22 March 2019
EMA/MB/188256/2019 Adopted
Management Board

Minutes of the 103rd meeting of the Management Board

Held in Amsterdam on 21 March 2019

The Vice-Chair of the Management Board, Grzegorz Cessak, welcomed members to the first meeting held in the Spark building in Amsterdam. This is a significant moment in the long history of the board, marking the extraordinary circumstance of Brexit. He thanked the Executive Director and his staff for the successful effort in the relocation of the Agency to Amsterdam. A special welcome was extended to the new members and alternates: Bogdan Kirilov, member for Bulgaria, Mátyás Szentiványi, member for Hungary, Marius Daniel Șișu, member for Romania and Roxana Stroe, alternate for Romania. The Vice-chair informed the board of the upcoming expiry of Prof Lemmer's mandate, whom he thanked for eleven years of support, as well as Gintautas Barcys, who had been a member of the Board since 2011.

1. Draft agenda for 21 March 2019 meeting

[EMA/MB/916015/2019] The agenda was adopted without 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 interests relating to the day's agenda were identified concerning the topics *"5.4 Amending Budget 01-2019; B.5 Revised implementing rules to the Fee Regulation as of 1 April 2019; B.12 EMA Policy on the Publication of Clinical Data: Revision of the Terms of Use: third party contractual rights; B.13 Preparation for a written procedure for the adoption of the Revision of the breach of trust procedure on declarations of competing interests for Management Board members".* 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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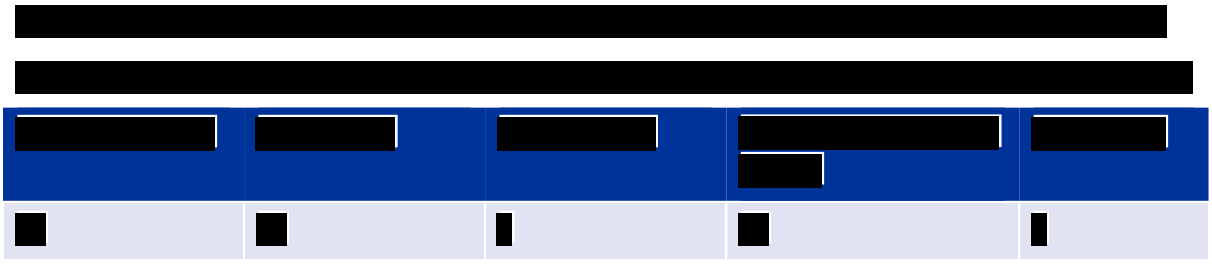
3. Election of the Chair of the Management Board (in camera)

[EMA/MB/916040/2019; EMA/MB/13585/2019] The election of the Chair was held *in camera* and was attended only by members or their alternates, the observers from EEA countries and a limited number of EMA staff.

In accordance with the election procedure the Vice-Chair announced votes by proxy:

- Ioannis Malemis (Greece), proxy to Loizos Panayi (Cyprus)

The Board appointed Runa Hauksdottir Hvannberg, Brigitte Batliner and Audun Hågå, observers from Iceland, Liechtenstein and Norway, to act as tellers. The vote took place by secret ballot.



The Management Board re-elected Christa Wirthumer-Hoche, representing Austria, as the Chair for further three years. The Chair thanked the Management Board and assured members of her ambition to ensure a strong partnership between EMA, the European Union national competent authorities and the European Commission, to facilitate EMA's important role of safeguarding human and animal health in Europe.

Following the election Christa Wirthumer-Hoche chaired the meeting. She invited nominations for Topic Coordinators for the Analysis and Assessment of the Executive Director's Annual Activity Report (AAR) 2018 to be delivered at the June meeting. Nancy De Briyne (vet representative) and Audun Hågå (Norway) were re-appointed and were joined by María Jesús Lamas Diaz (Spain). Anne Bucher was designated by the board as reporting officer for the appraisal of the Executive Director replacing Xavier Prats Monné.

4. Minutes from the 102nd meeting, held on 12-13 December 2018 adopted via written procedure

[EMA/MB/877601/2018] The Management Board noted the final minutes, adopted by written procedure on 20 February 2019.

