EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 December 2020
EMA/MB/695181/2020 Adopted
Management Board

Minutes of the 110th meeting of the Management Board

Held virtually on 16-17 December 2020

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

The Management Board appointed Sandra Gallina and Rui Santos Ivo as reporting officers in the process for the appraisal of the Executive Director of EMA. The role of appeal assessor is foreseen for the Chair, acting in her capacity.

The Executive Director informed the Management Board that a cyberattack on EMA had taken place and an investigation was being carried out by the Agency in close collaboration with law enforcement and other relevant entities. An initial review had revealed that the data breach was limited to one IT application and that documents belonging to third parties had been unlawfully accessed. The companies concerned at this stage had been contacted and duly informed. All potentially suspicious activity is being analysed under a risk-based approach. The Agency and the European medicines regulatory network remain fully functional and timelines related to the evaluation and approval of COVID-19 medicines and vaccines are not affected. The Agency will take any necessary step to prevent further incursions and will continue to provide information in due course, to the extent possible, given its duty towards the ongoing investigation.

A member suggested keeping the IT Directors of the NCAs closely informed of any developments.

1. Draft agenda for 16-17 December 2020 meeting

[EMA/MB/547010/2020] The agenda was adopted without amendments.

2. Declaration of competing interests related to current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential

competing interests relating to the day's agenda were identified concerning topics *5. Aplidin General Court Judgment and impact on the EMA handling of competing interests; B.2 Review of activities of the Working Parties of the EMA High-level implementation plan; B.8 Programming 2021-2024, Final programming document 2021-2023, Preliminary programming document 2022-2024; B.9 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation b) Mandate of the Monitoring Subgroup of the Clinical Trial Regulation Coordination group* and *B.11 Union Product Database (UPD) Access Policy under the Veterinary Medicinal Products Regulation (VMP-Reg).* The Secretariat informed the Board that all concerned members had been informed before the meeting. Should the need for a vote on the above topics arise, the Chair would take up the matter again.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interests were declared.

3. Minutes from the 109th meeting, held on 1 October 2020 adopted by written procedure

[EMA/MB/318294/2020] The Management Board noted the final minutes, adopted by written procedure on 14 December 2020.

4. COVID-19

• EMA Status Report

The Management Board noted the COVID-19 EMA Status Report. The Agency has continued discussion with pharmaceutical companies for 173 therapeutics and 47 vaccines. It has provided the European Medicines Regulatory Network (EMRN) and the European Commission with the most recent information on forecasted submission dates for COVID-19 treatments. There is a high degree of interest in the status of ongoing assessments, particularly in the media, it was recalled that this information on ongoing assessments is confidential. Two procedures for conditional marketing authorisation applications (CMA) for vaccines were started on 1 December 2020, as well as 2 rolling reviews for vaccines. Although (Co)-Rapporteurs at CHMP and PRAC level have been appointed for all procedures so far, the availability of expertise may be challenging to maintain as the number of applications increase. Multinational Assessment Teams (MNATs), spreading the workload across the network more evenly, are used to a greater extent, but might also signal workload increase and resource constraints faced by the Rapporteurs. In order to address these difficulties, there is a need to consider the next steps in the EMRN COVID-19 BCP (Business Continuity Plan), which in the current phase 2 makes sure that COVID-19 related procedures cannot be delayed under any circumstance, and that changes necessary for non-COVID-19 procedures are applied at the level of the concerned procedure. Where delays for a non-COVID-19 procedure are reported, a decision tree should be followed. EMA will get back to the next EMRN meeting at the beginning of 2021 with proposed solutions taking into account a further analysis of the situation. Following a meeting of EMRN on 25 November 2020 to update on COVID-19 vaccines, further meetings are organised weekly and are considered very helpful to facilitate preparation for COVID-19 vaccine roll out at the national level. Work has continued on the project related to forecasting the demand for medicinal products, resulting in the development of a draft Reflection Paper. A pilot to allow Member States (MS) to obtain more experience with its common principles and to identify the need for any amendments was launched and has been successful. Based on this pilot, changes to the draft Reflection Paper will be submitted for agreement by the Steering Group at the beginning of the year. Good communication remains a priority, and a COVD-19 sub-

group of the Working Group of Communication Professionals has been established. The public stakeholder meeting on COVID-19 vaccines held on 11 December to explain regulatory processes had a very wide audience and will be followed by a second public meeting on 8 January 2021. The first COVID-19 vaccine approval will be accompanied by a comprehensive communication package, with a number of measures introduced to enhance transparency post-authorisation.

Members of the board exchanged their experience with public and media interest, which has been very focussed on timelines. EMA has provided communication material to explain the differences between an Emergency Use Authorisation (EUA) which allows temporary use of a non-licensed product, sometimes for specific batches, and a CMA, which is an authorisation complete with all its features. The representative of DG SANTE highlighted the need for all actors to keep up the momentum and react within the short timeframes agreed and made the suggestion to prepare internal Question and Answers on frequently asked question. The Chair also suggested to keep the process for the Official Control Authority Batch Release (OCABR) in mind.

- **OPEN project**

[EMA/MB/688840/2020; EMA/691780/2020] The Management Board adopted a revision of the Rules of Procedure of the CHMP including an Annex on the Pilot project with a view to involve experts from international organisations or regulatory authorities in third countries in the initial scientific discussion in the Committee on COVID-19 medicinal products. The initiative, known as OPEN project, transforms the success of ICMRA collaboration and previous cooperation in extraordinary circumstances into a practical exercise with limited scope and time, providing a framework for active participation as experts to Health Canada, Swissmedic, Japan and WHO. These experts can contribute and enrich the scientific discussions on COVID-19 medicines at the Emergency Task Force (ETF) and CHMP, contributing to the main points with the assessment performed in parallel by their authorities, thus adding expertise to that of CHMP and ETF. These observers must fulfil all the conditions of experts but cannot participate in the decision-making process of the Committee. The international collaboration on COVID-19 medicinal products at CHMP will involve some additional workload at EMA, such as the need for personal data redaction of documents shared outside the EU, but will provide additional expertise to the CHMP and value to the EU system, as promoting convergence of authorities' conclusions will increase public confidence. The Management Board will be provided with a report at the end of the initiative. The amended Rules of Procedure have been agreed by the CHMP.

