15 June 2019
EMA/MB/335139/2019 Adopted
Management Board

Minutes of the 104th meeting of the Management Board

Held in Amsterdam on 12-13 June 2019

The chair opened the meeting by welcoming the new members and alternates to the board: Matthias Groote, representative of the European Parliament, and Gytis Andrulionis, member for Lithuania. She also thanked the outgoing civil society representatives for their work and support to the Management Board, in particular Yann Le Cam, who will not carry out a second mandate. Following their appointment by the Council on 6 June 2019, the three year mandate of the new members Marco Greco and Ionnis Natsis, representatives of patients' organisations, Nancy de Briyne, representative of veterinarians' organisations, and Wolf Dieter Ludwig, representative of doctors' organisations will begin on 15 June 2019. The chair informed the board that Grzegorz Cessak's mandate as vice-chair will run out on 5 October 2019. The election for a new vice-chair will take place at the beginning of the October meeting. The Secretariat will send Management Board members an invitation to submit nominations in the next month.

1. Draft agenda for 12-13 June 2019 meeting

[EMA/MB/157340/2019] The board adopted the agenda 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 interest relating to the day's agenda were identified concerning topic *B.11 Deliverables from the HMA/EMA Task Force on the Availability of Authorised Medicines; Draft Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA); Draft Best practices for public communication on medicines' availability issues*. 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 103rd meeting, held on 21 March 2019 adopted via written procedure

[EMA/MB/188256/2019] The Management Board noted the final minutes, adopted by written procedure on 16 May 2019 and agreed to the publication with the proposed redactions of section *6. Update on judgment of 30 Churchill Place* in order not to affect the ongoing negotiations on the sub-lease of the premises in London.

4. EMA Preparedness on Brexit

4.1 Update on EMA Brexit preparedness

4.1.1 Progress report on operational aspects

In anticipation of the UK becoming a third country the Deputy Executive Director informed the board that EMA has continued to monitor and track submissions of Brexit-related changes by companies for centralised products (CAPs) in order to ensure undisrupted supply of medicines in the EU 27/EEA. The vast majority of companies have now taken the necessary steps concerning marketing authorisation transfers, as just three marketing authorisations still need to be transferred. Good progress had also been made for products with Qualified Persons for Pharmacovigilance (QPPVs) and pharmacovigilance system master files (PSMFs) based in the UK. EMA has tracked and monitored all Brexit-affected medicines considered "at risk of supply" and subjected them to a criticality assessment. The Agency continues to follow up on the regulatory compliance status for human and veterinary medicines included in the two batches of criticality assessments conducted in collaboration with CHMP/CVMP and the NCAs in October 2018 and January 2019. Until 4 June 2019 EMA has received a total of 70 requests for exemption for batch testing of medicines in the UK. Of these only three are still pending. Although the deadline for submission of requests for exemption has been extended to 31 October 2019, the submission of new requests has decreased considerably. As a result of the outcome of the two rounds of criticality assessment as well as the requests for exemption for batch testing the current status can be summarised as 6 CAPs considered at risk of supply and 4 CAPs considered critical. EMA continues to monitor and track submissions of Brexit-related changes for Brexit affected CAPs, and continues to work with MAHs to address any outstanding issue before the withdrawal date. At the meeting in March, the board had agreed to a proposal to set up an EU Executive Brexit Task Force on Availability of Medicines to coordinate the approach in case of a disorderly withdrawal of the UK from the EU. The Task Force has been set up on the model of the existing EU Executive Task Force operational in the frame of the EU regulatory network incident management plan for medicines for human use and is composed of European Commission, Member States and EMA representatives representing both the human and the veterinary medicines field. The Task Force will provide the strategic direction in case of a crisis situation and will report to the Pharmaceutical Committee, the EMA Management Board and the HMA. Given uncertainty on the exact date for the UK's withdrawal from the EU until 31 October 2019 and the possible consequences for the network, EMA has requested advice from the European Commission in relation to the involvement of the UK in EMA procedures in terms of either continuing with the approach applied so far, or by fully implementing the redistribution of the UK product portfolio. In the exchange of correspondence tabled to the board in its letter of 7 June, the Commission supported the full implementation of the redistribution of the UK product portfolio taking into account the existing uncertainty with respect to the exact date of the UK withdrawal, and the need to ensure business continuity and limit any potential disruption immediately after the UK's withdrawal. The practical consequences will be that no new pre- or post-authorisation procedures will continue to be allocated to UK (Co)-Rapporteurs and the redistribution of the UK product portfolio to the new (Co)-Rapporteurs should now be fully implemented, making the new (Co)-Rapporteurs fully accountable and responsible for the products allocated to them. The distribution of

the annual fees revenue to the National Competent Authorities (NCAs) should accordingly be transferred as of 1 July to the new (Co)-Rapporteurs.

The board accepted the approach in the proposal to distribute the annual fee revenue to the new (Co)-Rapporteurs as of 1 July 2019, if feasible from a practical viewpoint. Consequently, the Decision of the Executive Director on the financial impact of the re-distribution of UK (Co)rapporteurships for post-authorisation procedures of centrally authorised medicinal products in view of the United Kingdom's withdrawal from the Union, endorsed by the board on 19 September 2018, will be amended accordingly.