5. EMA Preparedness on Brexit

5.1 Update on EMA Brexit preparedness

5.1.1 Progress report on operational aspects

The board was updated on the potential impact of Brexit on the supply of Centrally Authorised Products (CAPs). Following a two batches criticality assessment conducted in collaboration with the National Competent Authorities (NCAs) information has been received from most Member States. Eleven medicines were considered critical in total by NCAs for human and veterinary products, but the number had been further reduced at the time of the meeting of the board, as the situation is subject to daily changes.

As a follow-up to the 3rd Technical Seminar on Brexit organised by the European Commission on 18 February 2019, the Commission published a notice on EU rules for batch testing of medicines in relation to the UK's withdrawal from the EU by which MAHs may be allowed, for a limited amount of time and under strict conditions, to rely on quality control testing performed in the UK. A practical guidance and a template for requests were subsequently published by EMA to reach a harmonised approach within the network. For products found to be non-compliant after the UK withdraws from the EU, EMA and NCAs will contact the MAHs asking them to remedy the situation within a short time-frame and informing them that no new batches can be put on the market until the situation is rectified. A coordinated approach and communication on possible medicines shortages as a result of Brexit is needed for both CAPs and non-CAPs. It was proposed to use an existing forum, i.e. the EU executive task force operational in the context of the incident management plan for human medicines to steer the process in a coordinated way, and agree on crisis communication if needed. In order to achieve this, the composition of the task force (consisting of Commission, EMA and HMA representatives) would be revised and adapted to best address the current need. Following agreement by the board, EMA will reach out to HMA to discuss implementation. Finally, the board was informed that the EMA Working Groups on Committees' operational preparedness for human and veterinary medicines' teleconference on 22 March would focus on consequences of any extension of the 29 March Brexit deadline.

In the discussion that followed, members proposed to set a timeframe of three months instead of the one-month proposed for MAHs of non-compliant medicinal products to remedy the situation in order to reduce the risk of shortages. The representative of the European Commission reminded the board that this should be part of a greater discussion as all measures are under scrutiny from the TF50 at the Commission. She invited Member States to provide complete information for the criticality assessment of products as main problems arise with the large numbers of non-CAPs. The Deputy Executive Director added that the timeframe will be discussed with the CMDs, who will have to implement it, and internally at EMA and with DG SANTE, as the approach needs to be harmonised with all licencing authorities, including the Commission for CAPs. Concerning a specific question on whether supply chain disruption in ports had been considered in the risk and criticality assessment, the EMA replied that these data were not available to the Agency and had been outside the scope. The representative of the patients' and veterinarians' organisations stressed the importance of clear communication and suggested a flow of information making use of healthcare providers. The board supported the proposal to use the existing EU executive Task Force in case of need, and to discuss the approach with HMA.

5.1.2 Status update on EMA staff retention and ensuing impact on the 2019 EMA Work Plan

At its December meeting, the board had been informed that phase 4 of the Brexit Business Continuity Plan (BCP) would be launched as of 1 January 2019 and that a list of priorities in view of gradual restoring of currently suspended/reduced activities would be presented at the June 2019 meeting of the board. An update on the intention of EMA staff to relocate shows an estimated overall workforce loss of ca. 22%. These data are based on actual number of staff that have relocated to Amsterdam and on information on move dates provided by staff, and also take into account the loss of ca 125 short term contract staff. These updated figures can be considered more reliable, although there is a further need for confirmation on workforce available in Q3/Q4 2019. Based on currently available information in terms of staff retention, there is no need to amend the 2019 EMA Work Plan and the Agency will prepare a list of priorities for gradual restoring of activities to be discussed at the board in June. However, due to the estimated delta between the workforce needed for the full scope of EMA activities and the expected staffing levels at the end of 2019, the timing of a complete recovery cannot be estimated at this stage, and the EMA will remain in a reduced activity mode. The impact on the 2020 EMA Work Plan will be presented at the October meeting of the board.

5.2 Update on EMA-NL collaboration for relocation to Amsterdam

5.2.1 Update on EMA-NL collaboration for relocation to Amsterdam

All work-streams in the EMA-Dutch Authorities collaboration are on track with the exception of some delays with respect to practical arrangements to be put in place for security and protection of the EMA premises and their vicinity, concerning the implementation of Article 7 of the Seat Agreement, with discussions continuing over the next weeks. The work-stream on the temporary premises will be closed at the end of March.

