Board (TEAB) - will be deprecated during the summer to allow for the establishment of the new NPAG and NICTAC bodies. The EU Network Data Board (EUNDB) and the IT Directors community of practice will continue to function.

Four members and the representative from the veterinarians' organisations welcomed the well-prepared new governance structure and the closer interaction between NPAG/MB and EMA Portfolio Board. They noted EUTMB was properly consulted and had agreed a new governance is needed. Pilot is large enough to see some outcomes soon and it is important that there will be a stock taking opportunity as soon as possible. It is also important that Member States and industry are well represented. It was noted the telematics landscape will remain a complex system, but the change is positive and it is welcome that industry is more involved. The Chair asked when nominations for NPAG will have to be provided and EMA informed that the MB secretariat will organise a call for nominations with a view to establish the NPAG in September. The request for nominations to the NICTAC will also be sent during the Summer.

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

The board noted an update from DG SANTE and EMA on the preparation for implementation of the new Veterinary Medicinal Products Regulation (Regulation 2019/6).

The representative of DG SANTE informed that focus continues to be on the 12 acts part of the first and second packages to be adopted before or by 28 January 2022 and on 2 acts on the "horse passport". The Regulation on requirements for collection of data on the volume of sales and use of antimicrobials was published in the Official Journal. The Delegated Regulation on Criteria for reserving antimicrobials for use in humans was adopted on 26 May 2021 by EC and is under scrutiny by the European Parliament and Council. The act on Good pharmacovigilance practice and content of pharmacovigilance master file will go to the Standing Committee for consultation until 2 July. For the detailed rules on imports from third countries, the relevant expert group is being consulted. The act on format for the collection of data on antimicrobials is being drafted, while the GDP for active substance and for veterinary medicinal products are under consultation at the Standing Committee. The act on the common logo for online sales is reaching final adoption stage within the Commission. The Commission Delegated Regulation (EU) 2021/577 on the content and format of the horse passport and the Commission Implementing Regulation (EU) 2021/963 on the model forms for the horse passport were recently published on the Official Journal. As regards the feasibility study under Article 156 on active-substance-based review system ('monographs') and possible alternatives, a draft Interim report was received and is to be finalised by end of September 2021. Overall, the work is progressing on time and the Commission maintains its ambition for timely implementation.

EMA noted seven months are left until the date of application and the Agency is working hard to deliver on IT systems. Discussions focus on how to adapt business processes at EMA and at NCAs. All EMA's scientific advices have been published on the EMA website. The advices on the list of antimicrobials to be reserved for human use and on the list of substances not to be used or used subject to certain conditions under the 'cascade' are pending as they are dependent on the finalisation of the delegated act on criteria for reserving antimicrobials for human use, which is currently being discussed by the European Parliament. Both advices will have an impact on the delegated act according to article 118 on imports from third countries.

The work on the Manufacturer and Wholesale Distributors database is ongoing and EMA is waiting for the GMP/GDP Inspectors Working Group and the EU Telematics Management Board to appoint experts in the related Project Group (MWD PG). The Antimicrobial Sales and Use Project (ASU) is planned for Go-live by end 2022 and will run into 2023, while the Union Product Database (UPD) project is nearly finalised. The Union Pharmacovigilance Database (EVVet) project is progressing to plan and should also be ready by the end of the year, together with the UPD. Key risks for implementation of the VMP regulation remain COVID-19 and the delays in submission on legacy data in the UPD, as all

pharmacovigilance procedures and some other post-authorisation procedures (e.g. variations not requiring assessment, marketing status, submission of sales volumes) will not be possible if legacy data has not been uploaded by the application date. In July UPD will go live for upload. NAP legacy data can be submitted at any time, but for MRP/DCP products core legacy data will have to be submitted first by RMSs and then CMSs can complete later. Then it will be up for parallel trade products, which can be added once the reference products in the source and destination member states have been added to the UPD. EMA hopes to have a complete dataset by January 2022 but recognises that there will have to be a transition period after January to enrich the data. EMA presented a traffic light system on NCA progress in the submission of legacy data. The change management programme is being implemented and includes support to NCAs for mapping product data (substances, organisations and referentials), regular newsletters and webinars also via EU NTC. The current programme priority is supporting NCAs preparedness for legacy data upload and, due to ongoing development, it is not possible to offer training to industry in many areas yet, but EMA is hiring staff to support implementation of the complete training plans. The UPD Implementation Guide was published in May 2021, 6 weeks ahead of deadline, to guide Member States on how to prepare their legacy data for upload. It was recognised there is a lot of work ahead and 16 NCAs have not reported any data yet. After July EMA will provide a monthly update on the uploading of legacy data both to the CG and to the board. The EVVet Implementation Guide was published in early June for consultation. NCAs should fulfil legal obligation to submit legacy data completely by 28 January. A discussion is taking place on how to handle variations not requiring assessment, but there is no real back up plan in case of continued delays. The HMA TF is also looking into issues of sustainability of the new model. EMA thanked Hugo Hurts for his participation in the CG and his support to the VMP regulation programme. In February 2022 a new governance will be set up to discuss post MVP improvements. EMA informed the board on the Veterinary Big Data Stakeholder Forum organised on 1-2 June which will inform the development in 2022 of a data strategy for veterinary medicines together with HMA. A key take-away from the Forum is that big data is already happening and regulators need to adapt to exploit it. The Forum also identified the need to define new training curricula and establish an international cooperation forum. A second Stakeholder Forum will be organised by EMA in 2022.