4.1.2 Status update on EMA staff retention and priorities for reintroducing EMA activities for 2nd half of 2019

The Deputy Executive Director provided the board with information on staff retention from two data sets: a comparison between end of September 2018, end of November 2018 and March 2019 based on information entered by staff on the Agency's database complemented by the feedback of their line mangers, as well as on the actual available workforce in June 2019 and anticipated available workforce in August 2019. Current staffing levels continue to permit the Agency to perform activities according to phase 4 of the Business Continuity Plan (BCP). However, in view of the still considerable number of staff who have not yet decided if they will relocate, and the uncertain impact of the end of the temporary staff retention measures (in particular the consecutive teleworking scheme as of September 2019), there is further need to confirm the actual available workforce in Q3/Q4 2019. Therefore only selected activities can be considered to be reintroduced as of July 2019 in addition to the current activities performed under the Agency's Brexit BCP phase 4, meaning that EMA will remain in a reduced activity mode. EMA will aim, when prioritising and reinstating activities, to achieve longer-term sustainability, with fit-for-purpose processes and increased efficiency in operations. Reinstatement of activities will not necessarily follow the order in which they were temporarily suspended/reduced, and will be gradual, to allow knowledge acquisition by new staff. It will be handled according to three areas of priority, in the order specified and staffing levels permitting: activities aimed at ensuring that the organisation of the Agency is fit-for-purpose longer term and projects aimed at increasing efficiency; activities directly contributing to the core EMA activities, particularly EMA's coordinating role; Regulatory Science Strategy and the EU Medicines Agencies Network Strategy to 2025, preparation for new legislation, activities stemming from the European Commission or HMA action plans and increased ICMRA involvement. All other currently temporarily suspended/reduced activities will not be reinstated in Q3/Q4. A reflection on future-proofing the Working Parties system will be needed before reinstating them, starting from the requirements in the evolution in science and technology , evolution of classical guidelines to more agile and specific guidance, public engagement in evolving regulatory science areas with evermore increased transparency. More information will be provided to the board at the meeting in October 2019 on actual workforce at the end of Q3, impact on EMA output for 2019 and anticipated impact on the 2020 EMA Work Programme to be adopted at the December meeting.

Answering a question on whether the Agency will fill empty posts with new recruits, the Executive Director explained that EMA at the moment has strong reserve lists of mostly staff with a generic profile. There is capacity to conduct specific selections where needed, as the Agency has managed to bring down time for a selection to as little as 3 months. It should however be considered that it is impossible to foresee where vacancies will appear and how they will be concentrated, and that it takes time to induct and train new staff. The representative of DG SANTE asked whether EMA had ascertained whether short term staff could be hired under Dutch law. The Agency is working to achieve this, but it appears that contracts may have to have a very short duration compared to the conditions in the previous seat of the Agency. A better way to handle lower skill highly repetitive jobs

may be to pursue automatisation. EMA will further update the board, after more precise figures on staff loss will have become available at the end of August.

A request was made by a member for more information that may help the prioritisation exercise on Working Parties. EMA will have more detailed figures to present to the board in October on the activities of the whole range of EMA Working Parties and expert groups. Lorraine Nolan, Karl Broich and Zuzana Baťová were nominated as Topic Coordinators to participate in a review of the Working Parties of EMA.

4.2 Update on EMA-NL Authorities collaboration for relocation to Amsterdam

4.2.1 Relocation to the final EMA premises

The Deputy Executive Director informed the board that since March further intense discussions have taken place between EMA and the Dutch authorities to agree on definitions and on timelines for the delivery of the final building, based on the principle that continuity of EMA operations have to be safeguarded and there cannot be any interruption in the Agency's work. The outcome of these further discussions has an impact on the time-plan presented to the board in March. It is foreseen now that there will be a meeting-free period from 13 December to 11 January 2020 as technical material needs to be moved from the SPARK building to the final building. The Management Board meeting, scheduled to be held during this period, will be held off-site. During a pilot phase in January, certain meeting rooms will be piloted at the new premises, while the SPARK will host one meeting in January 2020 and will continue to be operational as a fall-back option, albeit reduced. In the next weeks the scenario document will be revised according to the main agreed principles, and the draft lease agreement will be adjusted accordingly, if needed. The board will be informed at its next meeting unless there is a need for earlier interaction.

5. Update on 30 Churchill Place

The Executive Director reminded the board of the discussion that had taken place at the March meeting and the potential scenarios regarding the former EMA's premises in London, together with their merits and costs. Initially, it had been foreseen that all relocation costs would fall back on the UK government, but this approach appeared to have changed. Moreover, the judgment concluding in first instance the court case brought against EMA in London stated that Brexit is not a cause for frustration, although the court could not refuse the fact that Brexit was an unforeseeable event when the commitment to rent 30 Churchill Place was taken in 2011, and thus allowed the Agency to appeal. At the time of the March meeting, the Council Budget Committee as part of the budgetary authority was still deliberating on the sub-let dossier. [redacted] Finally, it is doubtful that EMA's founding and financial regulations allow for EMA to engage in such a commercial activity, as well as to operate in a 3rd country. The Head of the Legal Department informed the board on the judicial aspects. The date for the appeal hearing has been set for 26 January 2020. The focus is now on a possible settlement agreement with the landlord, so that the sub-lease can start, hopefully in the next few weeks. The Head of the Administration and Corporate

Management Division provided an update on the financial side. [redacted] The expenses to be borne by the Agency will be paid from 2019 provisional appropriations, the 2018 positive outturn, and next year's EU contribution. Shortfall will need to be covered likely from EMA fees to be received in 2020.

Tonio Borg, representative of the European Parliament, summed up that given the ruling establishing that EMA has to pay for 20 years of rent, the scenario of sub-letting appears advantageous. The question of who should ultimately foot the bill remains however unanswered, as EMA has no fault for the situation. He wondered whether the issue had been raised at the level of the chief EU negotiator with the UK, who could have requested the money as part of the divorce bill. [redacted] The Executive Director confirmed that the issue had indeed been flagged to the negotiator, but was probably seen as a small aspect in a wide overarching negotiation. The Executive Director felt that it was his duty to suggest to the board that at the end of the negotiations with the UK the EU budget should take over responsibility for these disbursements, as EMA has always acted according to precise instructions that it could not remain in London after 29 March. At some point in time the costs for the building should be carried by the EU budget, as they would otherwise be supported from fees paid by industry. Matthias Groote, representative of the European Parliament, agreed that the issue should be raised at a political level and suggested to address the European Parliament and the new European Commission. A member was worried about the financial risks in the foreseeable future that may affect EMA, given that the inducements are going to be financed from EMA's budget in 2020. EMA replied that it has requested €54.5 million EU contribution for 2020, needed for public health responsibilities and for this project, but that at the moment the European Commission has agreed to only €48 million. The Agency still needs to understand precisely its running costs in its new location in Amsterdam, before it can exactly quantify the impact of this project on the EMA's 2020 budget and the need for an additional EU contribution.