5.2.2 EMA physical relocation: First experiences and next phase

The EMA's relocation, an unprecedented event for an agency of this size, has been guided by the principle that continuity of its operations should not be impacted despite an important staff loss concomitant with the physical relocation. The relocation takes place in two steps, with the move from London to the temporary premises at the Spark building in Amsterdam taking place before 30 March 2019, followed by a second move from the Spark to the final building. First experiences during the first week in the Spark building have been overall positive, with an average daily intake of staff of 74, leading to a current peak occupancy of 568, including 154 delegates. In the meantime, work on the EMA building is progressing well and according to plan. A current timeline for the final move extends from 15 November 2019, when the building will be handed over from the developer to CGREA (Dutch Central Government Real Estate Agency), until 20 January 2020, when the Agency is expected to become operational from the EMA building.

5.3 Revision of rules for reimbursement of expenses for delegates attending meetings

[EMA/MB/166807/2019; EMA/MB/279597/2018, rev.1] The Management Board adopted a revision of the Rules for reimbursement of expenses for delegates attending meetings. The rules were amended to continue to allow the possibility for delegates whose place of origin is less than 80 km from the place of the meeting to use hotels if the meeting finishes later than 19:30 and travelling time is more than one hour. The amended rules will enter into force on 30 March 2019.

5.4 Amending Budget 01-2019

[EMA/MB/171445/2019] The Management Board adopted an amendment to the 2019 budget increasing the number of SNE (Seconded National Experts) by 3 FTEs, and reducing the number of short-term contract agent FTEs by the same number. This headcount neutral measure allows to take up the offers of secondment to the Agency by NCAs to cover short term positions in areas requiring immediate support, taking into account staff departures and the need for knowledge transfer.

The representative of DG SANTE supported this pragmatic approach which meets flexibility requirements by the Agency concerning short term contracts.

6. Update on judgment of 30 Churchill Place

The Executive Director thanked the board for the readiness with which it had engaged in an extraordinary written procedure for the notification to the Budgetary Authority on 30 Churchill Place, in order to allow for an urgent submission of the building dossier to the budgetary authority on 4 March, in time for consideration at the respective budgetary committee meetings on 18 March 2019. Council

had concluded that the matter should not be the object of an accelerated procedure and was still examining the dossier, with a likely decision on 2 April. The Executive Director reminded the board of a number of decisions taken by European Parliament, Council and European Commission on various occasions in which the need for the two United Kingdom based Agencies to move to other locations within the Union's territory had been stated, together with the requirement that the EMA should take its new seat at the latest from 30 March 2019. Similarly, the same Institutions had issued statements to the effect that the costs of the EMA's move out of London would be expected to be considered in the negotiations on the withdrawal agreement between the Union and the UK government, and that some of the relocation costs may have to be pre-financed by the EU budget prior to the financial settlement. After the ruling by the High Court of Justice of England and Wales on 20 February 2019 that Brexit is not a cause for frustration of the Agency's lease agreement in London, EMA retains a right to appeal by 15 April 2019. The European Commission has been kept constantly apprised of all developments in the last months. [redacted] Furthermore, the Agency would take on duties and obligations of a real estate actor for a long period in addition to its public health mandate. Several members advocated an escalation for decision and support to the political level, since the Agency cannot be expected to bear the consequences of the wider decisions taken with regards to Brexit. The representative of DG SANTE made the distinction between 2 levels of negotiations, one concerning the building and the other one concerning the negotiations with the UK. She expressed support for EMA efforts to sub-let by looking at appropriate ways of providing a guarantee to facilitate the agreement of the landlord and indicated that the Commission works on within the existing legal framework under the Financial Regulation. [redacted]

A representative of the European Parliament expressed the opinion that by engaging in negotiations with the landlord, the Agency might be taking on responsibilities that belong to a political level, and questioned the rationale for an appeal. It was clarified that EMA did not initiate litigation, but was brought to Court by the landlord. In addition, the High Court of London granted EMA a permission to appeal on condition that the Agency continues to pay the rent and other costs of the Lease throughout the appeal proceedings. Based on these clarifications, a majority of board members expressed in favour of lodging an appeal, as it appears to sustain the Agency's rights of defence, and would keep further future options open.

