14 December 2018
EMA/MB/877601/2018 Adopted
Management Board

Minutes of the 102nd meeting of the Management Board

Held in London on 12-13 December 2018

The chair opened the last meeting of the Management Board to be held in the London premises of the Agency, and welcomed the new members and alternates: Anne Bucher, Director General for DG SANTE, Luca Li Bassi, member for Italy, Momir Radulović, member for Slovenia, and Giuseppe Amato, alternate for Italy.

Christa Wirthumer-Hoche informed the board that her mandate as chair will run out on 16 March 2019. The election for a new chair will take place at the beginning of the March meeting and Management Board members will be invited to submit nominations in the new year.

1. Draft agenda for 12-13 December 2018 meeting

[EMA/MB/297556/2018] The agenda was adopted with no amendments.

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 interest relating to the day's agenda were identified concerning the topics *"B.2 Revised policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market and revised guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS)/limited market, B.7 Yearly revision of the EMA Information Management Strategy and Information Management Strategic Plan, B.8 Programming, a) Programming 2019-2021, including 2019 work programme, budget, establishment plan, b) Draft programming 2019-2022".* 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.

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3. Minutes from the 101st meeting, held on 4 October 2018 adopted via written procedure

[EMA/MB/690649/2018] The Management Board noted the final minutes, adopted by written procedure on 7 December 2018.

4. EMA Preparedness on Brexit

4.1 Update on EMA Brexit preparedness

Preparations continue with a focus on those GMP inspections for CAPs where the involvement by the UK could extend beyond March 2019. These inspections will be re-assigned to other Member States. Similarly, the EMA inspection programme for 2019 will not include inspection requests to UK inspectorates.

Working Parties' elections of a new Chair/Vice-Chair will continue to take place at the end of their 3-year term, except for Working Parties where the Chair/Vice-Chair is from the UK. These elections will take place in February 2019. Similarly calls for expression of interest to replace MHRA and VMD experts have started to take place were relevant.

Actions to minimise the potential impact of Brexit on the supply of CAPs have continued, and the network has been provided with a current overview of the medicines which may be 'at risk', (based on timelines for submission of necessary regulatory changes), as well as a dedicated methodology for classification of critical medicinal products. The first step of the criticality assessment has been finalised by CHMP and CVMP in collaboration with the EMA secretariat. The therapeutic use criterion of the medicines 'at risk' was considered, and complemented by EMA with data on the availability of other medicinal products in the same class and generic medicines. As next steps EMA will send the complete dataset to each National Competent Authority (NCA) so that they can undertake the second step of the criticality assessment and conclude, after consideration of products and their alternatives available on their territory, whether the medicinal product should be considered critical in the Member State. Each NCA should provide the outcome of the second step of the criticality assessment to EMA, which will maintain a general overview at EU level of all critical CAPs. It should be noted that the information on medicinal products 'at risk' might be subject to change based on the regular monitoring of whether the necessary regulatory changes have or have not been submitted in the meantime taking into account updates provided by the Marketing Authorisation Holders (MAH).

At the October 2018 meeting it was agreed that EMA would base the draft 2019 and 2020 EMA Work Plan on the assumption that the number of staff who will be relocating will be sufficient to at least continue carrying out category 1A, 1B and Brexit activities. It is also assumed the anticipated staff levels as of the 2nd half of 2019 should allow EMA to gradually resume temporarily suspended/reduced activities as of July 2019, while activities in the period January to June 2019 would be further reduced as part of phase 4 of the BCP in view of staff loss, physical relocation and Brexit preparedness/implementation activities. It is planned that 2019 will be a year of transition, and 2020 will pave the way for the future. EMA's approach towards staff retention is based on robust planning and monitoring, as well as on prompt action where needed. Forecasts have been made more robust as staff are now providing information on their intended relocation date on an ongoing basis. These data confirm the trend seen over the past months. Figures at the end of November confirm the loss of short term contract staff reaching its peak by the end of February 2019, together with an increase in the numbers of longer term contract staff likely to resign. From March to June 2019, EMA will be most reliant on teleworking, and might see a further increase in longer term contract staff loss, partially compensated by recruitment of new staff and by the 40 Brexit related short term Contract Agents

which have been authorised by the Budgetary Authority to facilitate knowledge retention. From July to beyond 2020, further resignations are likely and will be matched with a further increase in recruitment of new staff. In view of the most recent figures on staff retention, the basis on which the Work Plan is set out will remain unchanged and will incorporate phase 4 of the BCP from January to June 2019. A gradual reactivation of activities will take place from July to December 2019, with a list of priorities including, where relevant and feasible, a reflection on longer term sustainability and will be presented for discussion at the June meeting of the Management Board. Robust monitoring of the volatile staff retention environment will be achieved through detailed planning at individual level, put in place by the Heads of Division in order to ensure that core activities can be carried out. Numerous elements including rules and policy, technology and equipment, as well as training have been put in place to ensure the robust planning and smooth implementation of extended teleworking of staff, as a key relocation support measure. A dedicated governance structure was set up and a dedicated methodology was developed in case urgent decisions concerning the re-allocation of staff need to be taken allowing fast track approval of resource replacement.

Members of the board appreciated the information provided and offered their support during the transition period. The Executive Director expressed gratitude and highlighted the possibility to backfill the 40 Brexit Contract Agents position with national experts on secondment (ENDs) for short periods, should there be delays in the hiring.

4.2 Update on EMA-NL collaboration for relocation to Amsterdam

The status report on the collaboration between EMA and the Dutch Authorities shows that progress is on track for the five work streams under the joint governance structure. For Work Stream 3 Financial and Legal Aspects, work is ongoing relating to the SLA and lease agreement for the Spark building, the accounting and reporting methodology for the EMA contribution for additional requirements for the final building, as well as for the implementation of Article 7 of the Seat Agreement with respect to security and protection of the EMA premises and their vicinity. Concerning the SLA and the legal agreement for the Spark building, those have to be finalised by 9 January 2019, in order to allow for the formal handover of the Spark building to the EMA, foreseen on this date.