A. Points for automatic adoption / endorsement

A.1 Management Board meeting dates 2020-2021

[EMA/MB/198583/2019] The Management Board adopted the meeting dates for 2020:

- Thursday 19 March
- Wednesday 10 June and Thursday 11 June
- Thursday 1 October
- Wednesday 16 December and Thursday 17 December

and noted the meeting dates for 2021:

- Thursday 18 March
- Wednesday 16 June and Thursday 17 June
- Thursday 7 October

– Wednesday 15 December and Thursday 16 December

A.2 Internal rules on possible restrictions of data subjects' rights in administrative inquiries, investigations and disciplinary proceedings

[EMA/MB/293415/2019; EMA/183213/2019] The Management Board adopted the *Decision on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of administrative inquiries and disciplinary proceedings carried out by the EMA*. The rules were drawn up in accordance with guidance from the European Data Protection Supervisor and will be published on the Official Journal of the European Union. The EMA Staff Committee and the EDPS were consulted.

B. Points for discussion

B.1 Highlights of the Executive Director

EU Activities

On 26 March 2019 the plenary European Parliament voted positively on the discharge for EMA's 2017 accounts. The report acknowledges the Agency's BCP and the work done by EMA's ORP task force in preparation of its relocation to Amsterdam. It also expresses strong concerns about the remaining financial liability for EMA's premises in London and urges the EMA and the European Commission to do their utmost to minimise the financial and operational impact of the unfavourable lease agreement. Following the European elections, together with the 4 other ENVI agencies (ECDC, EFSA, ECHA, EEA), EMA is preparing a common introduction to the new MEPs later in the year to explain the vital work that the agencies are doing for the benefit of all EU citizens. In a meeting with Jean-Eric Paquet, Director-General of DG Research, EMA had an opportunity to explore opportunities for funding under the guidance of DG SANTE.

International Activities

Under a considerable reduction under the BCP of international activities, the first EMA-EDQM confidentiality arrangement has been agreed. A lessons learned exercise on the handling of the sartans crisis has been initiated at EU level and will include a review of international collaboration. On the occasion of the meeting of ICMRA in San Diego on 23-27 June the new Chair and vice-Chairs will be elected. Two staff members were sent by EMA to the DIA in China (20-24 May 2019) to cover the nitrosamines impurities in sartans, GMP, regulatory science, patient engagement, and clinical trial methodology for biologicals and precision medicine. In coordination with the European Union delegation in Beijing, EMA also participated in a meeting with Health Councillors from various EU and non-EU countries. On the recent occasion of the visit to EMA of an Indian delegation with the European Commission, at the margins of an ICH meeting held in Amsterdam, notable progress in dialogue was confirmed.

European Ombudsman public consultation on pre-submission

The public consultation followed an enquiry opened in July 2017; it was launched in October 2018 and closed at the end of January 2019. The Ombudsman team has informed the Agency that 38 responses were received from a wide range of stakeholders, including NCAs and HMA, NGOs, patients' and healthcare professionals' organisations, HTA and payer organisations, and from industry. EMA has reviewed these responses, which contain interesting and helpful insights into stakeholders' views on pre-submission activities, and met with a delegation from the Ombudsman on 15th May. The

opportunity was provided to further clarify current safeguards in the system, recent efforts to improve transparency and how scientific advice is generated. The European Ombudsman emphasised that there is no question of the EMA acting in bad faith or manipulating data, and acknowledged that the system in place is robust. The view is that the perception of bias arises where experts involved in providing advice later assess the data generated based on that advice, and this may undermine trust in the system. The Ombudsman will publish the contributions received, as well as its recommendations before the summer. The Agency will keep the board informed of the outcome.

Information on Scientific Advice received in EPARs

In June 2018 the Agency had started to provide in the CHMP assessment report for initial marketing authorisation applications for PRIME products, detailed information about the support offered during the development, including information on the topics for which scientific advice was obtained. This initiative was extended to all products in January 2019 and the respective EPARs, including information on scientific advice, are now becoming publicly available. This initiative is also relevant in the context of the European Ombudsman' enquiry into EMA pre-submission activities and its particular focus on scientific advice.

Breach of Trust procedure for competing interests and disclosure of confidential information

In 2018, 3 breach-of-trust procedures were initiated. The Agency updated the Breach of Trust procedure in October 2018 to include disclosure of confidential information. In 2019, so far already 3 breach-of-trust procedures have been initiated. Committee members were reminded to refrain from consultancy to, strategic advisory role for and financial interests in a pharmaceutical company at any point in time during their committee membership, as well as from disclosing confidential information.

B.2 Report from the European Commission

Review of the EMA fee system

DG SANTE is currently finalising the Staff Working Document (SWD) on the evaluation, and the Inception Impact Assessment (IIA) on future policy proposal. Both will be published together with RAND's evaluation study once it is finalised in Q3. EMA and the NCAs will be invited to contribute to the IIA.

Evaluation of orphans and paediatrics

The evaluation of the orphan and paediatric legislation is progressing through a number of consultations. Next steps include a conference with stakeholders and Member States on 17 June in Brussels, to provide additional input to be included in the SWD, due in October 2019.

EU strategy on pharmaceuticals in the environment

With the Commission Communication adopted in March 2019, the Strategic Approach to Pharmaceuticals in the Environment set out 6 areas of action with 33 medium and long term measures. In May a first public Workshop on the EU strategy took place. The role of Commission, EMA, other EU Agencies and Member States will be important for its implementation, and prioritisation should be given to actions for a sustainable pharmaceuticals policy. It was noted that this EU strategy is also linked to the antimicrobial resistance Action Plan.

Falsified Medicines

Lessons from the first four months since the implementation of the safety features show that the system overall is working and a first case of falsification of a medicinal product was identified. Compliance by industry is good, although smaller companies are still experiencing some difficulties. Addressing false-positive alerts is critical for the stabilisation of the system. The importance of ensuring that information in EudraGMDP is correct and complete was highlighted.

International Good Manufacturing Practices

The EU-US MRA for human medicines is progressing and Luxembourg and the Netherlands were recognised by the FDA on 10 June. Two further members States need to be recognised by 15 July 2019. For veterinary medicines JAP audits are taking place for EU authorities, while the US Centre for Veterinary Medicines (CVM) was audited on 10-14 June. The goal is the recognition of half of the EU vet authorities and of the US CVM by mid-2020. Concerning APIs, there has been good progress with India, and Korea was added to the list of third countries on 14 May.