[redacted]

6.1 Management Board Decision on transfer of appropriations in budget 2019

[EMA/MB/135539/2019; EMA/MB/135526/2019] The Management Board adopted the Transfer No. 1-2019 from Title IX to Title II, in order to continue to honour the legal obligations related to the Agency's premises following the ruling by the High Court of Justice of England and Wales on 20 February 2019, and continue to pay rent, estate and building service charges as well as other costs related to the maintenance of the building. The funds, amounting to EUR 14 424 000.00, had been set aside in the budget adopted by the board on 14 December 2018 as provisional appropriations earmarked for various expenditure related to the Agency's departure from the UK.

A. Points for automatic adoption / endorsement

B. Points for discussion

B.1 Highlights of the Executive Director

Relocation of the Agency

The Executive Director thanked staff for their contribution to the achievement of excellent results in such a complex environment, apologising for not naming single individuals. The success in the move was due to the careful planning of all elements by the ORP (Operations and relocation preparedness) governance, which had started work well in advance and considered a multitude of details; the timely preparation and completion, in collaboration with the Dutch authorities, of the building facilities; the positive and optimistic attitude of staff, who managed, and is still managing, a period of personal challenges in a positive and orderly manner, and had received a gracious welcome by the NL host; and finally the absolute dedication with which a number of individuals had put the needs of the Agency over and above their own, and prioritised work over important personal commitments, such as their own move or search of a place to live.

EU activities

At a meeting of Heads of EU Agencies chaired by ECDC, sustainability was discussed. The Directors stressed to the DG BUDG representative that agencies can no longer manage further resource cuts and that de-prioritisation or even stopping of certain activities will be an unavoidable consequence. On 8 March EMA participated to a DG SANTE senior management meeting together with the heads of the 5 SANTE Agencies (EFSA, ECHA, ECDC, CVPO and EMA). Anne Bucher had organised this meeting to have a strategic reflection about the future of health and food safety policy in the EU and to identify areas for further inter-agency and DG SANTE cooperation. During the meeting the issue of how to handle Artificial Intelligence and big data, and how agencies can make better use of tools, skills and 'building blocks' provided by DG CNECT/DIGIT was discussed. The Commission agreed to set up an IT governance group and to organise a follow-up workshop amongst IT architecture experts. The Agency received a positive report in the European Parliament's Budgetary Control committee for EMA's accounts for 2017, recommending to grant discharge. On 19 March, Commissioner Vytenis Andriukaitis visited the EMA in Amsterdam. The visit was requested by the Commissioner himself in

order to express his personal support to the EMA staff who had to relocate from London. Mr Andriukaitis also met the Dutch authorities and visited both the Spark building and the construction site of EMA's future permanent building.

Handling of confidential information at EMA

Accidental disclosure of confidential information to unintended recipients is possible and needs to be prevented. The EMA is launching a more robust and overarching security strategy (covering both physical and IT security), initially focussing on ensuring that secure tools are always used to send confidential information and increasing quality control. An awareness campaign at the level of staff and the Scientific Committees has started.

The Management Board acknowledged the importance of ensuring that secure tools are always used. One member noted however that the design of the current secure tools presents practical problems in their day-to-day use and requested the possibilities to increase user friendliness of support systems like Eudralink. The Chair suggested a dedicated discussion at the June meeting should there be interest by board members.

International Activities

Most activities have been reduced due to the BCP. An Interim meeting of ICH will take place in Brussels on 1-2 April, allowing for a short follow-up of the EU-US bilateral on 3 April. EMA participated in the DIA Euromeeting in Vienna in Feb 2019.

B.2 Report from the European Commission

Review of the EMA fee system

The Commission is finalising the Staff Working Document and working on the Inception Impact Assessment for the legislative proposal. The Inception Impact Assessment will present the problems identified in the evaluation and the policy options proposed to address those problems. The evaluation study by RAND, the Staff Working Document and the Inception Impact Assessment will be published together at the same time in Q2. EMA, NCAs and other stakeholders will have the opportunity to be consulted on the Impact Assessment for one month. An exercise on the analysis of "additional activities" will be launched in April.

Evaluation of orphan and paediatric MPs

The study on orphan medicines is ongoing and due in April 2019. After discussion at COMP a presentation and discussion will take place on 1 April 2019 at the Pharmaceutical Committee meeting followed by a conference with stakeholders and Member States on 17 June 2019. Work on a Staff Working Document is ongoing and due in Q3 2019.