4.3 Report on the EMA Management Board delegation visit to the future EMA premises

[EMA/MB/841077/2018; EMA/8050171/2018] The board noted the report on the EMA Management Board delegation visit to the future EMA premises which took place on 7 November 2018 on invitation by the Dutch Authorities. The delegation consisted of the Chair and the Vice-Chair of the Management Board and the board Topic Coordinators for the EMA building Karl Broich and Audun Hågå, as well as the Executive Director and Deputy Executive Director of EMA with relevant colleagues. The delegation was provided an overview of the construction plot of the EMA building. The construction is on track. Questions on stability measures in view of the type of ground and on the technology used for fast construction were answered satisfactorily. The delegation was extensively briefed on the future development of the Zuidas area, including the construction of two large hotels in the vicinity of the building. The visit ended at the Spark building, which is almost ready to be made available to the Agency on 1 January 2019. The delegation could satisfy itself that the conference rooms have a comparable capacity to that in the EMA Churchill Place building, and that everything necessary to have meetings in the Spark building will be available. In conclusion, the delegation was impressed by the quality of the work performed and reassured on the timely delivery of the new EMA premises.

The chair of the Management Board took the occasion to inform the board that as of its first meeting in Amsterdam the timing of the sessions will be moved an hour later in view of the different geographical location and travel connections.

A. Points for automatic adoption / endorsement

A.1 Financial compensation and workload estimation of the revised EMA organisation of translations of product related information

[EMA/MB/781386/2018; EMA/781387/2018] The Management Board endorsed the increased flat-hourly rate of €45 for 2015.

B. Points for discussion

B.1 Clinical Trials Information System required by the Clinical Trial Regulation

a) Update on the CTIS Project

[EMA/MB/744007/2018; EMA/743977/2018] The board noted the Update on the status of the development of the Clinical Trials Information System (CTIS). There is a significant delay in the delivery of the system for the User Acceptance Testing (UAT7) of Release 0.7 (auditable release) after the ongoing Site Acceptance Testing (SAT) identified necessary bug-fixings and additional findings were identified in a Preliminary User Acceptance Testing (pre-UAT7) on 5-13 November, in which both Member State and Sponsor UAT Champions participated. Member States UAT champions concluded that Release 0.7 of CTIS is not yet ready for a full UAT. Release 0.9 (safety reporting) is being developed under another contract and is making progress as planned. At the October meeting of the Management Board, the EU CTR Coordination Group was mandated to work on the implementation of the main recommendations from the external review reports, to supervise UAT7 and prepare the action plan with a clear time frame for the December meeting. In view of delays and slow rate of bug-fixing, EMA discussed with the Coordination Group in November and December possible options within the current landscape, which were then also submitted to the Topic Coordinators so that recommendations on the way forward could be prepared for the board.

b) Update from the EU CTR Coordination group

The board heard and discussed the update from the EU CTR Coordination group presented by Xavier De Cuyper and endorsed the recommendation of the EU CTR Coordination Group on options to ensure CTIS delivery. At the meeting of the Coordination Group in Vienna on 20 November the progress in the implementation of the new governance and the successful performance of pre-UAT7 with the involvement of Member States champions and experts was acknowledged. However, the high number of bugs and issues reported, as well as the overall delays incurred, prompted the Coordination Group to ask EMA to prepare options to mitigate further delays and ensure delivery of CTIS. The presented options were compared on the basis of criteria referring to time to deliver, risk level, estimation of cost and level of uncertainty. On this basis at the meeting of 6 December 2018 the EU CTR Coordination Group identified the option to revise the delivery approach requiring the Contractor currently developing CTIS to modify its delivery team accordingly, as the most likely to deliver with minimal delay a system which is meant to increase innovation and competitiveness in the EU for the benefit of

patients. Key success factors would include: requiring adhesion to strict timelines; adjusting the working methodology to a transparent iterative process and strengthened participation by end-users; limiting change requests in the interest of go-live of the system as soon as possible, but retaining the possibility to extend functionalities in the future; close monitoring of progress against milestones and timelines by a small subgroup of the Coordination Group and careful implementation of the project assurance recommendations, particularly in strengthening project management. The Management Board would decide after six months of activity whether the new approach is deemed appropriate to enable the Contractor to deliver release and system ready for UAT7. The EU CTR Coordination Group, in view of the great complexity of the project and the importance and urgency of the system for the EU, invited the board to endorse the option proposed, mandating the Coordination Group to implement this decision focussing on the delivery of a functional (basic) EUPD and reporting on progress on the basis of key success factors at every meeting of the board. EMA, with the support of the European Commission would be asked to prepare a fall-back solution in case the expected results are not being delivered after six months of activity.

In the discussion that followed there was a request for further assurance on involvement of experts and on improved project management. The representative of the European Commission DG SANTE stated that the Commission could back the option proposed by the EU CTR Coordination Group, as the one presenting fewer risks and timelines allowing implementation of the legislation on Clinical Trials by December 2020. The other conditions proposed by the Coordination Group are very important, in particular the proposal to review the decision in six months. Other members stressed that the decision in front of the board was only a first step, and that the new governance in place will allow closer collaboration, while the implementation of the recommendations of the independent project assurance reports might bring further benefit. The proposed solution is pragmatic and workable, and will be accompanied by mitigation measures and a fall-back plan. The Executive Director informed that he had considered the option of terminating the current contract for the development of CTIS and exploring other manners of delivering the system, but accepted the analysis and recommendation of the Coordination Group to revise the delivery approach, while a possible fall-back scenario is being prepared in case the expected results are not being delivered after six months. He reassured the board that EMA will continue to build the system beyond going live, and that the new sprint methodology together with proper capacity and capability resourcing at EMA based on the profiles suggested by the independent project assurance reports will bring improvements. The board endorsed the recommendations by the Coordination Group, including the request for full commitment by the Member States and EMA, and a review in six months' time.