Following concerns expressed by some members on delays in the review of the fee system, the representative of DG SANCO stressed the importance of close cooperation with the Member States and the EMA in the current phase, which may minimise consulting time later on in the legislative process. Other members asked if there might be the possibility to prolong the stabilisation phase in the implementation of the safety features. DG SANCO was optimistic that the percentage of false-positive alerts seems to be decreasing and that a target can be set for September. The representative of veterinarians' organisations requested an update on the AMR Action Plan at the next meeting of the board.

B.3 Assessment of the Executive Director's Annual Activity Report (AAR) 2018

[EMA/MB/276306/2019; EMA/112688/2019; EMA/240861/2019] The Management Board noted the Annual Activity Report (AAR) and adopted the Assessment of the Executive Director's AAR 2018 which had been prepared by the Topic Coordinators María Jesús Lamas Diaz, Nancy de Briyne and Audun Hågå. The Executive Director introduced the report, which shows that the Agency has been able to correctly identify and defend core business activities, but that 2018 has been a challenging year with some activities that had to be stopped or reduced. He called the attention of the board to activities that had been impacted or were not carried out as a consequence of the BCP, and whose impact might not be immediately visible, but might emerge at a later time. Among these were the postponement of relevant IT systems upgrades, the stop or delay of the development of ca. 92 guidelines, the delay in the processing of certificates and parallel distribution annual updates leading to a backlog, postponement of crucial workshops and training, delays affecting the implementation of the EU DPR, and reduced level of engagement with key stakeholder groups.

EMA presented the structure of the report, calling the attention of the board on the Emphasis of Matter, which the Executive Director issued for the second year in a row to highlight the consequences of imposed reduction of 10% of the Agency's establishment plan since 2014, during the same period that fee-related workload (as reflected by increased fee income from like-to-like tasks) has grown significantly. This, combined with the permanent loss of short term contract staff following the relocation to the Netherlands, could result in risks to delivering on future public health and legislative responsibilities, especially once the Agency attempts to re-introduce the activities currently reduced or suspended to cope with the Brexit situation.

The topic coordinators agreed that 2018 had been another challenging year for the Agency and welcomed the results nevertheless achieved and presented in the annual report 2018. They were pleased with the work done in collaboration with the European regulatory network to prepare for the consequences of Brexit and ensure timely transfer of procedures and tasks to other EEA states, thus allowing for continued availability of medicines across the EU. Among the achievements highlighted to the board, were the high interest for PRIME and the first medicines approved which were supported through the scheme; the opinions for 84 new human medicines including 42 new active substances; the launch of the IRIS application to significantly reduce submission times for orphan medicines applications; the collaboration on AMR and particularly between EMA, FDA and PMDA to align data requirements for new antibiotics; the work of the HMA-EMA Taskforce to tackle disruptions in supply of human and veterinary medicines; the ePI project increasing accessibility to information on efficacy, side-effects and proper use of medicines. They commended the coordination of network actions via the Incident Review network after the EU authorities were informed of an impurity in blood pressure medicines, and appreciated the work of the EU Network Training Centre, which continues its important task of broadening regulatory knowledge in Europe. The Topic Coordinators were happy at the smooth move of IT infrastructure of the Agency following the relocation to Amsterdam, and noted that several Telematics projects had to be postponed or reduced. They commented that others were over time or over budget, in particular the delivery of the clinical trials programme, and suggested to keep close attention to the feasibility, delivery and budgeting of future Telematics programmes.

B.4 Preparation for the written procedure on the Amending Budget 2019

[EMA/MB/281638/2019] The board noted that action may be required before the next meeting of the Management Board in October to amend the budget by written procedure. The primary topics having a budget impact have been identified as likely to result in an amending budget in 2019 are: potential sub-letting of the Agency's former headquarters in London; the regular mid-year review of fee revenue stemming from scientific procedures and applications. Other budget related points of note include: early IT investment in the Agency' future headquarters at Amsterdam Zuidas in order to coincide with the building's construction schedule and uncertainties regarding staff changes following the Agency's relocation to Amsterdam.

B.5 Rules for reimbursement of expenses for delegates attending meetings

[EMA/MB/252390/2019; EMA/MB/279597/2018, rev.2] The Management Board adopted a revision of the rules for reimbursement of expenses for delegates attending meetings which increased the hotel ceiling rate to increase access to hotels in central Amsterdam. EMA responded to a letter by the chairs of the scientific committees which had been sent to the Executive Director and circulated to the board to request a number of improvements in the rules. After careful consideration of the completely different environment in terms of hotel and travel, and of different practices from the previous location, the Agency had recognised that there is an increasing pressure on the hotel infrastructure in Amsterdam, with an estimated increase of almost 12% in number of tourists in 2017 compared to 2016. Moreover, the hotel ceiling provided by the European Commission in September 2016 concern the Netherlands in general and not Amsterdam, which has experienced significant hotel room price inflation, an increase of its city tax on hotels and now ranks as the third most expensive city in Europe. The Agency will carry out a constant monitoring of the situation over the next year and will manage the service level agreement of the new travel agent. Other measures put in place following the considerations proposed by the chairs will be early sending of invitations to meetings in order to secure

better deals, looking into reducing the timing for changing flight arrangements from 4 hours to 2 hours in the event of meeting time fluctuations, and possibly organising a survey to understand preferences concerning breakfast arrangements of delegates. Greater flexibility of hotel and travel selection will be granted once the online booking tool is made available in Q3.

The representatives of the European Commission expressed a reservation to the increase of the ceiling which would put the conditions for reimbursement by EMA out of line with the other institutions, stating that conditions cannot be considered as exceptional and that it would be expected that EMA could leverage purchase power. It was pointed out in response that the situation is specific to how the Agency is set up to operate. Its operating model requires that seven committees and a large number of working parties and scientific advisory groups meet regularly during the year to perform their scientific duties. This places significant demands on delegates and experts attending meetings for many days a month and work long hours and is different from traveling on occasional missions. Options such as adding additional nights to reduce the price of hotels cannot be considered, as delegates need to travel home after extended absence to perform their work at the NCAs. Concerning power to negotiate, the Agency experienced that expectations on the EMA move to Amsterdam have actually been driving prices further up. The European Commission abstained concerning the decision to adopt the revised rules.

