16 March 2018
EMA/MB/167407/2018 Adopted
Management Board

Minutes of the 99th meeting of the Management Board

Held in London on 15 March 2018

The chair opened the meeting informing members that the Representative of patients' organisations Ilaria Passarani had recently been appointed as Secretary General of the European Organization representing Community Pharmacists (PGEU) and therefore had to step down as member of the board. Acknowledging her valuable contribution, the chair invited the European Commission to look into the procedures to appoint her successor, also in the context of the next appointments of civil society members by the Council, due in June 2019. The chair invited nominations for Topic Coordinators for the Analysis and Assessment of the Executive Director's Annual Activity Report (AAR) 2017 that will be delivered at the June meeting. Last year's volunteers Belén Crespo Sánchez- Eznarriaga (Spain) and Nancy De Briyne were joined by Audun Hågå (Norway).

1. Draft agenda for 15 March 2017 meeting

[EMA/MB/790/2018] The agenda was adopted.

2. Declaration of competing interest related to current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning topics *"B.4 Revised implementing Rules to the Fee Regulation and B.5 2016 and 2017 European Medicines Agency Annual Reports on Independence".* 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 interest were declared.

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3.a Minutes from the 98th meeting, held on 13-14 December 2017 adopted via written procedure

[EMA/MB/701078/2017] The Management Board noted the final minutes, adopted by written procedure on 23 February 2018.

3.b Minutes of the Extraordinary Management Board meeting for the building approval process of EMA premises in Amsterdam

[EMA/MB/102052/2018] The Management Board adopted the minutes of the extraordinary meeting for the building approval process of the EMA premises in Amsterdam, held in Lisbon on 28 February, for which some editorial comments had been received. The minutes will be published together with the minutes of the extraordinary meeting of 6 February 2018 which had already been adopted.

4. EMA Preparedness on Brexit

The board heard an update on the status of preparedness under the perspectives of actions taken at EMA and of the bilateral EMA-Netherlands collaboration. At the next meeting on 6 June a session will be dedicated to Brexit topics.

4.1 Update on EMA Brexit preparedness

Following the endorsement by the board at the December 2017 meeting of the recommendations relating to the redistribution of the UK centralised products' portfolio by the EMA working groups on committees' operational preparedness, the agreed methodology has been applied to centralised products and preparatory work is taking place pending greater certainty which may arise as the EU-UK negotiations progress in summer. The 1st and 2nd rounds of redistribution have taken place and a 3rd as launched. The MAHs of the products concerned will be informed at the end of April of the new (Co)-Rapporteurs for their products. Results from the redistribution exercise have been encouraging, as all veterinary medicines have been accepted by a new (Co)-Rapporteur and only few products remain to be distributed for human medicines. Next steps will include a proposal for a knowledge transfer package to be provided by EMA to support the newly appointed (Co)-Rapporteurs, which will be presented to the board in June.

The potential impact of Brexit on supply of medicines for centrally authorised products (CAPs) is being addressed in two work streams. EMA is undertaking an analysis for critical centralised products, which takes into account therapeutic use and available alternatives. An impact assessment on the number of variations necessary to implement the changes required by legislation has been conducted, and will inform budget and resources planning. In addition EMA is complementing the analysis with a survey of MAHs to identify centralised products potentially at risk of shortages and to obtain information on the timelines for submission of the necessary regulatory changes. The data are currently being analysed and EMA will liaise directly with MAHs to address any potential supply disruption that could impact on public or animal health in the EU.

At their meeting in January, the working groups also discussed closer collaboration with the HMA Brexit Task Force. A second survey of NCAs has been prepared by EMA and will be launched at the end of the month after comments by the HMA Brexit Task Force. It will address capacity for non centrally authorised products and training needs targeting all procedures. EMA has offered support to the HMA Brexit Task Force for the follow-up to this survey. Staff retention measures are being developed at the Agency in addition to existing entitlements foreseen by the Staff Regulation or support offered through the Dutch relocation helpdesk. Staff retention measures have been classified according to the period

when staff may move and will address diverse topics, such as provisions for consecutive teleworking, relocation visits and language training.

4.2 Update on EMA-NL collaboration for relocation to Amsterdam

The board noted the update on collaboration with the Dutch authorities, endorsed the guiding principles in the negotiation of the Agency's seat agreement in the Netherlands, and gave mandate to the Executive Director and to the Chair of the Management Board to finalise and sign the seat agreement.