B.2 Revised policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market and revised guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS)/limited market

[EMA/MB/706300/2018; EMA/308411/2014-Rev.1; EMA/CVMP/388694/2014-Rev.2] The Management Board adopted the revised policy. The revision had been adopted by the CVMP at their meeting of 6-8 November and the European Commission was consulted. No public consultation took place, as the aim of the revision is only to clarify that fee incentives can be granted only to applicants based within the EU.

B.3 Revision of the EVVET Access policy

[EMA/MB/697834/2018; EMA/113700/2008-Rev.1] The Management Board adopted the first revision of the EudraVigilance Access Policy for Medicines for Veterinary Use. The access policy now also refers to relevant new requirements from the New Veterinary Regulation (NVR), including changes that are dependent on the availability of new systems that are required for the implementation of the NVR in 3 years' time. However, taking into account the initiation of the EVVET3 project, the update to the Access Policy is due now to support the delivery of the new EudraVigilance functionalities. The draft revised EudraVigilance Access Policy for medicines for veterinary use was adopted for release for consultation by the CVMP in April 2018. An updated draft was subsequently endorsed by the PhVWP in July 2018, and adopted by CVMP in September 2018. The access policy adheres to the same overall principles, including personal data protection, as the access policy document regarding data held in EudraVigilance Human.

B.4 Impact of the new veterinary medicines legislation

The representative of DG SANTE introduced the main objectives of the NVR (New Veterinary Regulation) together with the upcoming steps and challenges in its implementation. When it becomes applicable in early 2022 it is expected that the NVR will provide incentives to stimulate innovation to increase availability of veterinary medicines and will strengthen EU action to fight antimicrobial resistance. The 26 implementing and delegating acts foreseen in the legislation have been split into 4 work packages staggered according to the urgency in the detailed deadline planning of the Commission. Seven mandates for scientific advice input from EMA are being elaborated within the first package. It is expected that all packages will entail work relevant for the network. The establishment of a Union products database and the further development of two other Union databases are foreseen. The Commission is in the lead of the implementation governance through the established institutional framework involving the Standing Committee, the Expert Group and EMA, but HMA will also be involved. In the meetings of 14 December of the Standing Committee and the Expert Group the process and the first mandates for EMA will be discussed. For the product database, the Commission proposes to act as the system owner during the development and will be in charge of quality assurance and control. Due to the date of adoption of the NVR it was not possible to include budget provisions (in addition to the ones already foreseen in the financial statement accompanying the proposal) in the 2019 EMA budget. For the 2020 budgetary procedure EMA will need to start discussions with DG SANTE's budgetary services already in January 2019 to justify resource requests which the Agency considers to be the result of additional tasks not initially foreseen in the legislative proposal.

EMA informed the Management Board on the proposed working methodology to deliver on its mandate. Following consultation of the Member States, the European Commission will mandate EMA to provide scientific advice or recommendations regarding certain implementing and delegated acts. It is expected that the first set of mandates will be provided to the Agency in mid-January, and EMA is preparing by setting up the expert groups that will work on these scientific advices. These will be made up of three to eight members, and will meet the first time physically at the Agency to agree approach and deliverables in order to be able to adhere to the demanding timelines mostly set for end of July 2019. After the first meeting, the expert groups will meet virtually every two weeks. CVMP discussion of the outcomes will be scheduled about 1 month before the delivery to the Commission is foreseen. CVMP will endorse the scientific advice as usual. Planning is ongoing at EMA to identify necessary resources due to the significant changes in provisions in the NVR since its inception in 2014, leading to much higher impact and cost than originally anticipated. For 2019 six or seven mandates are expected in January, at a time when the Agency will be most affected by the effects of relocation and staff lost. The current planning requires EMA to start work on an additional 12 mandates at the

same time between May and July 2019 bringing the total number of mandates to 19. EMA will issue requests for further experts to the NCAs once the mandates are received and understood.

In the discussion that followed the importance of a simple and transparent governance as a success factor was raised. Concern was expressed on the short timelines for the Scientific Opinions on the implementing and delegating acts. In this context the need for initial consultation of the mandates and for an involvement over two meetings of the CVMP before submission of the Scientific Opinions to the Commission was questioned, as well as for stakeholder workshops. Also, the governance for the IT databases involving EMA and HMA should be set up as soon as possible, since no mandate is needed, and more detailed information would be welcome. The representative of DG SANTE explained that timelines cannot be changed as they are included in the legislation, and implementing and delegating acts need to follow an established procedure. Optimisation of timelines might be achieved if some activities can be processed in parallel, and if members maintain close contacts with the members of the bodies that will eventually vote on the acts. Concerning IT out of the 3 databases foreseen in the NVR, two may be delivered by enhancing existing systems, while delivery of the Union Product Database may require delivery of a new system. After delivery, EMA will become the system owner of these IT systems. With regards to the role of CVMP, EMA specified that when the Agency is asked to deliver a Scientific Advice to the Commission, it does so through its committees which provide the best possible advice, and it is doubtful that this can happen over a single meeting. The Union Database will be pivotal for the success of the NVR and will need to be built with strong links to the other systems from the beginning. The possible impact on NCA fee income as a result of the changes envisaged in the New Veterinary Regulation was raised by one member. In response to a question on the composition of the expert groups, it was noted that nominations including CVs have been received, and are being used to populate the expert groups with good and committed experts.

B.5 Highlights of the Executive Director

EU Activities

The Executive Director had his 'annual exchange of view' at the European Parliament's ENVI committee on 19 November. MEPs were informed of the main achievements of the Agency in 2018, with a focus on activities related to Brexit preparedness, paediatrics, AMR, access to medicines, and regulatory-science strategy, as well as the next phases of the Agency's relocation to Amsterdam. The need to futureproof EMA and the regulatory framework and to develop a regulatory science strategy to address challenges and to inform future legislative changes together within the European Medicines Regulatory Network and with the EC was mentioned. MEPs were appreciative of the work of the Agency and also asked whether EMA had received sufficient resources to cope with the relocation on top of the constantly increasing workload. A revised Memorandum of Understanding on Working Arrangements between EMA and EMCDDA (European Monitoring Centre for Drugs and Drug Addiction) was signed on 7 December. Cooperation between EMA and EMCDDA in the area of new psychoactive substances was discussed.