The representative of DG SANTE added that the Annex to the Rules of Procedure had been drafted by the European Commission, which stands behind these provisions. The board decided to adopt the amended Rules of Procedure in order to allow them to be in force for the ongoing urgent discussions on COVID-19 medicinal products, including vaccines. Concerning a question on whether cooperation with ICMRA would include also post-marketing, members were informed that ICMRA would discuss ways to collaborate on vaccine safety at an upcoming meeting in January.

5. Aplidin General Court Judgment and impact on the EMA handling of competing interests

[EMA/MB/689087/2020] The Management Board endorsed option 2 proposed in the document on Aplidin General Court Judgment and impact on the EMA handling of competing interests. On 28 October the General Court delivered an important judgment annulling the Commission Decision refusing the granting of a MA for Aplidin on the basis that two SAG experts had alleged Conflicts of Interest as they are employed by an institute that controls and exercises a significant influence on a university hospital, as well as on a clinical research centre which performs development activities for pharmaceutical companies. Furthermore, the university hospital hosts a cell therapy centre manufacturing a product competing with Aplidin. EMA was not a party in the lawsuit and is of the view

that the General Court interpreted incorrectly EMA's policy on the handling of competing interests as adopted by the board. The judgment is immediately binding on the European Commission and the re-examination procedure for the MAA for Aplidin will restart with the convening of the SAG. EMA has taken immediate minimum measures for the immediate implementation of this judgment not only for the Aplidin case, but also for ongoing and planned regulatory procedures whilst a reflection on launching an appeal and/or revising the EMA policy takes place in parallel. The adverse impact 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. The Agency informed the EMRN on 10 November, highlighting the legal modalities for the Member States to launch an appeal if they so wish, for which the EMA would be willing to provide legal and regulatory support. Following further discussion at the HMA meeting in November, Estonia expressed interest in launching an appeal, which could include a request to ask the General Court to temporarily suspend the judgment. The Agency has identified three options for a way forward. These are: Option 1: amending the EMA Policy already at the current stage. This option is not supported by EMA as it will take time to discuss and amend the Policy whilst and appeal could be launched which could lead to setting aside the judgment; Option 2: continuing with the current minimum implementation measures; Option 3: continuing with the current minimum implementation measures but relying on the concept of "prominent" role played by the allegedly conflicted expert in the relevant working group or committee.

The board discussed Options 2 and 3. Option 2 was widely preferred in the current phase as easier and more rapid to implement. As a long-term plan, policies may need to be reviewed to adjust the Policy to a changing reality (e.g. in the sector of advance therapy medicinal products). Other Member States as well as the European Commission will be carefully considering whether to launch an independent appeal or intervene in favour of Estonia in the appeal proceedings.

6. Update on 30 Churchill Place

[redacted]

7. Update on Brexit

EMA continues to track and monitor the very few remaining Brexit-affected Centrally Authorised Products (CAPs), to implement the required changes to the EMA IT databases and systems, and to introduce the required adjustments to its processes in view of the implementation of the IE/NI Protocol. It appears that regulatory compliance will be largely achieved by 31 December 2020. Concerning inspections, due to the pandemic and restrictions to travel, the GMDP IWG extended the Risk Based approach guidance on GMP certificates for UK sites post Brexit, to sites located in 3rd

countries that have been inspected by UK authorities. After the transition period these GMP certificates will continue to be used under specific conditions. After 1 January 2021 certain elements of the EU Pharmaceutical Acquis will continue to apply in UK in respect to Northern Ireland. The UK will not participate in EU decision making and will receive only the outcomes of EMA procedures. It will have no access or only partial access to most EMA systems and databases, but retain full access to the PSUR repository and Eudralink. The new XI ISO codes and UK(NI) denominator will be introduced in the great majority of EMA systems. Changes will be needed for processes impacted by the change to country of authorization for UK NAPs in Art 57, and new processes will need to be established to exchange information with UK authorities in cases were access to EMA systems is removed. All changes to EMA systems have been identified and are planned for implementation by 1 January 2021. A communication plan has been agreed for industry, EMRN and UK authorities, including practical information on systems unavailability due to the deployment schedule.

The representative of DG SANTE confirmed that the European Commission will adopt a notice by the end of the year informing of special measures. Focus is now on Member States and regions historically dependent from the UK, such as Ireland, Cyprus, Malta, and Northern Ireland.

A. Points for automatic adoption/endorsement

A.1 Revision of budget remarks for budget 2021

[EMA/MB/116730/2020] The Management Board endorsed the revision of budget remarks for budget 2021, to create new budget items and to amend existing ones in order to adhere to the Agency's Financial Regulation which stipulates that the budget nomenclature shall comply with the principles of specification, transparency and sound financial management and show 'appropriate remarks on each subdivision' of the budget. The proposed changes shall come into effect for budget 2021.

A.2 Financial compensation and workload estimation of the EMA organisation of translations of product related information

[EMA/MB/623265/2020; EMA/623334/2020] The Management Board endorsed the flat-hourly rate of €46 which, taking into account the official inflation rate, remains unchanged for 2021.

B. Points for discussion

B.1 a) Audit strategy 2021-2023 and audit plan 2021

[EMA/MB/622416/2020; EMA/MB/434298/2020] The Management Board adopted the Audit Strategy 2021-2023 and the Annual Audit Plan for 2021.