The Chair asked for volunteers to replace Hugo Hurts as MB representative in the CG for the implementation of new veterinary regulation. One member put emphasis on the very challenging period ahead for NCAs. At beginning of the new year NCAs will have to accept that at Go-live there will be minimal data in UPD and so not all the data needed for variations not requiring assessment will be available. NCAs expressed concerns about the lack of resource increases at national level and of the possible impact of the enlargement of the optional scope of the centralised procedure. The representative of veterinarians' organisations congratulated the EMA and EC for their work and inquired with the EC about the Delegated Act on imports for third countries as this is still being drafted with only 7 months to go before Go-Live. Other NCAs members stressed that the necessary requirement for legacy data upload were not fully known until recently and the resource issues are very important for some Member States. EMA explained that on the variations the problem should not be exaggerated as many variations will not require UPD in order to be operated. For the variations not requiring assessment, if the full desired functionality is not complete, EMA will analyse which variations will be affected and develop an automated tool to assist for the first post-Go-live release. As regards the enlargement of the centralised procedure to generics, EMA surveyed industry on their intent to submit under the new regulation and to come for scientific advice in 2022 and the result is that a low number of generics are expected to be authorised via the centralised procedure (N=4 out of 30). This is much less than what could have been anticipated, which gives some time to develop more sustainable systems. All technical requirements are described in the Implementation Guides. Key is that EMA and EC continue the communication with NCAs. The representative of DG SANTE confirmed

that the Delegated Act on imports is under review with the expert group and then will go to the feedback mechanism for Member States and preparation is on track.

B.9 Big Data Steering Group update and progress report on DARWIN EU implementation

[EMA/MB/291650/2021; EMA/298378/2021/2021] The board noted an update on the implementation of the work programme of the EMA-HMA-EC Big Data Steering Group, including the DARWIN EU project.

The HMA co-chair of the DARWIN EU Advisory Board updated the board on the status of the DARWIN EU project. He explained what DARWIN EU is, what it will do and which services it will deliver. He clarified it is not a database, but a network of data, expertise and services that supports better decision-making throughout the product lifecycle with reliable evidence from real world healthcare data. Its services building on Real World Evidence (RWE) based studies will also become increasingly important for crisis preparedness and response and it was stressed how RWE studies helped to confirm at early stage the safety signal for TTS. Further epidemiological studies using RWE for COVID-19 are being conducted and they will progressively change the way regulators investigate suspected safety concerns in the future.

EMA explained that at the March 2021 board meeting the mandate of the DARWIN EU Advisory Board was adopted and the Advisory Board is being set up. Project funding has been secured and the tender for a service provider to act as the DARWIN EU Coordinating Centre was launched in early June 2021. A DARWIN EU page on the EMA website was also launched. To prepare for the tender, the Agency has extensively discussed with FDA and PMDA to learn from their experiences in running RWE studies. EMA explained the scope of the tender which covers: i) establishment of the DARWIN EU Coordination Centre; ii) conducting scientific studies and research questions in support of benefit / risk decision making by NCAs and EMA scientific committees; iii) maintenance of a regulatory catalogue of Real-World Data sources usable in the regulatory context. Selection of the service provider will be based on their scientific and research expertise, their experience in RWD analyses and value for money. EMA will be responsible for standards, contracting, instructing and overseeing the Coordination Centre and monitoring its performance. The Agency is undertaking a data protection impact assessment and will involve national data permit authorities in the project as appropriate. The first two years of the contract will be focussed on establishing the network, and the Coordinating Centre and the DARWIN EU processes. The contract could be extended at yearly intervals depending on results to date, up to a total duration of five years. It should be signed in December 2021, but if delays in the evaluation occur, the Agency might also sign in Q1 2022, which will require the board to endorse a budgetary carry over in December. EMA informed on the composition of the DARWIN EU Advisory Board, whose first meeting will be on 28 June.