International activities

The Executive Director was invited to give the keynote speech on Innovation at the Annual Japanese DIA meeting which took place in Tokyo on 11-12 November. He presented the EMA Regulatory Science Strategy with some first comments from the workshop. On 11-12 October EMA attended the bilateral EU-China near Shanghai. There was a follow up videoconference with on 11 December with participation of EDQM, the Italian GMP inspectors and the European Commission to discuss the Valsartan case.

MRCT Center of Brigham and Women's hospital and Harvard Annual Meeting, Boston

In his presentation, the Executive Director took the opportunity to explain to a qualified American public the principal features of GDPR as concerns have been raised about the use of secondary data in research in the EU. Upon return to London further questions were received, to which answers will be sought.

Court case on 30 Churchill Place lease

The trial will start on 14 January 2019 and a judgment is expected before 29 March 2019. EMA has been also pursuing a commercial solution, such as the assignment or sub-letting of these premises to another operator and is in touch with DG SANTE and DG BUDG for this matter.

16th EMA/EUnetHTA dialogue meeting on 7 December

On 7 December, the Agency hosted the 16th bilateral meeting with the European network for Health Technology Assessment (EUnetHTA). Key discussion topics were: progressing different aspects of optimising evidence generation prospectively; development of guidelines and opportunities for enhanced collaboration; optimising the exchange at time of market entry; principles for the wording of the indication; and joint analysis on the concepts of significant benefit and relative effectiveness.

European Medicines Agency (EMA) / Heads of Medicines Agencies (HMA) / European Commission (EC) workshop on electronic product information (ePI)

On 28 November, EMA hosted a workshop on the joint EMA-HMA-EC initiative on electronic product information (ePI). The workshop brought together patients, consumers, healthcare professionals, regulators, HTA bodies, academia and industry. The workshop opened with a video by Commissioner Vytenis Andriukaitis on the potential that digital technology and innovative tools have on empowering citizens by involving them at the centre of healthcare systems. The workshop is the culmination of a year-long mapping, analysis and consultation process on the topic. Member States, European Commission and stakeholders emphasised the importance of acting now, at EU level, to avoid parallel development of incompatible systems. An important first step in the implementation that will need to be prioritised is the selection of a common EU standard to ensure harmonisation. The workshop concluded with the agreement of draft key principles of a joint EMA–HMA–EC collaboration, setting the grounds for implementing ePI in the EU. These will be released for public consultation in January 2019. A roadmap will be proposed by HMA and EMA to guide implementation.

Several members welcomed the progress in the collaboration of EMA with HTA bodies. The representative of patients' organisations invited all to keep the requirements simple so as not to delay access for patients and not to negatively impact competitiveness in the EU.

B.6 Report from the European Commission

Brexit preparedness

The Commission held the 2nd Technical Expert Seminar for Brexit preparedness on 23 October to inform on state of play and preparedness at EU and Member State level. On 13 December the Commission adopted a Communication on a Brexit contingency plan. Medicines were assessed but no legislative proposal is envisaged.

Falsified Medicines Directive

The safety features on all prescription medicines have to be implemented by February 2019. Discussion continues on how to overcome difficulties for hospitals and pharmacies. Member States

were reminded to feed and update the information on wholesale distributors in EUdraGMP. A communication to citizens is planned for 9 February 2019.

EU orphan and paediatric

Public and targeted consultations for the evaluation of existing legislation will be held until the end of the year. All members of the COMP, PDCO and CAT have received an invitation to complete the survey. The evaluation will be completed in Q3 2019 in the form of a Commission Staff Working Document.

Review of the EMA fee system

The evaluation of the fees system is expected to be finalised in January 2019. Before finalisation the drafting of a Staff Working Document presenting the evaluation process, evidence base, analysis and findings as well as and internal review process and consultation are due. Next steps will address the analysis of "additional activities" starting in Q1 2019 and the launch of an impact assessment including possible policy options in Q2/Q3 2019.

Study on marketing authorisation procedures

The study is progressing, with written NCA questionnaire and its follow-up ongoing, while the EMA interviews have been completed. National case studies with 8 Member States are being launched and should be completed by February 2019.

International activities

The EU-US MRA is progressing and will lead to the reduction of duplicate inspection resources. Discussions are ongoing between the Commission/EMA and the FDA Centre for Veterinary Medicines to plan audits in 2019/2020. The US audit is planned to take place in Q3 leading to a possible recognition in July 2019. At the end of 2019, assessments of GMP compliance and of marketing authorisations for Montenegro and Serbia will take place, as they are priority EU candidate countries in the EU enlargement perspective by 2025.

Concerning preparations for Brexit, some concern was expressed by a member on the subject of NAPs, which form the majority of products in the EU, and for which there is currently insufficient information available regarding their preparedness . The representative of the Commission was aware of the difference in knowledge between CAPs and NAPs, but stated that much progress has been achieved for the latter in the last two months in terms of coordination and identification of medicines 'at risk'. Answering to a question on possible indications of intentions concerning future fees, the representative of DG SANTE praised the excellent cooperation which had taken place so far with the NCAs, and explained that facts and studies will now be used to prepare the inception impact assessment to start discussions.