Study on marketing authorisation procedures

Desk research and transversal analysis as well as National case studies are ongoing in Q1 and expected to conclude the evaluation work.

Falsified Medicines

Safety features have become mandatory since 9 February. Work is ongoing to reach full compliance by industry and end-users and addressing false positive alerts.

International activities

The EU-US MRA is progressing and counting Poland and Slovenia, 22 competent authorities have now been recognised. It is important that active cooperation continues with EMA and Member States and that the remaining 6 Members States are recognised by 15 July 2019.

Some members expressed their concerns about the timelines of the review of the current EMA fee regulation. If the procedure of drafting, discussing and adopting a legislative proposal to change the existing regulation will not be completed timely, they see a risk of lack of a legal basis for veterinary fees in central procedures at the time of implementation of the new veterinary regulation in January 2022.

Answering these concerns, the representative of DG SANTE confirmed that the timing for a review of the EMA fee system by January 2022 can be achieved if the legislative proposal is adopted by June 2020. This would allow 15 months for the preparation of the impact assessment, including the consultation period. Concern was expressed that current problems with the safety feature system might undermine it, and it was enquired whether a derogation is possible. The Commission reassured that false positive alerts seem to be decreasing, but a few more months will be needed until all actors are connected to the system.

B.3 Vacancy notice for the Executive Director's function

[EMA/MB/145888/2019; EXT/144734/2019] The board noted the Vacancy notice for the Executive Director's function which had been circulated to the board on 5 March for comments by 12 March 2019. A draft timeline had been tabled at the meeting, setting out the main steps for the appointment of the successor of the Executive Director, whose mandate expires on 12 November 2020. One comment had been received from the board, namely that the position advertised is for an AD14 and not AD15 grade as in the vacancy notice of 2014 according to which the current Executive Director was recruited. The representative of DG SANTE explained that the higher recruitment grade had been exceptional and that the guidelines for agencies state that Directors should be hired at AD14 grade and progress to AD15 through promotion. The Executive Director suggested that the possibility for a normal career progression to a higher grade should be made explicit when advertising the notice. The board appointed Xavier De Cuyper (Belgium) as observer for the Management Board to the preselection panel.

B.4 EMA Annual Report 2018

[EMA/MB/104102/2019; EMA/85499/2019] The Management Board adopted the Annual Report 2018. The report focusses on key achievements that have a positive impact on public health or interactions with the Agency's stakeholder, and provides statistics and trends on core activities. Due to the reduction/suspension of certain activities due to BCP, the chapter dedicated to interviews with EMA staff and stakeholders not been included this year. Major developments and activities are presented in the first chapter through interviews with three former Committee chairs, as well as with a focus on items such as the publication for consultation of strategic reflections on 'Regulatory Science to 2025', the 2nd anniversary of PRIME and the outcomes of the 2nd public hearing held at the Agency. Relocation preparedness activities for Brexit are included, with the impact on EMA's activities described in text boxes throughout the report providing examples of initiatives that had to be suspended or scaled down in 2018. Highlights for human medicines include 84 medicines recommended for approval, including 42 new active substances. There is an increase in scientific advice requested compared to 2017, and a substantial growth in ADRs reported to EudraVigilance following the new release of the system in 2017. For veterinary medicines also scientific advice is a growing area of activity, while the number of medicines recommended for marketing authorisation (10) is lower than in the previous year. Among the positive opinions, is the first stem cell-based veterinary medicine in the

EU and 3 new vaccines, of which two have the potential to reduce the need for antimicrobial treatment in food producing animals. A 30% increase in ADRs reported to EudraVigilance is also highlighted. For inspections and compliance activities, figures for GMP inspections are in line with previous years, while a slight increase in number for GCP inspections and a 30% increase in pharmacovigilance inspections are recorded. The Annual report had been circulated to board members for comments in the weeks preceding the meeting, and comments received had been incorporated. The report will be published by the Agency after finalisation of its formatting and design.

The Communication Department was congratulated on a report with an improved readability.