The Audit Strategy outlines the audit activities which will be undertaken at EMA, including both the audit plan for 2021 and the multiannual audit plan related to 2022-23. It relies on the analysis of the Agency's risk register, applicable legal requirements, priorities laid down in the EMA Multiannual Work Plan, and takes into account the EMA BCP and COVID-19 BCP. The audits will be performed by AF-Audit, ECA, the IAS and external audit service providers; this will be complemented by dedicated discussion with senior management of the Agency. It is foreseen that the Agency in 2021 will be subject to 12 audits. The team of the EMA Audit Function (AF-Audit) will also conduct regular follow-up of audit recommendations, implement the action plan for future-proofing of audit activities, conduct targeted audit-related training networking activities, participate in the BEMA SG work in preparation of

new methodologies for the BEMA V cycle, contribute to the revision of the anti-fraud strategy. The current Head of Audit will be retiring on 1 February 2021; while a replacement is being appointed transitional arrangements have been put in place.

b) Report to the Management Board on Pharmacovigilance audits carried out in the European Medicines Agency from 1 July 2018 to 30 June 2020

[EMA/MB/608386/2020; EMA/MB/597112/2020] The Management Board endorsed the 4th Report to the Management Board on Pharmacovigilance audits carried out in the European Medicines Agency from 1 July 2018 to 30 June 2020 presented to the board in conformity with Article 28f of Regulation (EC) No. 726/2004. The report outlines the key developments that have affected the EMA Pharmacovigilance system since the last report in the areas of organisation structure, responsibilities and resources, facilities and equipment, record management, data protection and training. Internal audit activity for the period under review includes two audits and two consultancy engagements related to the functioning of the EMA pharmacovigilance system. All corrective actions related to two audits carried out by the Internal Audit Service of the European Commission (IAS) have been implemented. For the previous reporting periods (1 July 2012 to 30 June 2018), all corrective actions have been implemented, apart from four actions which remain outstanding and whose extensions have been agreed. For the current reporting period there are no outstanding critical actions and three out of seven recommendations are still in progress.

The board expressed appreciation for 12 years of excellent collaboration and wished the Head of Audit all the best for her retirement.

B.2 Review of activities of the Working Parties of the EMA High-level implementation plan

[EMA/MB/650729/2020; EMA/650033/2020; EMA/634100/2020] The Management Board discussed the Report on a high-level implementation plan of the Management Board review of the activities of the EMA Working Parties and endorsed further activities of the Management Board review group without prejudice to the high level principles and recommendations adopted by the board in March. After the adoption in March by the board, of high-level principles and recommendations a cross-Agency project team was set up to prepare an implementation plan informed also by the EMANS strategy and the Regulatory Science Strategy to 2025. The high-level principles have introduced a dynamic positioning of experts in Special Interest Communities (SIC), Operational Expert Groups (OEG) and temporary Drafting Groups (tDG). Over the summer period a data gathering exercise was conducted with the chairs of the Working Parties to develop three-year work programmes. The workstreams or domains for quality, non-clinical safety, methodology, clinical and veterinary each proposed an operational model and meeting modalities which were presented to the Scientific Coordination Board (SciCoBo), the Management Board Review Group and the HMA. The new model is designed to deliver the strategic, tactical and operational goals of the domain, achieving simplification through a redistribution of expertise organised in more agile structures such as the OEGs, tDGs and SICs, and consequent reduction in number and membership of standing Working Parties. Efficiency and consistency are to be achieved by using resources only when required, while providing information to the network, and training development through the SICs. Strategic leadership is exercised by the Domains' oversight of the work programme and prioritisation of the activities undertaken by the Working Parties. Following endorsement by the Management Board, further reflection would continue in preparation for go-live which is likely to take place not before Q3 2021, after the expected COVID-19 workload peak.

The presentation was followed by a number of interventions from Board members. Concern was raised on the divergence from the current practice of representation by all Member States in certain Working Parties, as this change was perceived to penalise small Member States who cannot afford to have a high number of experts in specific fields, and might lead to decisions that do not take into account the reality in small Member States. The issue of lack of financial compensation to Working Party work by the NCAs was raised, together with the question as to whether a proposal on this topic would be put forward within the review of the Fee Regulation. It was also perceived that the methodology domain may have a reduced scope and may not guarantee access to all expertise required. Furthermore, the lack of a Pharmacovigilance domain was pointed out. A call for continuing full representation by Member States in certain Working Parties was also raised in the context of taking into consideration not only the scientific needs of the Centralised Procedure but also of the Decentralised Procedure. It was felt important to provide all Member States with the possibility to take part in or be informed by scientific discussions to foster continued development of EU experts, complementary to the training provided by EU NTC. The experience with large working groups was mentioned, where only a small core does most of the work. Passive participation is now made easier by remote access, however concerns of small Member States must be taken into consideration and discussed with the Chairs for the development of proposals. Achieving inclusivity and efficiency should not be mutually exclusive. It was also pointed out that there is no legal requirement for full Member State representation in Working Parties. In the veterinary domain it was perceived that the Quality domain should have a certain number of experts to deal specifically with veterinary issues. It would be further desirable to have a better understanding of the role of the SICs. In addressing these concerns, members were informed that currently only several Working Parties have a Member State membership. The practice for the majority of Working Parties has been nomination by expertise in the numbers needed for the activities concerned. The current proposal foresees a number of ways to contribute, in addition to membership of Standing Working Parties. These included temporary Drafting Groups on specific guidelines or hot topics such as nitrosamines for example; and Operational Expert Groups in support of high-volume product applications. SICs are meant to create a 'nursery' of expertise who can contribute to each of the preceding structures. The representative of DG SANTE agreed on the importance of knowledge management and noted that work on the fee proposal is in the stages of collecting information.

The chair decided not to put the proposal to a formal vote but to postpone its endorsement to the March meeting and request further work to be done to provide more precise information on the OEGs, tDGs and SICs with particular emphasis on how these allow all Member States to engage with the system, as well as to further reflect on pharmacovigilance, to ensure the plan would deliver on expectations across the different domains. This work is without prejudice to the high-level principles and recommendations adopted by the board in March, which continue to guide this review and their translation into implementation, and will continue to be overseen by the MB review group.

B.3 Information Management governance review

The current review of the EMA Information Management governance looks at a structure that has grown over the years around single stand-alone systems largely based on a waterfall model. An effort is needed to achieve a more agile model, not just for IT but for the organisation as a whole. Currently multiple governance structures wrap around the IT portfolio from conception to delivery. EMA will work initially with external consultants to support a baselining exercise and to provide informed recommendations on best governance practices. These will be reviewed by the EMA Executive Board, EU Telematics Management Board and the Management Board who will advise on further actions. Under the current governance, more structures are added with new systems. It is necessary to look at these structures, and at their Terms of Reference and stakeholders. The goal is to simplify the governance, increasing capacity and efficiency in order to move towards a portfolio management

approach. It must be ensured that all IT initiatives have a clear business goal and a business sponsor, thus improving the overall success rate for EMA and Telematics programmes. An appropriate delegation of authority should ensure that Business and IT agile development teams can take decisions within an agreed scope at the solution level. The current HMA MG initiative on the Telematics funding models should be considered as distinct but complementary to EMA's. The HMA MG will lead a review with partners including EMA to explore the options for a new Telematics funding model. The review currently being undertaken at EMA will feed into the HMA MG initiative with any relevant findings and recommendations. Interviews, research and formulation of recommendations will take place from November to February. Recommendations will be presented to the board in March and will be followed by consultations from March to April. From May onwards adoption and change management will take place. Interviews with EU TMB core members of the Management Board will take place during December and January and all board members are invited to contact EMA if they wish to be interviewed as well.