B.6 Revision of the Financial Regulation of the European Medicines Agency

a) Revision of the Financial Regulation

b) Revision of budget structure and nomenclature from 1st July 2019

[EMA/MB/911309/2019; EMA/MB/911312/2019; EMA/MB/186752/2019] The Management Board adopted the revision of the Financial Regulation of EMA following the adoption in 2018 by the European Parliament and the Council of a new revision of the Financial Regulation applicable to the general budget of the Union. In parallel, the budget commentary and structure will undergo some minor revision, which the board noted. The Agency has additionally requested the European Commission DG Budget to introduce some limited flexibility with regards to fee-financed posts. Should a positive reply be received, the board would be asked for the adoption of a revision of the Financial Regulation by written procedure. The board, with the abstention of the representatives of the Commission, supported the request, which would allow EMA to handle the establishment plan for fee related activities to reflect increase or decrease in workload, and asked the chair to consider writing a letter to convey this.

B.7 Annual report of internal audit and advisory activities at the European Medicines Agency 2018

[EMA/MB/258484/2019; EMA/MB/790888/2018] The board noted the Annual report of internal audit and advisory activities 2018 which the head of Audit is required to provide to the Management Board as set out in the Financial Regulation, and the 2018 confirmation of independence of the Internal Audit Capability of EMA (AF-Audit) to the Management Board of the Agency. The 2018 report provided information on 11 audit and consultancy engagements planned for 2018. Out of these, 3 audits were performed by external auditors; 2 audits were conducted respectively by IAS and ECA, while AF-AUD completed 3 internal audits and 1 internal consultancy. 2 external audits had to be postponed and

cancelled due to deferred fieldwork and due to the relocation of the Agency to the Netherlands. The status of the implementation of improvement action plans shows that in 2018 a total of 12 major recommendations were closed whilst 8 remained under implementation in line with their planning. Based on the results of past and ongoing audits, follow-ups, consultancy activities and analysis, the Head of Audit confirmed that the internal control systems put in place by the Agency provide reasonable assurance regarding the achievement of the business objectives in line with BCP arrangements. The Head of Audit further informed that an invitation had been extended to the IAS and ECA representatives to a meeting of the Management Board. It is expected that the Director General of IAS and the Director of ECA would be able to attend the October meeting.

A member referred to a finding concerning disclosure of confidential information to unintended recipients, attributed in the analysis to weaknesses in the design of controls of historic IT tools requiring a high level of manual intervention. The Head of Audit confirmed that the Agency is trying to resolve the problem with modernisation of its systems and the development of more sophisticated IT tools, such as IRIS, but in the meantime risks should be mitigated through reinforcing training on existing tools within and outside the Agency.

B.8 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

a) Interim report on CTIS development

[EMA/MB/245561/2019; EMA/245562/2019] The board noted and discussed the update on the Clinical Trials Information System (CTIS) Project for the implementation of the Clinical Trials Regulation. It provided an interim report after a 6 month monitoring period started, following the signature on 28 February of a restructured contract with the IT4U consortium. A decision on the continuation of the project will be taken by the board at the October meeting following recommendations by the EU CTR Coordination Group on the outcome of the monitoring. The progress status update shows timely delivery of code merger of the branch codes of Releases 0.7 (EUPD) and 0.9 (safety features). Safety reporting features have been developed as planned and presented to the Expert Group. Bug fixing of bugs identified pre-UAT7 is ongoing, while the New Delivery Model allowing agile ways of working with a key role to users of the system is being set up. 7 Member States and 6 Sponsor Product Owners (PO) are actively engaged, but 3 further POs from Member States are needed. The first development sprint started on 11 June 2019. A 'sandbox', allowing exploration of all functionality developed so far, was relaunched on 8 April and is currently used by the POs. EMA is working on the recruitment of additional external PMO support to complete the implementation of recommendations stemming from the Independent External Review for project assurance. The New Delivery Model will replace the previous methodology and the need for extensive UATs after a long development period. Each sprint is designed and its scope agreed with developer and user POs. Each sprint is subject to testing and validation by the POs. Releases will take place after four sprints and will be available for user testing in the sandbox environment. The current CTIS product vision foresees that the audit to assess full functionality, as agreed by the EU CTR Coordination Group and noted by the board at its meeting of 4 October 2018, could take place after two releases, as a minimum, however current indications are that this will take more than that. Enhanced features to deliver improved cooperation and interoperability would follow after audit and after go-live. Metrics for the reporting on progress of the project were presented, which were developed by EMA with IT4U and the monitoring subgroup of the EU CTR Coordination Group on the bases of eight criteria in the areas of predictability and quality. Key Performance Indicators have been agreed for each, together with measurement goals and calculation methods. The decision by the Management Board in October on whether to continue with the project will be facilitated through agreed success criteria and thresholds.

Members of the EU CTR Coordination Group confirmed their perception that the measures taken are driving the project in a positive direction. It was highlighted that the quality of the product is very dependent on support by POs and that there is the opportunity for Member States to participate in the process by providing further 3-4 POs. The representative of DG SANTE acknowledged a turnaround in the process, and reminded the board that preparation for implementation must now start addressing the whole system, addressing communication and connectivity with other stakeholders.

B.9 2nd EC report on the performance of pharmacovigilance tasks by the EU Member States and the EMA (2015-2018) – preparation for a written procedure

[EMA/MB/286639/2019] The board noted the intention to submit the 2nd EC report on the performance of pharmacovigilance tasks to the board for endorsement by written procedure on 14 June 2019. EMA compiled data and drafted content contributing to the Commission report to the European Parliament and the Council. All Member States supplied data and contributed. After the final contribution has been approved by PRAC and the EU-POG, it can now be submitted to HMA and the Management Board for a consultation and endorsement in parallel, before submission to the Commission.

B.10 Implementation of the new veterinary medicines legislation

The representative of DG SANTE provided an update on the implementation of the new veterinary medicines legislation. Five new mandates addressed to EMA are in preparation and were discussed at the Standing Committee and the Expert Group of 4 June 2019. Member States were invited to provide feedback, which may be incorporated as appropriate in the mandates before they will be sent to EMA. A second round of mandates will be sent out to EMA soon, while deliverables from the expert working groups under the first round of mandates are expected by end of August.