B.5 Revised implementing rules to the Fee Regulation as of 1 April 2019

[EMA/MB/909606/2019; EMA/MB/909612/2019] The Management Board adopted the revised implementing rules to the Fee Regulation as of 1 April 2019. In accordance with legal provisions on adjustment to inflation, fees covered by Council Regulation (EC) No 297/95 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. An amendment to Annex VII on implementation of the second paragraph of Article 9 of Council Regulation (EC) No 297/95 limits access to SME incentives for regulatory consultancies for human and veterinary medicines. All proposed changes have been given a favourable opinion by the European Commission.

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

[EMA/MB/102914/2019; EMA/84532/2019] The board noted and discussed the update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation. Following agreement by the Management Board at its meeting of 12-13 December 2018, the contract for IT delivery of CTIS was restructured and the development moved from one company to another within the IT4U consortium. The contract was signed on 28 February and initiates a six month monitoring period to the decision point by the Management Board in September 2019 on the continuation of the project with the supplier. The risk status appears to have improved since December 2018, with some risk remaining for scope creep and delays in the iterative delivery model, to be mitigated by agreeing a product vision and by robust release planning. EMA is working with IT4U on metrics to report on progress of the project to the monitoring subgroup for bug fixing, new code development, quality of code and on adherence to timelines. The Management Board will receive monthly high level reports and an Interim report to be discussed at its June meeting, when arrangements for the decision on the way to be taken in September, 6 months after the signature of the restructured contract, will be confirmed. The code merge of Release 0.7 (EUPD) and release 0.9 (safety reporting) has been completed. A ‘sandbox’ with the whole merged code base and all functionality developed until now will be put at the disposal of users to gain an understanding of the system and requirements for the new functionality, this will be rolled out progressively starting in April and will be updated as new versions of the code become available. The new iterative delivery model concept was presented to Member State champions, the EU CTR Coordination Group, CTIS Expert Group and Stakeholders Group. The recommendations from the external review are being implemented, as EMA is recruiting programme management support staff to replace interim staff on short term contracts who could not transfer to the Netherlands. Business Analysis capacity has been increased both at EMA and at the developer, with further analysts to be recruited at EMA. Frequent co-operation with the off-shore team is ensured by onsite presence at the Agency and by the continuous interactions with development foreseen in the new way of working.

Several members conveyed appreciation for the direction taken. It was emphasised that this agile development approach is challenging and requires close and very regular engagement of the user representatives (product owners in particular), the developers and the EMA team. Board members reminded their colleagues of the need to nominate additional experts from NCA users to support this activity. The representative of DG SANTE expressed her confidence in a positive outcome and on the fact that the project is on the right track, despite being aware of the difficulties ahead. She stressed that starting all over again cannot be an option and recommended the importance to follow the principle of creating a 'minimum viable IT tool'.

B.7 2nd EC report on the performance of pharmacovigilance tasks by the EU Member States and the EMA (2015-2018)

[EMA/MB/107241/2019] The Management Board noted the update on the 2nd EC report on the status of the 2nd EC report on the performance of the pharmacovigilance tasks by the EU Member States and the EMA, and agreed to conduct a written procedure to approve the content to be provided to the Commission after its endorsement by PRAC and EU-POG.

B.8 Implementation of the new veterinary medicines legislation

[EMA/MB/180984/2019; Ref. Ares(2019)1335557 - 27/02/2019; EMA/149791/2019] The Management Board noted the correspondence between DG SANTE and EMA on the final mandate for the recommendation to be prepared to inform the required Implementing Act relating to the technical specifications for the Union Product Database, and discussed the implementation of the new veterinary medicines legislation.

The representative of DG SANTE updated the board on the state of play since the last meeting. Work had started on the 26 legal acts necessary for the implementation. Following meetings of the Standing Committee and Veterinary Pharmaceutical expert committee, the draft mandates to provide scientific advice and recommendations regarding certain implementing and delegated acts were updated on the basis of comments received from the Member States and EMA. Seven mandates have been sent to EMA, including the mandate for the Union Product Database, which outlines the information required for the drafting of the Implementing Act and the orientations for the future IT development. It was recognised that it will be very challenging for the Agency to deliver on the mandates with the existing resources. For the development of the Union Product Database EMA was advised to target the achievement of a minimum viable product. Work on this mandate will be divided into phases, with phase 1 and 2 setting out by end of August technical specifications, practical and contingency arrangements, and possible additional information required for the drafting of the Implementing Act, and Phase 3 providing by end of 2019 the analysis and design for the IT development to follow. A 2nd package of mandates will be sent to EMA shortly by the European Commission.