It was confirmed that the EU TMB supports this initiative. It was also pointed out that successful digitalisation requires an overarching system and looking just at EMA may not be enough. EMA confirmed that the objective is to move away from silos and understand the complete digital landscape working towards greater interoperability.

B.4 Annual report on the implementation of the EMA's Anti-Fraud Strategy

[EMA/627416/2020] The Management Board noted the Annual report on the implementation of the Anti-Fraud Strategy (AFS). OLAF (European Anti-Fraud Office) is working on a revised methodology and guidance which will be used also for agencies and should be available at the beginning of 2021. Cooperation with OLAF is excellent and no investigations involving EMA have been opened in 2020. According to the AFS Action plan for 2018-2020, 3 actions were to be performed on an annual basis and have been regularly implemented in the last 3 years. For 2020, no additional action was needed and no administrative enquiry was launched. The Management Board decided in December 2014 that the AFS and action plan should be reviewed and updated every 3 years. A revision is now due in 2020, but given that the new Executive Director of the Agency took up her office on 16 November, it is too early to finalise a revision proposal. It was instead proposed to the board to submit the revision of the AFS at the March 2021 meeting. The board was also informed that OLAF has raised the question of whether the members of the Management Board of EU decentralised agencies are subject to its investigations. If needed, further updates on this matter will be provided at some future meeting. The board endorsed the postponement of the presentation of the revision of the AFS to the March 2021 meeting.

B.5 Report on the implementation by EMA of the EU Data Protection Regulation

[EMA/627417/2020] The Management Board noted the Report on activities related to data protection compliance. The EMA Internal Guidance on Personal Data Protection was adopted on 21 July 2020 to implement the EU Data Protection Regulation (EUDPR). This document constitutes the data protection governance system of the Agency. Ensuring compliance with the EUDPR at the Agency constitutes a high workload as it deals with personal data processing activities for pharmacovigilance, international collaboration, procurement, HR and staff-matters related personal data etc. It also entails the reformulation and periodic update of the documentation concerning over 85 personal data processing operations and managing records, privacy statements, joint controllership arrangements and data protection impact assessments. 25 cases of personal data breaches had to be handled in 2020, for

which 3 cases required a notification to be sent to the European Data Protection Supervisor (EDPS) for the appearance of high risk to the data subjects' rights. One case notified in 2019 concluded with the absence of further recommendations from the European Data Protection Supervisor (EDPS). The international transfer of personal data, which takes place when EMA shares documents containing personal data with international partners located outside of the EU/EEA, results in high workload which actually limits effective collaboration. Based on an EDPS Enforcement Order, all EU Institutions and bodies, including EMA, needed to complete a vast mapping exercise of all international data transfers at the Agency by 30 November 2020. An EDPS remote audit providing guidance and advice to the internal data controllers in respect of several EDPS proceedings was closed with the outcome that EMA is fully compliant; a further remote audit on newsletter subscriptions is still going on. Policy discussions regarding the interplay of data protection rules and scientific research included submission of comments to the EDPS' preliminary opinion on data protection and scientific research, preparation of draft Q&As on the secondary use of health data, and participation and consultation with DG SANTE regarding the European Health Data Space project. Staffing needs in this area remain a critical issue, as the Head of Legal Department has been serving as Acting Data Protection Officer (DPO) for over two years, and despite increasing workload and pressure, no AD posts have been allocated to the DPO.

The representative of DG SANTE acknowledged the resourcing issues and stressed the need for good collaboration in international fora. He suggested to keep DG SANTE's data protection coordinator informed on data breaches requiring notification to EDPS within 72 hours. It was suggested that further cooperation to deal with personal data could be taken at a European level, as NCAs also find it difficult to deal with workload and difficult interpretation issues. It was clarified that NCAs are subject to the respective national laws and regulations implementing in detail the "GDPR". Cooperation in the dialogue with industry to minimise personal data in their regulatory submissions could be one of the ways forward in reducing the workload.

B.6 Highlights of the Executive Director

European activities

Most of the Agency's European activities continue to be related to the COVID-19 pandemic and EMA has weekly calls with the European Commission and ECDC to discuss developments about vaccines and treatments and the status of shortages monitoring. EMA was invited to join an informal meeting of EU health ministers on 2 December and a meeting of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) on 10 December in order to give an update on the status of the COVID-19 vaccine authorisations. EMA's 2019 financial accounts are being reviewed by the European Parliament in the context of the annual discharge procedure and EMA will be invited to a hearing in the European Parliament on 7 January 2021.

Legal proposal to revise the EMA's mandate

The legal proposal to extend the EMA's mandate was published on 11 November 2020. EMA considers it as a positive acknowledgement of the Agency's work with the Network during the COVID-19 pandemic. The proposed new role for EMA in the medical devices area will require the Agency to bring in new expertise and scientific knowledge and to interact with a completely new set of stakeholders. EMA welcomed the additional resources for the new mandate and for COVID-19 workload proposed by the European Commission which were adopted in the EU Budget 2021 in December 2020. EMA has started to review the resource appropriations against the new tasks envisaged for EMA as set out in the legal proposal.

International activities

EMA continues to chair biweekly ICMRA meetings which recently focussed on regulatory agility, remote inspections due to COVID-19 related travel restrictions, and on pharmacovigilance. ICMRA and WHO have issued a joint statement describing their common objectives and collaboration. Work is continuing at ICH level on nitrosamines and how to revise relevant international guidelines, in particular M7, in light of the lessons learnt. EMA is working on data protection arrangements to keep exchanging scientific documents with international partners with whom it has confidentiality arrangements in compliance with EUDPR provisions. EMA is launching a pilot project to involve non-EU experts in the COVID-19 discussions at CHMP (OPEN project).