B.7 Yearly revision of the EMA Information Management Strategy and Information Management Strategic Plan

[EMA/MB/831845/2018; EMA/831036/2018; EMA/502708/2018] The Management Board endorsed the revised EMA Information Management Strategy 2019-2021 and the Information Management Strategic Plan 2019-2021. According to the EMA's IT governance, yearly review and endorsement by the board takes place as part of the yearly planning cycle to take into account changes in the environment and priorities. The current proposal was based on a reflection on how the Agency has delivered on its strategy in the last year. All activities relating to the relocation of IT and of the audio-visual systems, progressed extremely well and are on track. Concerning projects in 2018, work was performed according to plan, with the exception of the Clinical Trials Information System. In 2019 the

focus will continue to be on the fitting out of the final EMA building, but also on GDPR implementation and security, analytics, foundations for SMS and PMS, the Clinical Trials Information System and EVVet 3 capabilities, as well as the IRIS platform which will support all EMA tracking systems in the future. Limited capacity in staffing resources might prove a challenge for the implementation of the new veterinary Regulation and for the rationalisation of systems. The Information Management Strategy will put in place a Target Operating Model so that the Agency and the network can leverage technology efficiently and effectively to deliver on legislative requirements and business strategy. The main enhancements in the strategy and the plan will focus on upgrading technology underpinning core regulatory and administrative activities at EMA, putting in place better data analytics, strengthening information security while continuing to deliver legislative requirements. Main challenges will derive from 25 years of complex legacy, exponential growth of costs of portfolios, complexity of the ecosystem of the Agencies and the continuing relocation effort with its risk of loss of staff throughout 2019.

While supporting the Agency in the implementation of the strategy, some members suggested a future discussion on its cost-effectiveness. The representative of DG SANTE acknowledged the challenges that lie ahead in the next 12 months for this ambitious programme, and stressed the priorities of fulfilling legislative requirements and carrying out a successful relocation.

B.8 Programming

a) Programming 2019-2021, including 2019 work programme, budget, establishment plan

b) Draft programming 2019-2022

[EMA/MB/831121/2018; EMA/73195/2018; EMA/MB/847697/2018; EMA/639690/2018] The Management Board adopted the 2019-2021 Programming document and the budget 2019. The Programming document 2019-2022 is presented as a single document and is made up of the Programming 2019-2021, which includes the final 2019 work programme, budget and establishment plan, and the Draft programming 2020-2022. After adoption by the board, the Agency will include any comments received, update the final 2018 figures and divide the documents presented into two separate ones, which will be circulated to the board before being mailed to the European Commission and other institutions by 31 January 2019. In order to facilitate the discussion of the Programming document, the presentation to the board was structured according to the different components of the package: Work programme overview, draft budget 2019 and preliminary budget 2020, IT budget and projects. The Topic Coordinators Grzegorz Cessak, Catarina Andersson Forsman, Nancy De Briyne and Lorraine Nolan had performed the role of examining the evolving documents on behalf of the board over three months and took part in the presentation.

2019 will be a year of transition, which will take place in two parts. During the first half of the year EMA will have to go through with the physical relocation to Amsterdam while coping with important staff loss and an important workload increase as a consequence of Brexit arrangements. During this period the Agency will operate under phase 4 of the BCP. From July until the end of the year the Agency will gradually take up previously temporarily suspended or reduced activities taking into account the resources available, in line with the priorities identified in the network strategy to 2020, and based on a reflection on the most efficient way to achieve longer term fit-for-purpose processes and sustainability.

Over the years trends on workload and resulting fees for activities linked to innovation and development have been positive or reached a high and stable level. As far as authorisation and

maintenance workload trends are concerned, the Agency is experiencing a dip in initial applications for the next few years, mirrored by a decrease in revenue, as well as expected fluctuations in Type II variations. The total difference in the total expected fee income for 2019 compared to the budgeted 2018 amounts to a decrease by 2.4%. While these trends are not significant *per se*, the Agency will monitor and analyse these developments and their possible long term causes. Other workload trends, such as for pharmacovigilance activities, appear more stable. Further attention is needed for the intense workload to prepare the Agency for the implementation of the provisions of the new veterinary regulation that will come into effect in 2022. The Work programme takes into consideration the effects of Brexit and the need for the EMA to comply with its legal role. The Topic Coordinators recommended its adoption after an analysis of three main factors: EMA's core activities will be maintained at the same high level of quality and compliance with timelines, while maintaining the infrastructure of the EU regulatory system for medicines; the BCP is implemented clearly in the Work programme, indicating where temporary reductions and suspensions of activities are foreseen according to priority categories; risks have been clearly identified so that mitigating and corrective actions can be put in place. Reservations must however be expressed on the very limited budget foreseen for the implementation of the new veterinary regulation which will take place in the next three years and will require substantial human and financial resources to face increased workload and the running and maintenance of new databases.

On the budgetary side, different components contribute to a reduction of ca. EUR 7.3 million, partially offset by corresponding payments to NCAs and lower meeting costs due to the ongoing BCP. For 2019 Brexit related costs amount to EUR 45 million. Brexit related expenditure features in the 2019 and 2020, with expenses for staff relocation, removal costs, archiving, legal and consultancy expenses mostly in impacting the 2019 budget. Both 2019 and 2020 budgets assume an overall staff loss of 20%, mitigated by an intensive recruitment programme, and reinforced by additional Brexit contract agent resources (up to 40 FTE). On the basis of sound financial management, the 2019 budgets and preliminary 2020 budget include the level of provisional appropriations (EUR 14.4 million in 2019 and EUR 19.1 million in 2020) that can be borne while still presenting a balanced budget. Staffing at the Agency in 2019 is increased by 4 out of the 11 FTEs requested for 'business as usual' activities. For 2020 EMA will request additional 11 temporary agent posts to cope with growing fee-financed workload. A further headcount-neutral establishment plan evolution is provided by the conversion of 25 AST to AD posts in 2019, and further 25 conversions to be requested in 2020 in line with the evolving competency requirements of the Agency. Up to 40 time-limited Contract Agent posts will be recruited in 2019 and gradually phased out in 2020 and 2021 to support knowledge transfer and business continuity as part of the relocation. A detailed analysis of the evolution of the IT budget was provided, together with the reasons for requesting non-automatic carry-forwards from 2018 to 2019 for certain projects which were costed and included in the budget and Work programme 2018 but for which the Agency will not be in a position to conclude specific contracts with the respective service/goods provider before the end of the year. Benchmarking EMA's IT expenditure for services for 13.2% of the IT budget, compares favourably given the significant expenditure on Telematics, while an estimated 54% of IT expenditure goes towards the provision of IT services to the NCAs.