In its presentation, EMA informed that after receiving the first package of mandates, the composition and mandates of Expert Groups had been agreed. First meetings of the Expert Groups were held and work is progressing. Most scientific advice requested in the mandates is scheduled for first discussion at the June CVMP meeting, with endorsement at the July meeting, while the list of variations not requiring assessment is being discussed in a CMDv sub-group and is expected to be handed to the CVMP expert group at the end of March. The final mandate for the Union Product Database was received at the end of February following extensive discussion on its scope with the European Commission. The Agency considers that there is high risk for mandate work and for the subsequent project in 2020, due to the very stringent timeline and ambitious scope, even if applying minimum

viable requirements. In a written response to the European Commission on the mandate, provided to the board, the Agency considered that despite the challenges, it is committed to deliver phase 1 and 2 of the mandate, but cannot commit to phase 3 as the understanding of what will be required to do the work is not available yet. A light governance structure has been set up for phases 1 and 2, and a full project governance structure will be established when the development project goes ahead, on the model of the clinical trials governance. Provisions in the New Veterinary Regulation have significantly changed since the proposal in 2014, leading to much higher costs and resource requirements for EMA than anticipated, while no budget allocations where made for the Agency in 2019 and for 2020 a request is pending. Workload will be particular high between May-July 2019 when up to 20 mandates will have to be worked on simultaneously at a time when the Veterinary Division has suffered significant staff losses due to the relocation to Amsterdam.

Several members stressed the need for adequate resourcing of preparation of the implementation of the NVR and expressed concern on the demanding timelines. The early involvement of users in the development of the product database was welcomed. One member advocated greater input by the HMA through its Task Force for the coordination of the implementation of the veterinary legislation in decisions concerning the governance. The representative of veterinarians' organisations underlined the importance of stakeholder involvement. Other members pointed at the design of a single governance structure for all EU network IT projects as a possible way forward, to be discussed in the Telematics governance. EMA warned that a comprehensive discussion on resources will need to take place during the MB meeting in June on the basis of a report describing the project that EMA will prepare. It also called on the Commission to seek for additional resources as otherwise it might be necessary to have to choose which projects in the 2019/2020 EMA project portfolio will need to be deprioritised. The representative of DG SANTE recognised that it is a difficult situation and asked EMA to quantify the workload stemming from tasks that were added during the legislative process compared to the initial legal proposal. Data and figures are indeed essential to continue to to support a request for resources for the 2020 budget and supported the proposal to present a report at the June Management Board meeting.

B.9 9th Annual Report Veterinary MUMS/limited market

[EMA/MB/125805/2019; EMA/713390/2018] The board endorsed the 9th annual report on the MUMS/limited market scheme for veterinary medicines. The report provides information on the achievements of the policy, which since 2009 aims to promote the availability of veterinary medicines by means of classification and incentives. The scheme continues to be interesting to stakeholders, with 46% of requests originating from SMEs. Requests for classification/re-classification have been growing since the beginning of the scheme, and seem to have plateaued in recent years, with 28 in 2018. 21 of these were eligible for (re)classification, of which one for financial incentives. The scheme has resulted in a wide range of both minor species and major species/minor use/ limited market indications, leading to 3 centralised product authorisations in 2018. The policy and guidance were revised and adopted by the board in December 2018, and published together with related Q&A. The financial impact of the scheme on the Agency in terms of fees waived and reduced was lower than in 2017, due to a decrease in the number of requests compared to 2017.

B.10 Report from the PDCO Chair

Dr. Dirk Mentzer, Chair of the Paediatric Committee, presented to the board his perspective over achievements, challenges and the future of PDCO. The first ten years since the entry into force of the Paediatric Regulation were analysed in a report to the European Parliament published by the European Commission and EMA in November 2017. The Regulation has achieved its aim to increase high quality research for medicines for children, promoting the development and authorisation of medicines in the EU, and improving information on paediatric medicines, both for centrally and nationally approved