Since December 2017 collaboration has been progressing in five work streams. Following endorsement by the board at its 28 February extraordinary meeting of the notification of EMA's intention to move to a new building, the building approval procedure with the EU Budgetary Authority has now been launched. There has been a change compared to the building approval dossier as endorsed by the board on 28 February concerning the deduction from the annual rent. It had been decided to use € 15 million of the € 18 million incentive offered by the Dutch government to pay for the cost for additional EMA specific building requirements. The residual € 3 million would be used for an overall reduction of the annual rental costs over 20 years. The change relates to the possibility to double the reduction in any given year if needed. The lease for the temporary premises of the Agency in Amsterdam has been signed by the Dutch government on 29 January after it had formally accepted EMA's conditions. Preparations for the staff relocation are progressing, as general information sessions and sessions specifically targeted on schools have begun at the Agency, as well as one-on-one consultations with staff by the Dutch helpdesk. The joint EMA-NL governance structure was implemented in January, and work can now progress under it. A tracking tool for the Agency's relocation to Amsterdam was published on the Agency's website in March and will show progress with the main milestones and deliverables of each work stream.

The negotiation of the seat agreement between the representatives of the Dutch government and the Agency is proceeding. The agreement is the main legal instrument governing operations of EMA in the Netherlands and the relations between the Kingdom and EMA. The seat agreement regulates the immunities and privileges, which are functional privileges having the purpose to ensure the efficient performance of the functions of the Agency. These are based on Protocol 7 of the Treaty on the privileges and immunities of the EU and extend to the Agency, to staff members, Seconded National Experts, Management Board and Scientific Committees members. The privileges and immunities according to Protocol 7 are mandatory and non negotiable. Further 'courtesy' privileges are non-mandatory, but fall under Dutch Government practice. Negotiations are guided by the principles of respecting existing practice of the Netherlands while stressing the specificities of EMA and its internal organisation. A further meeting with the Dutch authorities is foreseen to resolve the last outstanding points. After receiving confirmation from EMA that the final draft is agreeable to the Chair of the Management Board and the Executive Director, the Kingdom of the Netherlands will initiate the internal constitutional process for approval, which is foreseen to take three weeks before the agreement can be signed. The entry into force of the seat agreement will ensure that its provisions apply in favour of EMA staff who will move for personal reasons to the Netherlands as early as summer 2018.

The representative of the European Commission enquired about the existing privileges and immunities in the current seat agreement with the UK. EMA informed that when the Agency was set up in London in 1995 only an exchange of letters setting up Protocol 7 took place. Proposals offered by the Netherlands to EMA are quite similar to the seat agreements signed with other European entities based there.

A. Points for automatic adoption/endorsement

A.1 Management Board decision – implementing rules on telework

[EMA/MB/80240/2018; EMA/MB/478899/2017] The Management Board adopted the implementing rules on telework.

These are based on the final ex-ante agreement from the Commission on teleworking and provide wider and more flexible arrangements than those foreseen in the pilot which has been running at the Agency since June 2015. As part of the staff retention measures additional flexibility will be applied for a transitional period under provisions 4.3 and 4.5 of the rules. This approach has been discussed with DG HR and support has been confirmed. The new rules shall take effect on 1 April 2018. Special conditions will apply in the transitional period from 1 April 2018 to 31 July 2020.

A.2 Management Board decision – derogation from European Commission Decision C(2017) 6760 final of 16 October 2017 on Contract Agent rules

[EMA/MB/83105/2018; Ares(2017)5115151 – 19/10/2017; EMA/MB/20915/2018] The Management Board adopted a decision on request for authorisation not to apply a Commission Decision governing the conditions of employment of contract staff employed by the Commission on the grounds that these rules are not suitable to apply by analogy to EMA staff. The Agency will await the ex-ante agreement containing model rules for agencies currently being prepared by DG HR.

A.3 Management Board decision – implementing rules on Learning and Development

[EMA/MB/81030/2018; EMA/MB/736151/2017] The Management Board adopted the implementing rules on Learning and Development based on the final ex-ante agreement received from the Commission on 9 October 2017. The decision shall take effect on 1 September 2018 to give the Agency sufficient time to introduce changes in the Learning Management System.