Senior managers leaving the EMA

The EMA Joint Committee, which is established under the EU Staff Regulations, has adopted on 4 November 2020 a general opinion on criteria and restrictions for senior staff applying for occupational activities after leaving the service. EMA is introducing increased transparency by publishing on its corporate website a specific register of the Joint Committee opinions/restrictions for senior staff leaving the Agency. The first Joint Committee decision to be published on this public register will be the one for the former EMA Executive Director, Prof. Guido Rasi. The assessment outcome for Prof. Rasi is that his declared activities are not in conflict with the legitimate interest of the service and are therefore authorised without restrictions.

Joint ECDC-EFSA-EMA report on consumption of antimicrobials and antimicrobial resistance in animals, food and humans (JIACRA)

In agreement with the European Commission, the publication of the third edition of this report, covering data for years 2016-2018, planned by end 2020, will be delayed until June 2021 due to the need to prioritise COVID-19 related workload.

EMA 25 years anniversary event

The EMA's anniversary event held on 22 October 2020 was attended by more than 500 participants, with a strong presence from national agencies, international partners and civil society stakeholders. Inputs collected during the audience discussion will be compiled and used by EMA in the next review of the European Medicines Agencies Network Strategy to 2025.

European Medicines Agencies Network Strategy to 2025 (EMANS)

Following inputs from the Management Board and HMA members, the Strategy was adopted by written procedure and published on 8 December 2020 together with the summary report on the public consultation. The EMA/HMA Coordination Team working together with EMA planning teams have translated appropriate actions from this Strategy into the EMA multi-annual work programme 2021-2023 for adoption at this Management Board meeting. A review of the strategy will be conducted every 18 months to ensure that goals and objectives are still applicable, and reports on progress will be presented regularly to the board.

1st Public stakeholder meeting on COVID-19

The stakeholder event was organised on 11 December to inform citizens on the EMA's role in fighting the pandemic and to listen to the concerns and needs of the public. The event was broadcasted live, with an audience of approximately 3,500 following remotely. Further public stakeholder meetings will be planned once the first vaccines are authorised and will be organised in collaboration with the European Commission and HMA.

Following the presentation a request was put forward for an update at the March meeting on recent experience with the additional safeguards (to be) put in place for securing the robustness and independence of the scientific review process for MAAs for COVID-19 treatments.

B.7 Report from the European Commission

Health Union: strengthening of EMA

The examination by EU institutions of the EC legal proposal on EMA will start in early 2021. The legal proposal aims to codify the activities put in place by EMA and the Network during the first phase of the COVID-19 pandemic and to establish strengthened processes, as well as IT and data infrastructures, to allow public authorities to monitor, prepare and respond to future health crises in the EU. The new proposed tasks on medical devices are also meant to be transferred from the Commission to EMA in order to build synergies and expertise in that area, in line with the increasing technological integration between medicines and medical devices. A final agreement on the next EU health programme (EU4health) was reached in mid-December 2020 and will fund EU activities to support crisis preparedness.

Pharmaceutical strategy for Europe

The Commission Communication was adopted on 25 November and it proposes several legislative and policy activities to achieve four main objectives: promoting accessibility and affordability, supporting innovation, enhancing resilience and ensuring a strong EU voice globally. The implementation of the actions announced in the strategy is well underway, for example with the revision of the orphan and paediatric regulations in 2021. The Commission aims to propose a revision of the basic pharmaceutical legislation by end 2022, which will require intense preparation with the Network in the coming months.

EMA fees

The external contractor performing the study supporting the EC impact assessment will consider the requests from HMA on knowledge management costs. The study report is expected for Q3 2021 and a legislative proposal for Q4 2021. A Management Board decision will have to be adopted by that time in order to clarify that the current fee system for veterinary procedures is maintained *ad interim* until the new EMA fees regulation enters into force.

Update on evaluation of the Blood, Tissue, Cells (BTC) legislation

The revision of the BTC legislation was agreed and included in the Commission's 2021 work programme published in October 2020. An inception impact assessment was published on 17 November 2020 to describe the objectives of the revision and the policy options under consideration. The overall objectives of the initiative are ensuring a high level of health protection for EU citizen, through a more flexible alignment to science and technological developments. A public consultation and targeted stakeholder consultations, including with EMA and NCAs, will be launched in early 2021. A dedicated workshop and external studies will be organised to support the preparation of an impact assessment and the final legal proposal, which are both planned by end 2021.

Following the presentation, a representative of patients' organisations asked about the involvement of patients in the monitoring of shortages and about the regulation of cord blood banks in the future BTC legislation. For the shortages, it is too early to anticipate what exactly will be in the new legislation, but all voices in the field, including patient representatives, will be heard during the preparatory phase. Concerning BTC, the Commission is observing trends in the global markets that will contribute to shape the proposal. The issue was raised on whether the Commission is considering further changes to the legal framework on medical devices. The representative of DG SANTE informed that there is no intention to change again the system and that notified bodies will retain their role. A member

welcomed the reinforced role of EMA and the ETF, and requested further information about the interactions between the ETF and CHMP and PRAC. The need for further clarification was acknowledged. The Executive Director stressed the opportunity to build on the strengths of all scientific bodies and noted work has already started to optimise their interactions in the context of the current evaluations. Representatives of veterinarians' organisations and other members asked why both the EMA legal proposal and the Pharmaceutical Strategy are focusing only on human medicines, noting that the current pandemic is a zoonosis and future health threats may also generate from animals. Provisions for cross-agency cooperation are included in all legal proposals for a Health Union, particularly in the one on cross-border health threats which foresees collaboration with EFSA regarding zoonoses. All comments and suggestions on the legal proposal for EMA are welcomed and the Commission is open to consider them in future debates with the Council and the European Parliament; EMA will also be invited to join the Commission in those discussions.

a) Commission legal proposal for extending the mandate of the European Medicines Agency

[EMA/MB/651887/2020] EMA informed that the EMA legal proposal is expected to enter into force 20 days after adoption by the co-legislators. EMA is therefore preparing for a rapid implementation, including by reflecting on how to increase the efficiency of the existing EMA activities at the same time, and will prepare proposals for further discussion at the next MB meeting.