Concerning resources needed the European Commission remains in close contact with EMA. DG SANTE has engaged with DG BUDGET on the budgetary procedure for 2020 but with no results, as it is maintained that EMA needs to re-deploy resources internally, and that the Management Board should prioritise the development of the Union Product Database (UPD) within the EMA project portfolio. The UPD governance needs to take into account that time and resources are going to be a major constraint and there will be a need for scope management and stakeholder buy-in. The project should therefore be kept simple and in line with the existing governance. During Phases 1 and 2 a small expert working group of 6 Member States is working on the mandate. Deliverables will be reported to TEAB and the EU NDB who will inform the EUTMB. The governance will be expanded in Phase 3 to involve more Member States.

EMA informed the board on the impact of the preparation for implementation on budget/resources and prioritisation in the Agency Work Programme. The Agency is working to provide the scientific advice/recommendations regarding certain implementing and delegated acts (IA/DA) which need to be provided, as per the Commission mandates sent to EMA, in a relatively short timeframe. Expert groups with selected Member State representation have been established. Work is progressing well and most recommendations will be discussed at the CVMP meeting before the end of the drafting period and endorsed in the next month, so that submission to the Commission can take place. More packages of mandates will follow over the next 3 years, with the highest workload expected 2019 and 2020. Several projects with IT elements will need to be scoped and prioritised over the next 3 years and will require an adequate governance structure with Member State representation for all topics in order to facilitate a successful implementation. Other work streams for the implementation concern structured change management to ensure business/network readiness for process and IT changes in

2020-2022, and review of business processes impacted by legislative change from the NVR or associated delegated/implementing acts at the latest in 2021. An overview of the timeline of all work streams and projects in the EMA internal programme shows intense activity until 2025. Concerning resourcing for the mandates for the IA/DA work, until now all work has been done without additional human resources being made available, which required suspending other activities to prioritise the NVR as much as possible. It is estimated that the preparation of the recommendations will absorb an estimated average staff cost of ca €81000 per workstream, therefore a total for 2019-2025 of about €1,700,000 without taking account of meeting costs, plus ca. additional €300,000 for lead staff on standby for Commission questions (not including mission costs). Depending on the requirements laid out in the implementing acts, the cost of implementation of IT systems for the NVR has the potential to be of the same order of magnitude as the cost of developing Clinical Trials Information System. FTE involvement will decrease from 8 in 2019 during the following years, but an update will be needed from 2020/2021 once the operation efforts of the NVR will need to be assessed. High risk for success of implementation are a high dependency on availability of experts from Member States to facilitate success through the expert groups, project governance etc., prohibitive lack of internal resources in the Veterinary Medicines (V) and Information Management (I) Divisions also due to loss of experienced staff, and lack of budget for delivery of IT systems which much business requirements. The board was asked to take note of the issues and provide advice, given that the resource issue is becoming unsustainable as further mandates to be received in June/July will likely cause core business tasks to suffer, no additional funding to support the preparation for the implementation has been granted through the budgetary procedure, and that adequate provisions for the 2020/2021 budgets as well as the allocation of suitable resources to deliver on the NVR have to be made.

The board discussed the topic extensively. A member reminded the board of the importance of the NVR also for human public health concerning the safety of residues in food. The NVR has made a number of regulatory procedures, including safety related, entirely reliant on IT tools that need to be developed by 2022 and for the development of which no additional resources for EMA have been made available in the Agency's proposed budget. The Executive Director elaborated on the Agency's position. He acknowledged that lessons learned from the CTIS project can be helpful, although a full analysis has not taken place yet. What is known is that from the increasing time dedicated to its discussion at every board meeting since 2014 it is clear that 'mission creep' should be avoided. The impact assessment that accompanied the legislative proposal for the NVR in 2014 would today lead to very different results. It took experience to develop a fit-for-purpose governance for the CTIS. Unfortunately the veterinary network is not exposed to the CT implementation and is scarcely represented in the Management Board, so a greater involvement is necessary to ensure that lessons are learned from the implementation of the CT regulation. Concerning the review and reprioritisation of projects in the EMA project portfolio suggested by the Commission, the portfolio projected for 2020 is mainly composed of the CTIS, EudraVigilance for veterinary products, SPOR and update of EMA systems which is long overdue and is necessary to free up human resources through automatisation to compensate for EMA staff loss. Financial resources are under strain as well, as the issues related to the Churchill Place premises will require EMA budget to fund shortfall in 2020 for reasons still to be clarified. The possibility that running expenses for the Agency might be lower in the Netherlands still needs to be fully evaluated, but it should be borne in mind that even a positive outturn might not be beneficial if there is no adequate human resources capacity to deliver implementation of projects.

Members reacted by stating that the governance model does not appear to be a problem now, but that resources are a matter of great concern also for the national authorities. Several members considered that reprioritising projects by EMA would be impossible, as they are needed for the functioning of the whole EU regulatory system. A member brought forward the perspective of small Member States, who are completely reliant for implementation of the legislation on availability of centralised IT tools. The representative of DG SANTE suggested waiting until October to get a better idea of the 2020 budget

once the development of the EMA's costs due to changes in the staffing structure and therefore of remuneration of staff will be clearer, as well as running costs for the Agency in the Netherlands. It appears however unlikely that there will be any change to the budget approach of the Union. EMA stressed that additional FTEs are needed in any case to support a higher expenditure in the veterinary or IT area. The yearly budget for IT projects is of roughly €12 million, so the cut to other projects for 2020 would need to be in the order of 50%. It should be kept in mind also that additional resources will be needed for the implementation of the EU DPR. EMA started work on the NVR mandates freeing up internal resources in order not to delay the process, under the assumption that further resources would be made available, and is now working at the limits of what the organisation can bear. If the Agency has to deprioritise other activities, it would need to receive explicit instructions from the European Commission as this would result in non-compliance with other legal obligations which would need to be scaled back. The proposal by the representative of veterinarians' organisations to set up a small Task Force with membership by Commission, European Parliament, Member States and EMA to look for possible solutions in a short timeframe found wide support by the board. Matthias Groote advised to open up the discussion and raise the budgetary constraints with the European Parliament and the new Commission. In the meantime he would assist the Task Force by identifying a relevant person at the European Parliament. The board nominated as Topic Coordinators Nancy de Briyne, Hugo Hurts and Jean-Pierre Orand, as members of the Task Force to be led by Ivo Claassen. EMA will be represented by Hilde Boone and Nerimantas Steikūnas and further colleagues as needed. The scope of the work will be to look at the costs for the implementation in detail and how to support EMA obtaining the necessary financial and human resources. The mandate will depend on requirements to be decided. The representative of DG SANTE suggested Sabine Jülicher as the responsible person at the Commission.