The representative of DG SANTE warned that growth in staffing levels will become increasingly harder to achieve. The Executive Director acknowledged this and thanked the Commission for its support and guidance.

c) Preparation for written procedure on non-automatic carry-over of appropriations from 2018 to 2019 for EvVet3 project

[EMA/MB/844868/2018] The board noted the preparation for the adoption by written procedure of the non-automatic carry over of appropriations to be launched in January 2018.

B.9 Revision of rules for reimbursement of expenses for delegates attending meetings

[EMA/MB/804662/2018; EMA/MB/279597/2018] The Management Board adopted the revised rules for reimbursement of expenses for delegates attending meetings. The rules were revised to adapt to the new location of the Agency in Amsterdam, while achieving administrative streamlining and maintaining the overall entitlement for the delegates, and will come into effect on 30 March 2019. The Agency has been considering improving its processes taking into account modern technologies to modernise travel and booking tools. The main changes compared to the previous rules are the replacement of 'Place of employment' with 'Place of origin'; a new booking method directly through the EMA maintaining the same previous level of flexibility, and establishing a flat rate accommodation reimbursement for bookings not processed through EMA; access to EMA negotiated rates also to non-reimbursed participants. Processing of individual reimbursements relating to bookings not processed by EMA will no longer be possible, given the labour intensive handling of such requests at a time of reduced staffing. The simplification in reimbursements will shorten the time limit for requests from 60 to 30 calendar days. An online booking tool[*] will be set up by a contractor starting in May-June 2019. In the meantime the contractor will secure hotel rooms in the vicinity of the Spark building for the meetings taking place in February and March 2019.

In the discussion that followed some members questioned travel conditions and rationale for certain ceilings applied to reimbursements, and expressed concerns over possible loss of flexibility in accommodating delegates' requests. The Executive Director explained that ceilings and travel rules are derived from Commission rules, and assured that flexibility of arrangements will be assured through a wide offer of hotels at negotiated rates, as well as by maintaining freedom of choice for NCAs over modalities of reimbursements. Concerning the possibility of making changes to daily allowances for certain groups of delegates, this should be part of a separate discussion at the board. The chair decided to put to a vote the adoption of the revision of the rules for reimbursement of expenses for delegates attending meetings. The results were as follows:

Total no. votes	Not present	Votes cast	Votes in favour	Votes against	Abstained
36	1	35	29	3	3

The vote took place electronically and openly, in full view of all present. The full details of votes by delegation and proxies can be found in Annex 1.

B.10 Audit Strategy and Annual Audit Plan

a) Audit Strategy 2019 – 2021 and Annual Audit Plan for 2019

[EMA/MB/758750/2017; EMA/803113/2017] The Management Board adopted the Audit Strategy 2019-2021 and the Annual Audit Plan for 2019. The Audit Strategy was prepared on the basis of the analysis of the Agency's risk register and applicable legal requirements and was discussed with EMA Senior Management. In 2019 the number of audits to be performed will be lower than in 2018 as a consequence of BCP. Workload will instead shift during the first semester, when no audits are scheduled to take place, to consultancy engagements and planning activities ahead of the audit

[*] At the end to the meeting the company selected by EMA to handle its travel operations provided a demonstration of the functionality of the system that will be used to deliver services to delegates.

engagements. The Agency will be subject in 2019 to 6 audits and 4 consultancy engagements. Any change to the Audit Plan would be submitted to the Management Board for agreement.

b) Final Audit Report on Signal Management conducted in 2018 by the IAS

[EMA/MB/797878/2018; EXT/797887/2018] The Management Board noted the Final Audit Report on Signal Management in the European Medicines Agency conducted in 2018 by the Internal Audit Service of the European Commission. The audit scope covered the entire signal management process from the detection of new safety signals for CAPs to the issuance of PRAC recommendations on signals from CAPs and NAPs. The IAS concluded that the design and practical implementation of the management and internal control system in the EMA with regard to its mandate, role, responsibilities, and tasks related to the process of signal management are effective and efficient. No major findings were raised, however among the four recommendations rated "important" the IAS recommended as a priority to develop an integrated automated tool to cover all steps for the process of signal management.

A member requested information on whether IAS or ECA would be able to attend a meeting of the board to report directly. He was informed that both bodies had been approached and would try to find time in their busy schedule.

c) Report to the Management Board on Pharmacovigilance Audits carried out at EMA from 1st July 2016 to 30th June 2018

[EMA/MB/826417/2018; EMA/703195/2018] The board endorsed the Report to the Management Board on Pharmacovigilance audits carried out in the European Medicines Agency from 1 July 2016 to 30 June 2018 presented to the board in conformity with Article 28f of Regulation (EC) No. 726/2004. The report outlines external and internal audits performed on the Agency's tasks and activities that impact on the operation of the EMA Pharmacovigilance System. The report provides the status of implementation for critical and very important actions related to previous reporting periods and no critical action is outstanding, while five corrective actions are ongoing due to projects reprioritisation.

B.11 Revision of the Internal Control Framework - 2018

[EMA/804508/2018; EMA/11654/2018] The Management Board adopted the revised Internal Control Framework (ICF) which is based on the revised Commission's framework which was adopted on 19 April 2017. The board had adopted the Internal Control Standards for effective management in 2008 and revised them in 2010 and 2015. This new revision moves away from a purely compliance-based to principle-based system.

B.12 Improving completeness of Art 57 database

[EMA/MB/788636/2018; EMA/788639/2018] The Management Board endorsed the document Improving completeness of Art 57 database - Plan to continue mapping national databases. The submission of data on medicines by the MAHs is a legal requirement introduced by Article 57(2) of Regulation (EU) No 726/2004. To date the so called Article 57 data base contains information on ca. 700,000 products of 5,000 MAHs and is the single most complete repository in the EU. MAHs are responsible for the data provided, and EMA can check completeness and quality of the information only against the SmPCs provided in it. Based on a 'completeness exercise', conducted by EMA comparing 15 national product databases with information contained in the Article 57 database, the completeness level is estimated to be 97-98%. In order to satisfy a recommendation by the IAS, EMA would like to continue the 'completeness exercise' with the remaining Member States to improve the completeness of the database. Pending the long term solution provided by the implementation of the ISO IDMP

standards, EMA proposed a plan to extend the exercise to all NCAs in blocks that will take into account resources at the national and the EMA level. NCAs taking part in the exercise will provide an export of their national database to EMA which will perform the comparison with the Article 57 database. EMA will liaise with NCAs to identify participating authorities and facilitate the implementation plan.