B.8 Programming 2021-2024

a) Final programming document 2021-2023

b) Preliminary programming document 2022-2024

[EMA/MB/663790/2020; EMA/592220/2020; EMA/380399/2020; EMA/MB/664792/2020] The Management Board adopted the 2021-2023 Programming document, including the 2021 budget. The Programming document 2021-2024 is presented as a single document and is made up of the Programming 2021-2023, which includes the final 2021 work programme, budget and establishment plan, and the Draft programming 2022-2024. After adoption by the board, the Agency will include any comments received, update the final 2020 figures and divide the documents presented into two separate ones, which will be circulated to the board before being mailed to the European Commission and other institutions by 31 January 2021. The Topic Coordinators Grzegorz Cessak, Rui Santos Ivo, Nancy De Briyne and Lorraine Nolan examined the evolving documents on behalf of the board over three months and took part in the presentation.

2021 will be a year still largely shaped by the response to the COVID-19 pandemic, alongside the other priorities of the preparation for the veterinary legislation, implementation of the public health strategies EMANS and RSS to 2025, communication, international activities, digital innovation and preparation for the proposed extension of the EMA mandate. The 2021 budget will include increased revenues due to a higher number of scientific applications and a higher EU contribution in view of the potential mandate extension. Staffing will increase as well to cope with the workload peak related to COVID-19, while the IT budget will also grow to ensure delivery of legislative responsibilities. The pandemic outbreak continues to substantially reduce travel and meeting costs, while the EMA building costs in Amsterdam stabilise in line with forecast. On the income side, fee revenues are expected to increase by 7.7% to €330.4 million, with workload for NCAs and EMA increasing accordingly. The 2021 revenues also include EU/EEA contributions of €55.5 million of which €27.8 million related to the revised mandate. For 2022 a further increase in fee income by 6.4% is foreseen.

On the expenditure side staff-related costs increase from €115.4 million to €128 million, reflecting among other additional TA posts for COVID-19 (40) and for the extended mandate (21), and interim services for €6.7 million. Infrastructure and administrative costs are reduced from €85 million to €56 million now that the Brexit driven expenditure is largely finished. Payments to NCAs follow the increasing application trends.

Concerning the evolution of TA and CA posts for 2021, potentially challenging aspects might be a possible increase in turnover rate once the relocation is completed and changes in teleworking patterns take place, as well as increased loss of workforce due to various types of personal leave. For 2022 EMA will request 20 additional TAs and 2 additional CAs, mainly necessary to face the workload linked to the growing portfolio of products, while the remaining 25 short-term CA posts granted to cope with Brexit are being phased out.

Concerning the Work Programme, Topic Coordinator Grzegorz Cessak introduced the Single Programming Document 2021-2024's main features. Focus areas, strategic goals, objectives provide a framework for the annual actions, contributing to their achievement in the MAWP. The mandate extension is captured with a high-level description of the European Commission's proposal in terms of activities, funding and human resources. Once approved, a revised document will be submitted to the Management Board. The multi-annual EMA programming 2021-2024 has been developed by clustering activities around 3 main pillars: products related activities, strategies and public health activities, programmes and projects. Actions are grouped according to a 2-tier priority level in order to identify reduced priority actions in relation to the higher public health priority of the response to the COVID-19 pandemic: tier 1 covers actions that might be activated in the second half of 2021, tier 2 includes actions that might start after the activation of tier 1 actions in case sufficient resources are available.

EMA answered a number of questions. The representative of DG SANTE enquired after the vacancy policy and whether the Agency had faced difficulties in its recruitment during the pandemic. Information was also requested on the shift from AST to AD positions, and on whether EMA had started a reflection on how to hold meetings in a post-COVID world. Concerning cover for vacancies, this depends on the type of leave taken by staff. For unpaid leave of 6 or more months depending on the type of contract, posts thus vacated can and are being filled, while for maternity, parental and family leave substitutes can only be interims. Recruitment procedures have accelerated and on average now take under 3 months from publication of job offer to list of candidates (so called reserve list), but the actual taking up of the post overall takes longer taking into account administrative steps and notice periods that candidates have to give to their employers. Over the last few years a number of positions have been moved from AST to AD (headcount neutral effect), reflecting the changes in required competencies and job structure. A question was asked as to different rate in increase in fee revenue and remuneration to NCAs. This is due to different ways of budgeting of revenue (which is budgeted when funds are actually received) and expenditure (which is committed in the budget at the time of validation of applications); furthermore both income and expenditure reflect a different mix of fees weighting which changes between years and affects the proportion of payments between NCAs and EMA. The representative of veterinarians' associations considered that 2021 will be a crucial year for veterinary issues and EMA will need to be ready for the entering into force of the new legislation in January 2022 while also dealing with the issues of shortages, availability and AMR. The IT component will be the biggest project in the implementation of the veterinary legislation and will not be finished after 2022, as the IT systems developed will meet only minimal requirement and will need further work and enhancement. She reminded the board that success of the Union Product Database will also depend on the readiness by all NCAs to transfer their legacy data to EMA.

Taking stock of what was planned for IT for 2020 it can be considered that, despite the deviations that were made necessary by the COVID pandemic, key milestones for large legislative programmes were met. For 2021 similar objectives are set with the go-live of CTIS in December 2021 and the Union

Pharmacovigilance and Product data bases in January 2022. The implementation of IRIS for Scientific Advice has met with wide appreciation by R&D stakeholders. The current IT landscape is changing and will need to adapt to a new playing field, created by the EMANS strategy 2020-2025, legislative requirements, new mandates etc., demanding a greater coordination effort. Today's operating environment includes 116 applications of which 90% are bespoke, with more than 50% of systems approaching end of life, providing support to 892 users and 60,000 external users, with over 1400 workstations and 2 data centres to look after. This landscape needs to be cleaned up in order to help ramp-up the output. Budget Topic Coordinator Lorraine Nolan contributed with her analysis of the IT budget examining 5 years of IT budget evolution, and the 2020 planned vs actual investments. The COVID pandemic in particular meant additional operating costs, which together with additional investment in large legislative initiatives and EMA modernisation, brought about a budget increase of €13.8 million during 2020. For 2021 the budget is €52.0 million, excluding carryovers, therefore largely similar to the final budget for 2020. Within the 2021 project SPOR is again assigned a sizeable budget with €2 million for 2021. Looking at 2022 and beyond, uncertainties on the IT requirements of the new EMA mandate will require additional investments that are difficult to gauge at the present time. Other investments will be needed to maintain and enhance CTIS, data analytics and digital transformation. A stable budget and good planning will be critical to avoid large carryovers and swings in capacity. EMA intends to shift its focus from systems to business outcomes, and improve procurement and framework contracts in an effort to do more with the same.