B. Points for discussion

B.1 Highlights of the Executive Director

Appointments

The Executive Director introduced the new Head of the Veterinary Medicines Division, Dr Ivo Claassen, who joined the Agency on 1 March 2018. He also thanked Fia Westerholm again for her work as interim Head of Division during the past year.

Outcome of the ENVI visit and vote

On 22 February a 'fact-finding' mission of a delegation of the ENVI Committee of the European Parliament led by Giovanni La Via took place in Amsterdam with the objective to obtain up-to-date information on the EMA's transfer to the temporary and the permanent buildings. The Dutch authorities confirmed the agreed transition deadlines and reassured the MEPs on the commitment of their government to ensure a smooth transition of EMA. On 12 March the ENVI Committee voted on the proposal for an amendment of Regulation no 726/2004 as regards the location of the Agency,

confirming Amsterdam, and requesting quarterly reports on progress of the buildings to ensure the move of the Agency to its temporary location no later than 1 January 2019 and to its new permanent headquarters no later than 16 November 2019. A further vote on the proposed legislation by the European Parliament plenary was scheduled for 15 March 2018[1].

Meeting with the UK government

On 19 February 2018 an EMA delegation together with representatives of DG BUDG and DG SANTE of the Commission visited the Treasury Department of the UK Government. EMA asked for the implementation of Paragraph 86 of the EU/UK Joint Report of 8 December 2017 and to discuss how the UK can help reduce EMA's withdrawal cost from the London premises. The UK team visited the Agency's building on 7 March 2018, also to understand the situation with regards to the lease. The board will be kept informed on developments.

EU activities

EMA hosted a visit of Commissioner Vytenis Andriukaitis on 12 February. He discussed key topics of common interest with staff and management , such as AMR, vaccination, paediatrics, eHealth, the European Commission proposal for a regulation on health technology assessment and Brexit. The 2016 budgetary discharge procedure is underway and EMA has received a positive recommendation from the EP Rapporteur. The vote in the CONT committee is expected later in March, and the final vote in the European Parliament plenary in April.

International activities

The US-EU MRA implementation is progressing successfully with further four Member States included in the agreement. EMA participated in the 3rd Pharma meeting in India on 15 February, on invitation by the Indian authorities. Main points of interest were the European model and complex supply chains. A second edition of the Awareness session on EMA and the EU network took place on 8-9 March and was attended by 86 participants from 28 countries, in particular from academia. Main points of interest were expert roles, benefit-risk assessment, ATMPs and clinical trials.

EU Telematics Management Board Joint meeting with industry associations

The meeting took place on 15 February as part of their annual engagement. Industry received updates of the status of Telematics programmes and the development of the Telematics strategy 2015, while it provided an update on their IT initiatives in the Telematics domain.

Launch of EudraVigilance

On 14 February the final major release of the EudraVigilance system was launched delivering additional improvement after its go-live on 22 November 2017. The system contains over 12 million safety reports, ca. 8 million cases and information on ca 800,000 medicines. Data are also regularly transferred to the WHO Uppsala Monitoring Centre Digibase database.

First year report on Clinical data publication

EMA is the first and only authority worldwide so far providing open access to clinical data submitted by companies within their marketing authorisation applications. Reports on 50 medicines made publicly available as of 20 October 2017. The published data has attracted a total of more than 36,000 users resulting in over 80,000 document downloads for non-commercial research purposes in one year. Progress in 2018 will depend on the extent of the business continuity arrangements the Agency has to put in place.

[1] Post meeting note: The draft legislation enacting the European Medicines Agency's relocation from London to Amsterdam, due to Brexit, was approved by MEPs on 15 March 2018. Informal three-way negotiations ('trilogue') with the Council Presidency and Commission will now start, with a view to achieving a first-reading agreement on the new EMA seat.

Public hearing outcome and next steps

After its first Public Hearing PRAC has reached is final conclusion on valproate in February 2018. A thorough analysis of the experience will be presented to the board in June 2018.

Veterinary medicines highlights 2017

EMA published an overview of its key recommendations for veterinary use. 18 medicines were recommended in 2017, with an increase of 60% compared to 2016.

Paediatric workshop

The Agency is organising together with the European Commission a workshop on 20 March 2018 to identify and discuss potential improvements of the Paediatric Regulation.