B.13 Communication on EMA regulatory processes

[EMA/MB/840333/2018; EMA/103813/2018] The board noted the content of the communication material prepared by EMA to explain its pre-submission and authorisation processes in a simple language which will allow a larger audience, in particular those who have an interest in EMA but are not familiar with its processes, to understand better how the Agency and the Network work to assess medicines. The content will be delivered on the website with interactive features, and as brochures, presentations, videos and in scientific publications for more specialised audiences.

Several members intervened in the discussion to stress the importance of addressing misconceptions concerning regulatory work and independence, in particular the pre-approval processes, and providing clear explanations of the regulatory system to all stakeholders including healthcare professionals. The representative of DG SANTE underlined the importance of continuous engagement with stakeholders and the European Ombudsman to substantiate transparency and vigilance of the processes.

B.14 HMA-EMA Joint Big Data Taskforce Report

[EMA/MB/796769/2018; EMA/799916/2018] The Management Board discussed the HMA-EMA Joint Big Data Taskforce summary report to be adopted by written procedure by the board and by HMA in January, as a requirement for publication, and endorsed the extension of the Taskforce mandate for 12 months. The mandate of the Task Force foresees mapping of relevant sources of big data and defining the main format in which they are expected to exist; identifying areas of usability and applicability of data for decision making; describing the current state of expertise, future needs and challenges and generating a list of recommendations and a Big Data Roadmap. In order to finalise the work of the data analytics subgroup and to plan for the next phase of work, the Task Force has requested an extension of the current mandate for 12 months. HMA agreed, noting that this extension has no resource implications beyond the current Task Force membership. HMA further emphasised the need for engagement with the Telematics Management Board and the need to include Big Data topics within the EU NTC training programme. The Task Force will report back to HMA and to the Management Board at 6 months for feedback including an estimate of resource needs and at 12 months with proposals for implementation.

Members supported the extension of the work of the Task Force and stressed the importance of preparing the European regulatory system for the challenges but also the opportunities presented by new datasources. New ethical implications and pooling of fit-for-purpose resources will have to be looked into, as well as into the identification of areas where concrete advancement is possible. The representative of DG SANTE congratulated the Task Force and pointed out that the stakeholder mapping has identified a number of players. The Commission is reflecting on an operational framework and on how to integrate big data into current work on standards. The question on the link to the work on regulatory strategy also arises. EMA agreed that work on Big Data will feed into the discussion on regulatory strategy, and assured the board that the Task Force intends to do further work on data protection now that GDPR is in force.

B.15 Implementation of medical devices and in-vitro diagnostic regulations

The representative of DG GROW updated the board on the state of play concerning the implementation of the new EU Regulations on medical devices. Following their entry into force on 25 May 2017, the

transitional period has begun with full application of the of the Regulation on medical devices (EU) 2017/745 on 26 May 2020 and of the Regulation on in vitro diagnostic medical devices (IVDs) (EU) 2017/746 on 26 May 2022. A strenghtened EU governance framework was laid down in the new Regulations and foresees reinforced coordination through the newly established Medical Device Coordination Group (MDCG), chaired by the Commission, with technical scientific and logistic support provided by DG GROW, DG SANTE and DG JRC. Furthermore, a Committee on Medical Devices will act as the "Comitology" Committee for both medical devices and IVDs. The establishment of the new technical Expert Groups (MDCG subgroups) will be completed in Q1 2019. The new designation procedure for the Notified Bodies was launched through the adoption of a specific Implementing Act by the Commission on 26 November 2017 and by November 2018, 35 applications had been received by the Commission services and 25 joint assessments scheduled or completed. Full scope of MDR and IVDR is covered in the applications. The plan for the implementation of functional specification of the EUDAMED database was completed in May 2018 and work is ongoing on design and establishment. The Commission has developed a rolling plan to monitor the implementation of the Medical Device Legislation which is updated four times a year and is publicly available on the Internet. Cooperation with EMA staff is very constructive and addresses areas that are linked to medicines such as drug/device combination products and companion diagnostics. Regular teleconferences take place between services of DG GROW, DG SANTE and EMA and address for the time being the topics of application of Article 117 of the new Regulation on medical devices, in vitro diagnostics (i.e. companion diagnostics) and borderline issues.

EMA informed the board about how the Agency is preparing for the parts of the regulations that will affect it. The MDR and IVDR will lead to new or revised roles and responsibilities for medicines authorities and the EMA. Specifically, the consultation by a Notified Body on medical devices composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body, and the consultation on companion diagnostic are new. Furthermore, marketing authorisation dossiers with medicinal products with integral device component will need to contain a declaration of conformity (CE mark) or a Notified Body opinion (MDR Article 117). Implementation is progressing in all areas. On integral drug – device combinations (MDR Art. 117) in particular, QWP/BWP are preparing a draft guideline on dossier requirements; in addition, EMA received feedback by the Commission on a first draft Q&A on implementation of Art 117. In the Commission and CAMD implementation roadmap the EMA has been specifically identified as responsible party for companion diagnostics and combination products. The Agency has taken every opportunity to raise awareness on requirements with stakeholders, such as SMEs and industry. Significant concern has been expressed on Article 117 as to the level of interactions required between the Agency and the Notified Bodies. Initial feedback from a survey conducted by industry on planned submission of drug-device combinations has been shared. Further topics on which EMA would like to reflect on concern the need to further strengthen cooperation between medicines and device agencies, identifying contact points at each national competent authority for medicinal products, as well as, depending on the impact of Notified Bodies availability, potential alternative solutions on the approval of medicines that contain an integral device component.