B.9 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/594006/2020, rev.1; EMA/MB/594004/2020; EXT/613767/2020] The Management Board noted the Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation, and endorsed the mandate of the Monitoring Subgroup of the Clinical Trial Regulation Coordination Group.

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

The focus of the project is now on the preparations for Go Live in 2021. After the audit, a period of code quality stabilisation will follow, leading to the release of a Minimum Viable Product (MVP) in which EV, XEVMPD, OMS, RMS, IAM, OBI DWH have been integrated, as required. Once the MVP has been produced this will constitute the functionality for the go-live version and it will be subject to code freeze of about 6 months prior to the go-live, to enable stabilisation of the system in its production environment, and extensive testing until go-live. The readiness confirmation (RC) testing carried out on Release 14 (the version submitted to the audit) by MS and sponsor product owners, between 3 and 9 November, revealed that expectations for the quality of the system in RC14 were not met. The developer has committed to ensure the quality of CTIS and correct the RC14, testing and audit findings prior to the second audit visit. Analysis and delivery of go-live is put temporarily on hold and will be resumed after Release 15 has been submitted and tested.

The prioritisation of technical and functional items for go-live and post go-live versions was carried out as of July 2020 by the Prioritisation Group. The delivery of possible go-live scope will resume at the earliest in April 2021, after the second audit visit. The definition of the MVP must be done in parallel to the Release 15 implementation once uncertainties are resolved. The first audit field work took place from 18 November to 10 December 2020 with Product Owners from the European Commission and five Member States participating as observers. The audit plan includes two control frameworks and audit

interviews to assess user-friendliness and EUPD functionalities. The draft audit report on 1st audit field work, the Implementation Action Plan in response to that, and EMA's impact assessment on the go-live of the system will be available on 18 February 2021 and will be sent to the CTIS governance. The Management Board will hold an ad hoc meeting on 23 February, followed by a meeting of the CTR Coordination Group on 2 March 2021 and further discussion at the meeting of the Management Board on 11 March 2021. On 8 April the Draft of the Final Audit Report & review of the Agency's project plan will be mailed to the CTIS governance, followed by the Final Draft on 14 April 2021. Two days later the Management Board will hold a preparatory meeting before its final extraordinary meeting on 21 April 2021. A contract with the current developer of the system is in place until July 2021 and replacement of the current framework contract is estimated to be in place by the end of 2020. A very extensive and detailed training programme 2020-2022 is being developed with input by Master Trainers from the Member States.

b) Mandate of the Monitoring Subgroup of the Clinical Trial Regulation Coordination group

The EU CTR Coordination Group agreed to an extended and revised mandate for its Monitoring Subgroup to monitor the progress in establishing and executing a remediation plan, improving ongoing testing, implement audit findings and identifying and resolving the underlying root causes; to monitor closely the progress in fixing the remaining regression bugs for the second audit visit of CTIS; to monitor the implementation of the go-live and post go-live prioritisation list, focus on the list of audit blocking issues and findings of the auditors to be fixed at the latest by mid-March 2021, to revise the existing KPIs on quality.

B.10 Update on preparation for implementation of Veterinary Medicinal Products Regulation

The representative of DG SANTE provided an update on the implementation of the Veterinary Medicinal Products Regulation. Focus is now on the 1st and 2nd package (12 acts) which have to be adopted before or by 28 January 2022. Work on all these acts is on track. Concerning the feasibility study under Article 156 (active-substance-based review system or other potential alternatives for the environmental risk assessment of VMPs), the winning contractor is planning to contact some NCAs shortly and will then deliver its final study report by end of September 2021. The Commission maintains its ambition for timely implementation and relies on the commitment of EMA and of all Member States.

EMA reported on progress in 2020 about the Union Product Database (UPD) and the Union Pharmacovigilance Database (EVVet3), noting the VMP-Reg programme is on track to deliver on the minimum viable product; work on two advices to the European Commission is also proceeding on schedule. The Agency was able to source additional financial resources, increasing the budget for veterinary IT development from €3.7 million to €5.7 million, and delivering more functionalities. As regards outlook for 2021, the VMP-Reg programme will be expanded with two new projects, the collection on sales and use data of antimicrobials and the manufacturer and wholesale distributor database. The COVID-19 situation might however delay some procurements and reduce overall IT capacity. The Agency plans to deliver by summer 2021 the components of the UPD that will enable NCAs to submit legacy data, which are crucial for EMA to effectively operate the new signal detection and management system from early 2022. A considerable budget of €9.400.000 has been allocated to the various projects and should enable delivery of the programme by end of 2021. A Change management workstream was established. EMA called on all NCAs to make sure that all legacy data can be uploaded into the UPD by the second semester 2021 as without them the pharmacovigilance

system cannot become fully operational, and to join the Regulators Change Network of HMA (HMA TF CIVR). For pharmacovigilance activities during a transition period to EVVet3, NCAs can continue the submission of reports in DEG format for at least 6 months and have to prepare to be able to read VICH standard messages from go-live onwards. Member States were encouraged to acquire a backwards/forwards converter developed by an NCA in order to change/adapt to a DEG/VICH format.

Some Board members recognised challenges to upload all legacy data in UPD on time and welcomed the change management activities under preparation by EMA to assist NCAs in that regard.