B.11 Deliverables from the HMA/EMA Task Force on the Availability of Authorised Medicines

[EMA/MB/288386/2019; EMA/299737/2019; EMA/674304/2018; EMA/632473/2018] The Management Board discussed the *Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA*) and adopted the *Best practices for public communication on medicines' availability issues* developed by the HMA/EMA Task Force on the Availability of Authorised Medicines as part of their work programme. The guidance document, which includes a common definition of shortage and provides a harmonised template to be used by MAHs to notify those NCAs that do not currently have one, was subjected to a consultation process with CMDh, CMDv and human and veterinary stakeholders representing mainly industry. A teleconference to address comments raised by industry associations was held by the Steering Committee of the Task Force on 29 May 2019. The Guidance should be considered a living document and its implementation will be piloted for 6 months to assess whether its requirements are realistic and manageable. The best practices document underwent consultation by CMDh, CMDv, HMA Working Group of Communication Professionals and human and veterinary stakeholders.

During the discussion at the board there was wide appreciation for the deliverables of the Task Force. Some members considered that global causes for shortages, affecting for example generics, should be addressed in the future. The Executive Director reminded the board that the current effort will lead to an inventory of shortages across the EU in a harmonised format, which will be the starting point to build knowledge. The representative of patients' organisations welcomed the guidance to which groups of patients and healthcare professionals had contributed extensively. Some members discussed changes to the requirements for the timing of the notification by MAHs to NCAs of a temporary or permanent interruption in the placing on the market of a product, as well as distinctions between planned and unplanned interruptions to supply. It was agreed that the minimum timeframe for notification of two months is established in EU legislation, but that a fine-tuned wording would be

proposed to the HMA for adoption and subsequently to the board by written procedure to impress the need for the notification to be made as early as possible[1].

B.12 Annual report 2018 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use

[EMA/MB/265471/2019; EMA/258793/2019]

The Management Board endorsed the Annual report on the performance of the Agency's scientific procedures: *Key Performance Indicators (KPIs) evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use* under the agreed pilot project started in 2011 with the aim to provide transparent reporting of the performance of NCAs under the Cooperation Agreement (CA) between NCAs and EMA for services provided. Overall the report shows good performance across the portfolio and lifecycle of procedures. Since last year, following request by the board, MNATs (multi-national assessment teams) are included in the statistics. Experience remains limited, as there are no data yet for veterinary scientific advice and human or veterinary post authorisation procedures. Although the number of first assessment reports for human scientific advice on target has decreased year on year since 2015, performance has improved in the second phase for 2018. Performance for veterinary scientific advice remains substantially unchanged from the previous year. Almost all QRD comments were received in advance or on the target date as in previous years. For MAA and Annex I applications the number of reports on target has increased for human and veterinary procedure since 2016. The number of MNAT involved in human MAA and Annex I applications has increased in 2018 from 6% in 2017 to 11% for Rapporteurs and from 11% in 2017 to 31% for Co-Rapporteurs. No veterinary MAA were assessed by MNATs in 2018. In 2018 only 26% of the GMP inspection reports were received on target, although overall, 100% of the GMP, GCP and PhVig inspection reports were received within their KPI.

A member pointed out that due to high workload and increasing complexity of procedures and interactions with different bodies, Scientific Advice procedures are under increasing stress, and suggested to look into their long term performance. The Executive Director added that the Agency may need to consider internally at other metrics that may help to understand whether action may be needed.

B.13 Outcomes of the Study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use

Two representatives of EY presented preliminary findings of the study, commissioned by the European Commission as part of the legal obligation to re-examine every 10 years the operation of the EU marketing authorisation procedures on the basis of experience gained. The scope of the study extends over the years from 2009 to 2017 and focusses on the three EU marketing authorisation procedures for human medicines: Centralised Procedure, MRP and DCP. Work has been organised in five Thematic Work Packages: the European medicines regulatory network, procedures preceding submission of marketing authorisation applications, Initial Marketing Authorisation Procedures, Post-Marketing Authorisation Procedures and Support Activities. The methodology for the study has been based among other on desk research; interviews with the EMA Secretariat, NCAs European Commission, and

[1] Post meeting note: A consultation procedure for the adoption of revised guidance on detection and notification of shortages for MAHs, reflecting the changes as per the outcome of the June board meeting was launched on 24 June 2019 and finalised on 1 July 2019.

a broad range of stakeholders; an online survey of members of EMA Committees and Working Parties); direct observation of CHMP and CMDh; 8 Member State case studies and 14 product case studies (mix of CP and MRP/DCP). As next steps a draft final report will be submitted to the EC on 20 June, and a final report in July. Preliminary findings of the study will also be presented to CHMP, CMDh and to the Pharmaceutical Committee before finalisation of the report.

It was pointed out to the representatives of EY that careful fact checking will be required in the report before it can be released to wide public scrutiny. The representative of patients' organisations stressed the importance of drawing the attention of the European Parliament and to Council the risk that new missions are given to EMA without an adequate budget for their development.

B.14 Update on EudraLink and secure communication

The board heard an update on how the Agency together with the network intends to ensure an effective management of confidential information to prevent incidents which could seriously harm the interests and reputation of third parties, EMA and the European Medicines Regulatory Network. Steps have recently been taken to further improve security and the application of EMA's security policy. An information package was provided to EMA staff, Committee participants and experts. Over the course of 2019 and 2020 the Agency aims to modernise and digitise the systems that support its core regulatory activities, including putting in place a new platform for securely collaborating on documents and on procedures for EMA , NCA experts and applicants which will largely replace Eudranet and Eudralink. While it is recognised by the Agency that Eudralink is not so user-friendly, it is considered that investments should be more effectively directed at new tools rather than to upgrading old systems.