B.2 Report from the European Commission

HTA

The proposal for a Regulation on health technology assessment was adopted on 31 January 2018. Leveraging on work done at EMA and EUnetHTA the Regulation aims to establish a support framework and procedures for cooperation on HTA at Union level, as well as rules for the joint clinical assessment of health technologies. While it is desirable to address possible apprehensions on subsidiarity upfront, the Regulation is designed not to affect the rights and obligations of Member States with regards to the organisation and delivery of health services and medical care and the allocation of resources assigned to them. The proposed system is Member State-driven for content and for strategic decisions. The proposed scope will address medicines with a centralised marketing authorisation which are new active substances, or extensions of indication of an existing active substance, as well as some medical devices in the highest risk class. Focus will be on clinical assessment aiming at high quality and timely output. Further objectives are the avoidance of duplication, as the HTA reports are to be used at national level, and full transparency. A phase-in approach delaying entry into force for three years with a transitional period of further three years is foreseen to ensure a gradual implementation. The governance should be provided by a central secretariat at the Commission and all funding should come from the EU budget. The Commission sees an opportunity to build on synergies between regulators and HTA while preserving national competences, and is ready to work bilaterally with the Member States.

EU-US MRA

The implementation continues in a climate of good collaboration. The next milestones foresee the stepwise recognition of all other 16 Member States by July 2019.

Falsified Medicines Directive

With less than a year to put in place the safety features on all prescription medicines, further work is needed with stakeholders to assure implementation in all Member States. There is serious concern on hospital preparedness, which appears to be the weakest link in the system. The Commission expert group will continue to address the technical questions and facilitate the communication with the stakeholders.

Brexit technical seminar

The Commission convened a technical expert meeting on Brexit with Member States representatives on 8 March to inform about the state of play, discuss preparedness of the pharmaceutical network and relevant mitigation measures taken for CAPs and NAPs (nationally authorised products), also concerning the expected increased workload after the UK's withdrawal, and in order to identify any

potential gaps and actions to be taken within the next 13 months to safeguard continuous supply of medicines.

B.3 EMA Annual Report 2017

[EMA/MB/142589/2018; EMA/91688/2018] The Management Board adopted the Annual Report 2017.

The report is structured in three main chapters, providing a focus on key achievements that have a positive impact on public health or stakeholder interaction, interviews from the Agency's partners and stakeholders on the topic of innovation and access to medicines, and statistics and trends on core activities. Major developments and activities included key Brexit-related milestones, the outcome of the first public hearing, the new framework and action plan for interaction with academia, the new EudraVigilance system and the first anniversary of the PRIME initiative (PRIority Medicines). The interviews provide the views of partners and key stakeholders on promising trends in personalised medicines, on ways in which pharmacovigilance enables innovation, and a reflection on evolving collaboration between regulators, HTA bodies and payers. Statistics on performance of the Agency and trend analyses are included. Highlights for 2017 include: 92 medicines for human use recommended for approval, including 35 new active substances, 7 accelerated assessments, 2 ATMPs and 2 conditional marketing authorisations. 603 Scientific Advices were delivered, of which requests for protocol assistance increased by 26% on 2016. For pharmacovigilance, 2,062 potential safety signals were reviewed and 82 assessed by the PRAC. For veterinary medicines 18 medicines including 7 new active substances, the first monocolonal antibody and 10 new vaccines were recommended for marketing authorisation. Over 50,000 ADRs were reported to EudraVigilance for veterinary products, a 33% increase on the previous year. GMP inspections decreased by 40%, reflecting the implementation of the EU-US MRA, while the number of GCP inspections increased by 12% and the pharmacovigilance inspections doubled, bringing their number up to 15.

Members of the board appreciated the wealth of data contained in the report, the progress achieved with the PRIME initiative and the increased safety reporting, particularly by patients. It was suggested that achievements of the Agency that are important to the general public could be further enhanced and complemented with more visual targeted information to stakeholder groups. The Agency informed that the report will be published after finalisation of its formatting and design, which will increase its readability, and reminded the board that within EMA's communication framework strategy there are a number of initiatives to provide targeted and accessible information through infographics and short videos. It was agreed to adopt the report, while extending the deadline for comments by two weeks in order to collect suggestions that could further improve communication to the public.

B.4 Revised implementing rules to the Fee Regulation as of 1 April 2018

[EMA/MB/57356/2018; EMA/MB/114433/2018;] The Management Board adopted the revised implementing rules to the Fee Regulation as of 1 April 2018.