B.11 Union Product Database (UPD) Access Policy under the Veterinary Medicinal Products Regulation (VMP-Reg)

[EMA/MB/631606/2020; EMA/633343/2020; EMA/632902/2020] The Management Board adopted the Union Product Database (UPD) Access Policy which had been drafted in collaboration with the UPD Project Group. The Board also noted the overview of comments received by the EMA during a public consultation held between mid-July and mid-September 2020. The UPD Access Policy will be published on the Agency website after publication of the UPD Commission Implementing Regulation in the Official Journal, expected for early January 2021.

B.12 Big Data Steering Group workplan update DARWIN EU implementation approach

[EMA/MB/617432/2020; EMA/636401/2020] The Management Board noted the progress report on the implementation of the work plan of the Big Data Steering Group (BDSG), which focussed on the key achievements in 2020 and planned activities for next year. For DARWIN EU, in 2021 EMA plans to focus on preparing the coordination centre; in 2021 EMA will also start collaborating with existing national data permit authorities and other relevant EU projects such as the European Health Data Evidence Network (EHDEN). By 2023 the Agency will deliver a first version of DARWIN EU, which will then evolve through to 2025 to be fully aligned with the European Health Data Space (EHDS) infrastructure thereby acting as an EHDS pathfinder initiative.

A member expressed satisfaction for the initial set up of the project, and asked whether the medical device use cases could also be supported by DARWIN EU. The BDSG co-chairs replied that this idea is not in the BDSG workplan, but it has been considered as very important by the Big Data Task Force in view of the increased integration between medicines and devices and can be further discussed in the future. The representative from DG SANTE confirmed that the additional resources given to EMA in the Health Union proposal including staffing and funding should cover the establishment and launch of DARWIN EU as a node in the EHDS. Concerning the financing of the project after the 3-year start-up phase, work is ongoing to create a link to the revision of the EMA Fee Regulation. The representative from DG SANTE encouraged all Member States to participate in DARWIN EU and reminded members that a legal proposal on the EHDS will be presented by the European Commission by end of 2021.

B.13 Renewal of the cooperation agreements between the NCAs and EMA

[EMA/MB/642653/2020; EMA/641097/2020] The Management Board noted that no objection had been received from any NCA within six months before the cooperation agreements governing the services provided by the NCAs to EMA elapsed on 31 December 2020, and that therefore a tacit renewal of the agreement for a subsequent 5-year period would take place. A copy of the renewed

cooperation agreement, incorporating all previous addenda will be sent to all contracting parties for ease of reference.

List of written procedures finalised during the period from 16 September 2020 to 26 November 2020

- Consultation no 18/2020 on the appointment of Ilko Getov as CHMP member as proposed by Bulgaria ended on 29 September 2020. The mandate of the nominee commenced on 24 October 2020.
- Consultation no 19/2020 on the appointment of Hrvoje Pavasovic as CVMP alternate as proposed by Croatia ended on 5 October 2020. The mandate of the nominee commenced on 6 October 2020.
- Consultation no 20/2020 on the appointment Santa Ansonska as CVMP alternate as proposed by Latvia ended on 28 October 2020. The mandate of the nominee will commence on 1 December 2020.
- Consultation no 21/2020 on the appointment of Daniela Philadelphy as CHMP alternate as proposed by Austria ended on 29 October 2020. The mandate of the nominee will commence on 1 January 2021.
- Consultation no 22/2020 on the appointment of Johanna Lähteenvuo as CHMP alternate as proposed by Finland ended on 11 November 2020. The mandate of the nominee commenced on 12 November 2020.
- Consultation procedure for the adoption of the Amending Budget 01/2020 ended 16 September 2020. The procedure was adopted.
- Consultation procedure for the adoption of the European Medicines Agencies Network Strategy to 2025 ended on 13 November 2020. The procedure was adopted.

Documents for information

- [EMA/MB/578488/2020; EMA/569531/2020] Report on EU Telematics
- [EMA/MB/640539/2020] Outcome of written procedures finalised during the period from 16 September 2020 to 26 November 2020
- [EMA/MB/585327/2020; EMA/MB/586754/2020] a)Summary report on implementation of assigned revenue b) Summary of transfers of appropriations in budget 2020
- [EMA/MB/628469/2020; EMA/623780/2019] Biennial Report on EMA's interaction with industry stakeholders (2018-2019)
- [EMA/MB/624477/2020; EMA/124131/2020] Stakeholder engagement biennial report: engaging with patients, consumers, healthcare professionals and academia (2018-2019)

List of participants at the 110th meeting of the Management Board, held virtually on 16-17 December 2020

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier de Cuyper *(member)*
Bulgaria	Bogdan Kirilov *(member)*
Czech Republic	Irena Storová (member)
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)* Mette Hansen *(alternate)* Nikolas Jørgensen *(observer)* Nikolai Brun *(co-presenter for B.12)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	Eleftherios Pallis *(member)*
Spain	César Hernández *(alternate)* Maria Alcaraz *(observer)*
France	Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Nicola Magrini *(member)* Pietro Erba *(observer)*
Cyprus	*Apology received*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Mátyás Szentiványi *(member)* [1] Beatrix Horvath *(alternate)*
Malta	Anthony Serracino-Inglott *(member)*
Netherlands	Hugo Hurts *(member)* Michiel Hendrix *(observer)*
Austria	Thomas Reichhart *(alternate)*
Poland	Grzegorz Cessak *(member)*
Portugal	*Apology received* Maria Joao Morais *(observer)*
Romania	Cristina Racoceanu *(alternate)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Momir Radulović *(member)* [1]
Finland	Eija Pelkonen *(member)*
Sweden	Asa Kumlin Howell *(alternate)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points 5; B.2; B.8; B.9.b and B.11.*

European Parliament	Matthias Groote Tonio Borg
European Commission	Andrzej Rys (DG SANTE) *Apology from Kerstin Jorna (DG GROW)* Kristof Bonnarens DG SANTE (*observer*)
Representatives of patients' organisations	Ioannis Natsis Marco Greco
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdottir Hvannberg (Iceland) 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 Peter Arlett Edit Weidlich Stefano Marino Michael Lenihan Maria Alves Hilde Boone Mario Benetti Monica Dias Riccardo Mezzasalma Marie-Agnes Heine Frances Nuttall Silvia Fabiani Rebecca Harding Sophia Albuquerque Apolline Lambert