EMA provided an update on the work plan and membership of the Big Data Steering Group. The 2022-2023 workplan will be circulated for information by late July and will be published after the summer. A progress report for all the actions in the current work plan 2021-2022 was provided. EMA detailed activities on: development of a data quality framework; workshop on data discoverability; network trainings; review of use of RWE analytics for supporting scientific assessments; network processes for using rapid analytics in the committees, including a review of the use of RWE in marketing authorisation applications in 2018-2019; development of a Data Standardisation Strategy and collaboration with other international regulators; recommendations on ethics and data protection; and organisation of stakeholder workshops. EMA replied to some of the questions recently raised by HMA on data quality, data standards and catalogues of real-world data sources. EMA showed preliminary results of a research on the use of RWE in marketing authorisation applications and extensions of

indication. Analysis of this review is ongoing and EMA plans a workshop in Q4 2021 in order to discuss how to more systematically track RWE submitted in applications to regulators and to learn from their assessment. EMA updated the board on the changes in membership in the Big Data Steering Group. The representative of DG SANTE suggested that EMA also engages in discussions with international partners to embed as much as possible personal data protection into the design of future activities of the Steering Group.

B.10 Management Board liaison on PRAC composition – Liaison after 9 years of PRAC in 2021

[EMA/MB/157966/2021; EMA/MB/275601/2021; EMA/MB/43845/2015, EMA/411582/2015] The board endorsed the assessment of the current composition of the PRAC and of the areas of expertise identified by EMA as beneficial for future PRAC activities.

EMA referred to the Management Board agreement from 2015 on a process for a review and update to the Board every three years on the composition of PRAC, as required by legislation and by the Rules of Procedure of the PRAC, which state that "Member States shall liaise with the Management Board and the Commission in order to ensure that the final composition of the Committee covers the scientific areas relevant to its tasks". EMA presented an overview of the current PRAC composition and areas of expertise as self-reported by PRAC members and alternates. Core expertise of PRAC members and alternates is foreseen in the legislation and in 2012 PRAC identified complementary expertise. All required expertise areas, both core and complementary, are covered by the current PRAC composition. However, the following areas of expertise have been identified by the Agency as key areas which would be beneficial to the activities of the PRAC: statistics (medical statistician); pharmacoepidemiology / real world data; vaccines; pharmacogenomics; risk communication; clinical specialists in oncology and ATMPs, biologicals and biosimilars, medical devices, new digital technologies (e.g. in Risk Minimisation Measures). Member States will be invited by EMA through nomination invitation letters to take these identified areas into consideration when nominating for new PRAC members and/or alternates.

List of written procedures finalised during the period from 13 February 2021 to 25 May 2021

- Consultation procedure for the adoption of the Annual Report 2020. The procedure was endorsed.
- Consultation procedure for the endorsement of the of the revision of budget remarks for budget 2021. The procedure was endorsed.
- Consultation procedure for the adoption of the minutes of the 110th Management Board meeting, held on 16-17 December 2020. The procedure was adopted.
- Consultation procedure for the adoption of the minutes of the 111th Management Board meeting, held on 11 March 2020. The procedure was adopted.
- Consultation procedure for the adoption of the minutes of the Extraordinary Management Board meeting, held on 21 April 2021. The procedure was adopted.

Documents for information

- [EMA/MB/249517/2021; EMA/249544/2021] Report on EU Telematics
- [EXT/321688/2021] Feedback from the Heads of Medicines Agencies
- [EMA/MB/315817/2021] Outcome of written procedures finalised during the period from 13 February 2021 to 25 May 2021

- [EMA/MB/58488/2021, EMA/58487/2021] Summary of transfers of appropriations
- [EMA/MB/257659/2021] Preparation for written procedure on the adoption of transfer of provisional appropriations within budget 2021
- [EMA/MB/252487/2021] Summary of implementation of assigned revenue
- [EMA/MB/226594/2021; EMA/113700/2008-Rev.2] EudraVigilance access policy for medicines for veterinary use
- [EMA/MB/292994/2021; EMA/579063/2020] Framework strategy for external communication and stakeholder engagement 2021-2025

List of participants at the 112th meeting of the Management Board, held virtually on 17 June 2021

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier de Cuyper *(member)*
Bulgaria	Bogdan Kirilov *(member)*
Czechia	*Apology received (member)*
Croatia	Siniša Tomić *(alternate)*
Denmark	Mette Hansen *(alternate)* Nikolas Jørgensen *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	Eleftherios Pallis *(member)*
Spain	María Jesús Lamas Diaz *(member)* César Hernández *(alternate)* Maria Alcaraz *(observer)*
France	Christelle Ratignier-Carbonneil *(member)* Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	*Apology received (member)* Pietro Erba *(observer)*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Jānis Zvejnieks *(alternate)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	*Apology received (member)*
Hungary	Mátyás Szentiványi *(member)* [1] Beatrix Horvath *(alternate)*
Malta	Anthony Serracino-Inglott *(member)*
Netherlands	Paula Loekemeijer *(member)* Hugo Hurts *(alternate)* Michiel Hendrix *(observer)*
Austria	Thomas Reichhart *(alternate)*
Poland	Grzegorz Cessak *(member)*
Portugal	Rui Santos Ivo *(member)*
Romania	Roxana Stroe *(member)*
Slovakia	Judita Hederová *(alternate)*
Slovenia	Momir Radulović *(member)* [1]
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.6.d, B.7 and B.10*

European Parliament	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) *Apology received* (Liechtenstein) Audun Hågå (Norway)

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