In accordance with legal provisions on adjustment to inflation, all fees and related remuneration to national competent authorities increase by 1.7%, rounded off to the nearest € 100, and to the nearest € 10 for administrative charges. A fee reduction is introduced for the 2nd and subsequent multiple marketing authorisations on usage patent grounds for veterinary medicines, to align with provisions for human medicines. All proposed changes have been given a favourable opinion by the European Commission. The amendment of the levels of fees and remuneration to the national competent authorities is pending the adoption of the corresponding Commission regulation adjusting the fee levels of Council Regulation (EC) No 297/95.

B.5 Annual review of the EMA independence policies: 2016 and 2017 Annual Report

[EMA/MB/139395/2018; EMA/463632/2017] The board noted the Annual review report on independence 2016 and 2017 and endorsed the recommendations for further improvements as outlined in section 5 of the report.

Annual reporting was requested by the European Commission in January 2015 and the report describes the status of the various EMA policies relating to independence for scientific committees' members and experts, Management Board members and Agency staff, as well as their implementation. The current report encompasses 2016 and 2017. Over the years the three policies applicable at EMA have been aligned as much as possible. Policy 0044 applies to scientific committees' members and experts and was last revised in 2016 to introduce clarifications in the area of previous employment with a pharmaceutical company in an executive role or lead role in the development of a product, as well as in the case of an expert intending to become an employee in a pharmaceutical company. In 2016-2017 the first step of the Breach of Trust procedure (the 'clarification' step) was activated in 5 cases and further information was requested. Assessment of the additional information concluded that there was no need for further action. *Ex-ante* and *ex post* controls were carried out leading to a number of findings, however with no impact on involvement of the experts in the Agency's activities. Pre-screening of Declarations of Interests of all nominated CxMP members took place before formal acceptance. For Management Board members Policy 0058 applies. It was revised in October 2016 and *ex ante* controls were introduced. The revision of the Management Board decision on rules for EMA staff took place in 2016 and became effective as of 1 January 2017. The Joint Committee procedure, which is applied when staff leaves the Agency, lead to 41 applications in 2016-2017, and resulted in 10 cases of restriction in activities after leaving the Agency. Following review of the 2016 and 2017 experience, the recommendations proposed to the board include changes such as further alignment of the various policies and changes stemming from the 2016 and 2017 *ex post* controls. Other suggestions with respect to EMA staff came from the European Ombudsman as regards the declaration for transparency reasons of current and past intellectual property rights related to medicinal products or uses of such products. The action plan for 2018 will depend on the availability of the necessary resources as a consequence of the relocation of EMA, and priority will be given to those initiatives not requiring changes to IT systems.

B.6 Proposal for streamlining the process of assessment of eligibility of patients', consumers' and healthcare professionals organisations

[EMA/MB/70289/2018; EMA/698917/2017; EMA/24913/2005 – rev 3] The board adopted the proposal for streamlining the process of assessment of eligibility of patients', consumers' and healthcare professionals' organisations.

Formal frameworks adopted by the Management Board have been in place since 2005 for patients and consumers and 2011 for health care professionals. These include eligibility criteria to ensure that the Agency works with the most appropriate organisations. At present 62 organisations are eligible and the current process requires that they are re-assessed annually. Based on positive experience of compliance over the years, and on the fact that organisations have become more transparent, the Agency proposed to streamline and simplify the process, while maintaining the same strict criteria for eligibility. The new process foresees maintenance of the full initial evaluation by the Agency of new organisations applying for eligibility, a yearly self-declaration via an online form containing links to published information for the annual reassessment to be validated by EMA, as well as a full annual assessment of up to 20% randomly selected organisations.

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

[EMA/MB/107646/2018, EMA/13407/2018, EMA/144764/2018, EMA/145011/2018, EMA/143046/2018, EMA/143047/2018, EMA/162308/2018; EXT/161854/2018, EMA/158533/2018, EMA/142167/2018, EMA/166815/2018] The Management Board discussed and noted the report.