Questions from board members to DG GROW focussed on concerns regarding possible delays in the development of EUDAMED and on the availability and competence of the Notified Bodies in order to fulfil the requirements of Article 117. The representative of DG GROW indicated to the board that the Commission is monitoring the implementation process in a proactive and transparent manner together with entities empowered by the Regulations (MDCG and Committee). This includes the development of EUDAMED, also through a detailed rolling plan, and is engaged in analysing capacity and capability of the Notified Bodies, but finally the Member States remain the key player for final designation.

B.16 EMA's Regulatory Science to 2025

The board heard how EMA intends to address challenges and opportunities across the European Regulatory Framework responding to the needs of the 21st century patient. The reflection is needed now to identify key priorities where new or enhanced engagement is essential to the continued success of the Agency's mission and in order to prioritise use of resources and external collaborations to strategically advance regulatory science. This is defined at EMA as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied medicinal science and social sciences, and contributes to the development of regulatory standards and tools. By discussing technology platforms and elements of transformation with a multitude of stakeholders a Human and a Veterinary vision for the EMA Regulatory Science to 2025 are emerging. These ambitions are captured under strategic goals discussed during two large workshops (one Human on 24 October 2018, the other veterinary on 6 December 2018), to launch stakeholder consultations. EMA is grateful to the European Commission and members of the board who attended the workshops and supported the initiative. The public consultations will extend until Q2 2019 and will be followed by a consolidation workshop in Q4 2019 ahead of feeding into the discussion on EMRN Strategy to 2025 in Q1 2020.

Members were very appreciative of the initiative which will be helpful in identifying goals and hurdles and defining ambitions at the EU level. The representative of DG SANTE reminded the board of their joint work with DG Research in the area of health within Horizon Europe.

B.17 Annual report on the implementation of the EMA's Anti-Fraud Strategy (AFS)

[EMA/MB/856579/2018] The Management Board noted the Annual report on the implementation of the EMA's Anti-Fraud Strategy. In December 2017 the Management Board adopted the revised Anti-Fraud Strategy and related Action Plan for 2018-2020. All the 7 foreseen actions were duly implemented, however the one concerning the Document Classification Policy will be fully operational in 2019, as it requires the use of IT tools and training activities to facilitate implementation. 2 actions to be performed on an annual basis were also finalised. No administrative enquiry was launched. Overall the implementation of the AFS and of the related Action Plan was positively completed in 2018. Some points, like the finalisation of the implementation of the Document Classification Policy and the IT tools supporting it, will require attention in 2019. Training activities for staff and contractors will continue as planned.

a) Intellectual property rights for EMA staff members

[EMA/259494/2016, Rev. 1] The board adopted the revised Decision on rules concerning the handling of declared interests of staff members. The amendment focussed on the declaration by EMA staff members of past intellectual property rights related to medicinal products or uses of such products, including patent ownership and patent applications, along the lines of a Recommendation by the European Ombudsman. The amended declaration of interests form will be fully operational starting from the declaration of interests due in 2019.

List of written procedures finalised during the period from 11 September 2018 to 23 November 2018

Documents for information

- [EMA/MB/810771/2018; EMA/766615/2018] Report on EU Telematics
- [EXT/860318/2018] Feedback from the Heads of Medicines Agencies
- [EMA/MB/810142/2018] Outcome of written procedures finalised during the period from 11 September 2018 to 23 November 2018
- [EMA/MB/832177/2018] Summary of the transfers of appropriation 2018

List of participants at the 101st meeting of the Management Board, held in London, 4 October 2018

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	*Apology received from Bogdan Kirilov*
Czech Republic	*Apology received from Irena Storová*
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)*[1] Mette Aaboe Hansen *(alternate)* Tina Engraff *(observer)*
Germany	*Apology received from Karl Broich* Wiebke Loebker *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	*Apology received from Aikaterina Antoniou*
Spain	María Jesús Lamas Diaz *(member)* César Hernández *(alternate*) María Jesús Alcaraz Tomas *(observer)*
France	Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Luca Li Bassi (member) Giuseppe Amato (alternate) Gabriella Conti (observer)
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	*Apology received from Laurent Mertz*
Hungary	Beatrix Horvath *(alternate)*
Malta	John-Joseph Borg *(member)*
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)* Maria Joao Morais *(observer)*
Romania	*Apology received from Adriana Cotel*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Momir Radulović *(member)* [1]
Finland	Eija Pelkonen *(member)*
Sweden	Catarina Andersson Forsman *(member)* Åsa Kumlin Howell *(observer)*

[*] *Competing interest declared resulting in no participation in decision with respect to agenda points B.2, B.7, B.8, B.8.a and B.8.*

United Kingdom	Jonathan Mogford *(alternate)*
European Parliament	Björn Lemmer *Apology received from Tonio Borg*
European Commission	Anne Bucher (DG SANTE) Carlo Pettinelli (DG GROW) Jerome Boehm DG Sante *(observer)* Chloe Spathari (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 Tomasz Jablonski Zaide Frias Christine Bugge Anabela Marcal Marie-Agnes Heine Monica Dias Mario Benetti Michael Lenihan Edit Weidlich Franck Diafouka Frances Nuttall Hilde Boone Silvia Fabiani Sophia Albuquerque

Annex 1 - Vote on the adoption of agenda item B.9 Revision of rules for reimbursement of expenses for delegates attending meetings

Proxies announced by the Chair

- Tonio Borg (European Parliament) to Bjoern Lemmer (European Parliament)
- Bogdan Kirilov (Bulgaria) to Thomas Senderovitz (Denmark)
- Irena Storova (Czech Republic) to Zuzana Batova (Slovak Republic)
- Karl Broich (Germany) to Xavier de Cuyper (Belgium)
- Aikaterina Antoniou (Greece) to Loizos Panayi (Cyprus)
- Laurent Mertz (Luxembourg) to Hugo Hurts (Netherlands)
- Adriana Cotel (Romania) to John Borg (Malta)

In favour	Against	Abstained
29	Cyprus Greece Malta	Hungary Slovenia The Netherlands