One member confirmed his ongoing concern about the difficulties that users experience with the day-to-day use of Eudralink and informed the board that he had circulated a list of practical problems to the HMA MG. He also stressed the importance to discuss any new system with its future users. The Executive Director welcomed the compilation of a list of issues, which is pursued also at EMA. He informed however that while it may be possible to identify and implement quick fixes, no major investments will take place on old systems which are planned to be retired.

B.15 Interim update on the activities of the HMA-EMA Joint Big Data Taskforce

The board noted an interim update presented by representatives of the HMA-EMA Joint Big Data Taskforce. At the HMA II meeting in Vienna and at the December meeting of the board, the Task Force had reported on Phase I of its activities. A Summary Report had been adopted and the mandate of the Taskforce extended for 12 months in order to finalise the work of the data analytics subgroup and to plan for the next phase of work. Following a request by the HMA to engage with the Telematics Management Board, several actions were undertaken and a representative was invited to join the Taskforce to contribute to the data standards and quality subgroup. Going into Phase II the 6 subgroup reports that had been generated in Phase I have been complemented by a cross-cutting report and recommendations from the data analytics subgroup. The recommendations from the Phase I subgroups are being prioritised and planned according to an agreed methodology to generate the final Taskforce plan. An interim plan will be presented at the HMA meeting on 20 June and a full final plan to the board and to HMA in Q4. An estimate of resources for 2020-2021 is based on the expectation that the Taskforce may need to move into a more professional setup to implement its recommendations, although some of the needs will be addressed through expansion/rationalisation of existing working parties. External collaboration will be key, as well as training initiatives to increase capacity and capability. Resources will be required for 4 specific pilot projects of direct regulatory relevance in 2020. The collective contribution over 2020-2021 can be estimated to amount to 10 FTE

across the Network. Possible sources of funding include support by NCAs, EMA and EU and leveraging third-party initiatives. A Phase III will be required to co-ordinate the implementation of the recommendations. The board was asked to endorse by written procedure the data analytics report and recommendations as well as the external publication of the subgroup reports.

The Executive Director acknowledged the impressive work done by the Taskforce, and thanked DG SANTE for its support in connecting the Agency with other DGs that may provide resources. The representative of DG SANTE listed a number of initiatives that are being developed within other networks, such as DG Connect, Digital Europe and IMI.

List of written procedures finalised during the period from 23 February 2019 to 16 May 2019

- Consultation no 4/2019 on the appointment of Maris Kodols as CHMP alternate proposed by Latvia ended on 21 February 2019. The mandate of the nominee commenced on 22 February 2019.
- Consultation no 5/2019 on the appointment Melinda Nemes-Terenyi as CVMP alternate, proposed by Hungary ended on 11 March 2019. The mandate of the nominee will commence on 24 May 2019.
- Consultation no 6/2019 on the appointment of Niels Christian Kyvsgaard as CVMP member, proposed by Denmark ended on 1 April 2019. The mandate of the nominee commenced on 2 April 2019.
- Consultation no 7/2019 on the appointment of Spyridon Farlopoulos as CVMP alternate, proposed by Greece ended on 6 May 2019. The mandate of the nominee commenced on 7 May 2019.
- Extraordinary urgent written procedure for the notification to the Budgetary Authority on 30 Churchill Place ended on 4 March 2019. The procedure was endorsed.
- Consultation procedure for the Revision of the EMA breach of trust procedure on declarations of competing interests for Management Board members ended on 11 April 2019. The procedure was endorsed.
- Consultation procedure of the draft minutes of the 103rd Management Board meeting ended on 15 May 2019. The procedure was adopted.

Documents for information

- [EMA/MB/270904/2019; EMA/255216/2019] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/270926/2019] Outcome of written procedures finalised during the period from 23 February 2019 to 16 May 2019
- [EMA/MB/245070/2019] Summary of the transfers of appropriation

List of participants at the 104th meeting of the Management Board, held in Amsterdam, 12-13 June 2019

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	*Apology received from Bogdan Kirilov* [1]
Czech Republic	Irena Storová *(member)*
Croatia	Siniša Tomić *(alternate)*
Denmark	Mette Aaboe Hansen *(alternate)* Tina Engraff *(observer)*
Germany	Karl Broich *(member)* Wiebke Loebker *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	*Apology received from Ioannis Malemis*
Spain	María Jesús Lamas Diaz *(member)* César Hernández *(alternate)* María Jesús Alcaraz Tomas *(observer)*
France	Dominique Martin *(member)* Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Luca Li Bassi (member) Anna Laura Salvati (observer)
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Mátyás Szentiványi *(member)* [1]
Malta	*Apology received from John-Joseph Borg*
Netherlands	Hugo Hurts *(member)* Michiel Hendrix *(observer)*
Austria	Thomas Reichhart (alternate)
Poland	Grzegorz Cessak *(member)* Magdalena Pajewska *(observer)*
Portugal	Rui Santos Ivo *(member)* Maria Joao Morais *(observer)*
Romania	Marius Daniel Sisu *(member)* [1]
Slovakia	Zuzana Baťová *(member)*
Slovenia	Momir Radulović *(member)* [1]
Finland	*Apology received from Eija Pelkonen*
Sweden	Catarina Andersson Forsman *(member)* Evelina Kaarme *(observer)*

Competing interest declared resulting in no participation in decision with respect to agenda point B.11.

United Kingdom	Jonathan Mogford *(alternate)*
European Parliament	Matthias Groote Tonio Borg
European Commission	Andrzej Rys (DG SANTE) Carlo Pettinelli (DG GROW) Laura Fabrizi DG GROW (*observer*)
Representatives of patients' organisations	Yann le Cam
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdottir Hvannberg (Iceland) Brigitte Batliner (Liechtenstein) Audun Hågå (Norway)

European Medicines Agency	Guido Rasi Noël Wathion Nerimantas Steikūnas Agnes Saint-Raymond Alexis Nolte Enrica Alteri Fergus Sweeney Ivo Claassen Melanie Carr Anthony Humphreys Stefano Marino Zaide Frias Marie-Agnes Heine Monica Dias Frances Nuttall Hilde Boone Maria Alves Silvia Fabiani Apolline Lambert Sophia Albuquerque