A high level update on the progress of the EU Portal and Database (EUPD) project within the CT programme, including presentation of the revised project plan submitted by IT4U on 2 February 2018, was provided to the board. The board was also asked to consider draft proposals for an interim revised programme governance and for a third party review of programme assurance. Following submission by the developer, IT4U, a revised project plan on 2 February 2018, leading to audit (in accordance with Article 82 of the clinical trial Regulation) of the EUPD in early 2019, was circulated to the EU TMB, EU CTR Coordination Group and HMA and considered a step in the right direction. The plan was also circulated to the Management Board. With successful completion of release 0.6 SAT the first milestone in the revised plan was met and the team's capacity considered sufficient to fix the backlog of remaining bugs. The planning taskforce is now finalising the revised metrics and reporting, embedding the agreed improvements in the EMA/IT4U collaboration. The revised plan leads now to an audit in early 2019 with a follow-up visit about four months later and it is believed that the results will be available for the Management Board in June 2019. IT4U is delivering releases up to 0.8 within the available framework contract which can be extended until July 2020 if needed with 12 further months until July 2021 to deliver work signed up for in contracts before July 2020. Following UAT 6 EMA organised a series of workshops to increase understanding of the overall system and of the key priorities to be implemented beyond the agreed 'Must' requirements. A core group of the on-site UAT 6 testers and other experts were invited to participate. The workshops started in January and are scheduled until April, further workshops will be planned thereafter as needed. In preparation for the audit required by Article 82 of the clinical trial Regulation EMA will use a company either under its own framework contract or that of the Commission. The Agency will arrange a meeting of the lead auditor with the EU CTR Coordination Group and the co-chairs of CTFG ahead of the main audit visit in early 2019 after UAT 7.

At the meeting of the EU CTR Coordination Group held in Lisbon on 28 February, it was recognised that the CT programme governance is too complex and that there is a need for immediate interim adjustments pending analysis of the governance by the Coordination Group as part of the Programme Assurance review. It was proposed to give the EU CTR Coordination Group, retaining current membership, a mandate reporting to the EMA Management Board. The Coordination Group should nominate some members to take the task of overseeing the external review of the programme.

The board discussed the proposal for the revised governance. It was suggested to leave overall responsibility and oversight with the EU CTR Coordination Group, instead of limiting its role to oversight of the EUPD. As for its chairmanship, change to a system of co-chairmanship would not provide added value, as what is important is that all responsible parties are present, particularly that the European Commission and the Executive Director of EMA participate. It was suggested that the Commission continues to chair the Coordination Group. This was supported by the Executive Director, who stressed the essential role and the neutral nature of Commission chairmanship, where Member States and EMA may in some situations be interested parties. The representative of the European Commission acknowledged the call for continuous involvement of the Commission by the board, and stressed the importance of delivering as soon as possible a high quality IT system allowing Member States to fulfil their obligations by ensuring that the IT provider makes all necessary adjustments for this purpose. Postponing the audit to early 2019 can be agreed on, if making sure that the planning is robust. A question was raised concerning the governance structures below the EU CTR Coordination

Group, and the need for two representatives per Member State in the Member State group. This is due to the involvement of Ethics Committee as well as National Competent Authorities. Concerning the question of how involvement of experts is guaranteed, this is achieved since they are present in the Expert Group and in the Member State group to a large extent. Those should communicate with and consult other experts for specific issues and technical discussions. The board endorsed the principle of the simplification of the governance and the joint ownership of the programme by the Commission, Member States and EMA. It was agreed that there should be joint ownership by EMA and Member States reflected in co-chairing by EMA and Member States of the CT Information system Expert Group and Member States Group meetings. The EU CTR Coordination Group should act as arbitrator and decision maker when escalation is exceptionally required to reach a decision.

A detailed proposal for the streamlining of the governance will be prepared within the next two months by the EU CTR Coordination Group.

At the December meeting of the board it had been proposed to carry out a 3rd party Programme Review to provide assurance to the board that adequate project management controls are in place to deliver the EU Clinical Trials portal and database. After further discussion in the past two weeks two proposals could be presented to the board for a review by an independent third party contractor under sponsorship of the EU CT Coordination Group. With Option 1 a first Project Assurance Management Report could be delivered in June, while the remaining report would be available at the October Management Board, while a more time-compressed Option 2 would deliver the entire review by the June meeting of the board. Budget impact and availability still need to be confirmed for this activity, which was not foreseen for 2018. Furthermore, it is important that the Programme Review impacts only minimally on the current delivery of the project by EMA/IT4U.

In the discussion members supported the option for a thorough review (Option1), although including, if possible, in the first phase the review on capability to deliver the project, so that potential problems would surface in time for discussion at the June 2018 meeting of the Management Board. The precise scope of each review phase will be established under review by the EU CT Coordination Group. The representative of the European Commission stressed the need to avoid additional work for the developer by ensuring that the review can be managed in parallel and does not deflect from the core work. The board concluded that once further experience with the project plan is gained, and an external party has reviewed it and reported to the board, it will be possible to agree to a revised timeframe for implementation of the Regulation.

B.8 8th Annual Report Veterinary MUMS/limited market

[EMA/MB/66856/2018; EMA/795802/2017] The board endorsed the 8th report on the operation of the policy on veterinary medicines for Minor Use Minor Species (MUMS)/limited market.

There is continued interest by stakeholders in the scheme, with 31% of requests originating from SMEs. The number of requests for classification appears to have reached a steady-state with 29 requests in 2017, 27 of which were classified/reclassified and resulted in eligibility for financial incentives for 5 products for food producing species. The number of MUMS centrally authorised products per year is also stable, with overall 16 products assessed and approved since the introduction of the scheme, of which 3 were in 2017, for a wide range of both minor species and major species/minor use/limited market indications. The full financial impact of the revised policy is expected in the coming years when all initial classifications under the scheme will have expired.

B.9 Report from the CAT Chair

Martina Schüssler-Lenz, Chair of the Committee for Advanced Therapies since February 2017, presented an overview of achievements of the committee and current and future perspectives. The

products for which the committee is responsible offer new treatment options that are potentially game-changing and even curative for rare diseases and for patients with high unmet clinical needs. An example of this is the first product with genetically modified cells approved for a very rare disorder which has so far given very encouraging results. The most important task of the CAT is preparing the assessment which is then submitted to the CHMP as a draft opinion. The Committee observes rapidly evolving scientific and technical innovation entering the fields of ATMPs, such as *ex vivo* gene editing, recombinant adeno-associated virus (AAV) vectors for gene therapy and CAR T cells. The CAT needs constant access to advanced expertise for the products that appear in the pipeline. There is one recombinant AAV vector among the 14 ATMPs in the PRIME scheme, and 26 rAAV products for which scientific advice has been requested. Clinical trials on CAR T cells have been rapidly increasing in the last two years and the committee needs to prepare for the scientific and regulatory challenges that lie ahead. These include manufacturing aspects such as EU versus US manufacturing comparability issues, as well as complex supply chains. Regulatory aspects may be caused from lack of harmonisation between EU Member States, and the Committee is working with the Commission to reduce gaps. To address specific safety and efficacy follow-up, a workshop on CAR T cell therapy registries with participation by all stakeholders was organised at EMA on 9 February 2018. Currently five products are under evaluation by CAT, of which two are under PRIME. The CAT is routinely involved in the Scientific Advice procedures for ATMPS, which have had a substantial increase over the period 2012-2017, with 76% of Scientific Advice in 2017 requested for gene therapy products. The expertise present in the CAT is wide-ranging as a result of far-sighted provisions in the Regulation on advanced therapy medicinal products and includes also representatives of doctors and patients' organisations. Good communication, close interaction between committees, working parties and stakeholders, together with continuous learning are fundamental to further develop expertise and stay abreast of innovation.

Answering a question on whether the Regulation and the current overall processes can be considered fit-for-purpose and working well, Dr Schüssler-Lenz confirmed her satisfaction with the existing framework. When being elected chair, she focussed on a better interaction with other Committees. After one year she was happy to confirm that links to colleagues from CHMP and PRAC had been deepened and a procedural guidance on interactions between CHMP, CAT and PRAC had been finalised. The Executive Director thanked the chair of CAT for her work and for her leadership and contribution in the Scientific Coordination Board, which had helped colleagues to improve coordination. Referring to a previous report at HMA, he invited her to take the opportunity to make the board aware of any needs of the CAT. Dr Schüssler-Lenz confirmed that access to expertise had improved, although the extremely complex nature of advanced therapy products will always require access to additional clinical expertise.

B.10 EVVET Access policy update

[EMA/MB/74862/2018] The board noted an update on the revision of the EudraVigilance Veterinary (EVVet) access policy, first adopted by the Management Board in December 2010.

The policy, which outlines the data elements and the principles of providing access for various groups to adverse event reports held in EVVet, needs to be revised due to the ongoing update of the veterinary pharmacovigilance reporting IT system (EVVet3 project). The current timeline foresees adoption by the CVMP and CMDv after a public consultation and endorsement by the CVMP Pharmacovigilance Working Party, with submission for adoption to the EMA Management Board expected at the October 2018 meeting.

List of written procedures finalised during the period from 21 November 2017 to 21 February 2018

- Consultation no 21/2017 on the appointment of Elena Kaisi as CHMP alternate, proposed by Cyprus ended on 6 December 2017. The mandate of the nominee commenced on 7 December 2017.
- Consultation no 01/2018 on the appointment of Tita-Maria Muhonen as CVMP member, proposed by Finland ended on 17 January 2018. The mandate of the nominee commenced on 18 January 2018.
- Consultation no 02/2018 on the appointment of Katariina Kivilahti-Mantyla as CVMP alternate, proposed by Finland ended on 17 January 2018. The mandate of the nominee commenced on 18 January 2018.
- Consultation on the adoption of the non-automatic carry-forward (C2) ended on 22 January 2018. The procedure was adopted.
- Consultation no 03/2018 on the appointment of Mark Ainsworth as CHMP alternate, proposed by Finland ended on 9 February 2018. The mandate of the nominee commenced on 10 February 2018.

Documents for information

- [EMA/MB/111032/2018;EMA/58551/2018] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/92046/2018; EMA/7552/2018] 2017 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2017
- [EMA/MB/21882/2018; EMA/21884/2018] Sixth six-monthly report on ex ante and ex post evaluation of projects for the period 1 July to 31 December 2017
- [EMA/MB/114032/2018] Outcome of written procedures finalised during the period from 21 November 2017 to 21 February 2018
- [EMA/MB/1127/2018] Summary of transfers of appropriations in budgets 2017 & 2018

List of participants at the 99th meeting of the Management Board, held in London, 15 March 2018

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	Assena Stoimenova *(member)* Bogdan Kirilov *(alternate)*
Czech Republic	Jiří Bureš *(alternate)*
Croatia	*Apology received from Siniša Tomić*
Denmark	Thomas Senderovitz *(member)*[2] Mette Aaboe Hansen *(alternate)* Tina Engraff *(observer)*
Germany	Karl Broich *(member)* Wiebke Loebker *(observer)*
Estonia	*Apology received from Kristin Raudsepp*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	Despoina Makridaki *(alternate)*
Spain	Belén Crespo Sánchez- Eznarriaga *(member)* César Hernández *(alternate*)
France	Dominique Martin *(member)* Miguel Bley *(observer)*
Italy	Nando Minnella *(alternate)* Gabriela Conti *(observer)*
Cyprus	*Apology received from Loizos Panayi*
Latvia	Jānis Zvejnieks *(alternate)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	*Apology received from Laurent Mertz*
Hungary	Csilla Pozsgay (member) Beatrix Horvath *(alternate)*
Malta	Gavril Flores *(alternate)*
Netherlands	Hugo Hurts *(member)* Birte van Elk *(observer)*
Austria	Thomas Reichhart *(alternate)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)* Magdalena Pajewska *(observer)*
Portugal	Rui Santos Ivo *(member)*
Romania	Alexandru Velicu *(member)* Ada Georgescu *(observer)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Andreja Čufar *(member)*[3]
Finland	Esa Heinonen *(alternate)*

2,3 Competing interest declared resulting in no participation in decision with respect to agenda points B.4 and B.5

	Participants
Sweden	Catarina Andersson Forsman *(member)* Sara Rosenmuller *(alternate)* Annika Wennberg *(observer)*
United Kingdom	Ian Hudson *(member)* Jonathan Mogford *(alternate)*
European Parliament	Björn Lemmer Tonio Borg
European Commission	Xavier Prats-Monné (DG SANTE) Carlo Pettinelli *(DG GROW)* Jerome Boehm DG Sante *(observer)* Chloe Spathari (DG GROW) *(observer)*
Representatives of patients' organisations	*Apology received from 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 Agnes Saint-Raymond Alexis Nolte Anthony Humphreys Enrica Alteri Fergus Sweeney Ivo Claassen Melanie Carr Nerimantas Steikūnas Stefano Marino Zaide Frias Edit Weidlich Anabela Marcal Wim Nuyts Monica Dias Marie-Agnes Heine Hilde Boone Silvia Fabiani Sophia Albuquerque