medicines. Significantly more new medicines, new indications and age appropriate formulations are now available for children in regions with paediatric legislation, such as EU and US, compared to other regions. Among the achievements of the PDCO, the integration of innovative clinical trial methodology in paediatric investigation plans (PIP) opinions, the inclusion of patients, the inter-committee collaboration, and the optimised interaction with the SAWP and CHMP can be listed. PDCO is further working for similar close interaction with CAT, COMP and PRAC members and reaching out to HTAs. Over the last ten years the workload has increased by over 50% at PDCO, with PIPs/PIP waivers growing from 60 to 100 a month. Drug development is mostly triggered by adult needs, with endocrinology-gynaecology, infectious diseases, oncology, cardiovascular and pneumology –allergology accounting for approximately half of them. Timing of PIPs, as well as their deferral, concerning the majority of applications, can significantly delay drug development. Dr. Mentzer warned that the number of PDCO members who work in Academia or with clinical expert knowledge is decreasing, and that missing members and alternates nomination put the committee at risk of less robust /lower quality opinions in the plenary. Information and assessment on additional requirements for non-clinical testing for development of medicines for children is essential, but PDCO has only one expert in this field. After a multi-stakeholder workshop was held on 20 March 2018 to better apply the Paediatric Regulation to boost development of medicines for children, the Commission, EMA and PDCO drafted an Action Plan to cover the period until 2020. Working Groups on topic areas were appointed and timelines were assigned according to priority. For the future, it will be necessary to evaluate the possibility for non–legislative changes to the implementation of the paediatric Regulation. It was suggested to that the fact that PDCO activities are not remunerated should be part of the review of the upcoming fee regulation. In addition effort by the Member States to bring approved paediatric medicines to the bedside of patients should be continued.

Members congratulated PDCO on its achievements. The request for the reinforcement of clinical expertise was supported with the suggestion to Member States to consider missing expertise when nominating members and alternates

B.11 Composition of the Paediatric Committee – Joint membership

[EMA/MB/101854/2019; Ref. Ares(2017)446809 - 27/01/2017; EMA/101960/2019] According to Article 4(1)(a) and (b) of the Paediatric Regulation (EC) No 1901/2006 the PDCO's composition includes among others 5 CHMP members, with their alternates, appointed by the CHMP to the PDCO, and a member and alternate appointed by each Member State whose NCA is not represented through the CHMP appointment. In practice, it has proven difficult to appoint 5 joint CHMP-PDCO members and the 4th position has been vacant since 2016, and the 5th since 2010. In 2016 the European Commission had agreed to a proposal to fill vacant CHMP nominated joint positions in PDCO with members and alternates appointed by Member States whose NCA is not represented through the members appointed by the CHMP, in a situation where the CHMP is objectively not able to appoint five members with their alternates. The Commission requested that the Management Board of the Agency would be notified by the CHMP in writing that it was not in a position to nominate five members, so that the board could take note of this notification or consider whether other measures should be taken to improve working conditions of joint members. The Management Board noted a letter by the CHMP chair, Harald Enzmann, notifying the board that CHMP supports the application of the 2016 proposal by the European Commission also for the next 3-year mandate of the CHMP-PDCO joint memberships in case no 5 joint members can be appointed in April 2019. EMA indicated that the proposal for CAT/PRAC dual membership should be analysed and considered in collaboration with DG SANTE.

B.12 EMA Policy on the Publication of Clinical Data: Revision of the Terms of Use: third party contractual rights

[EMA/MB/139474/2019; EMA/144064/2019 Rev. 1] The Management Board adopted the revision of the Terms of Use annexed to the EMA policy on publication of clinical data for medicinal products for human use (Policy 0070). The wording of the Terms of Use included provisions specific to the application of the law of England and Wales, comprising third party contractual rights. In light of Brexit and the relocation of the Agency, it was deemed necessary to change the governing law and jurisdiction of the Terms of Use to make reference to Dutch Law and to the jurisdiction of the Amsterdam District Court effective 30 March 2019.

B.13 Preparation for a written procedure for the adoption of the Revision of the breach of trust procedure on declarations of competing interests for Management Board members

The board was informed that the written procedure for the adoption of the Revision of the breach of trust procedure on declarations of competing interests for Management Board members, already announced at the October meeting of the board, would be launched shortly.

List of written procedures finalised during the period from 24 November 2018 to 22 February 2019

Documents for information

- [EMA/MB/93695/2019; EMA/4422/2019] Report on EU Telematics
- [EXT/175868/2019] Feedback from the Heads of Medicines Agencies
- [EMA/MB/124139/2019; EMA/906394/2019] 2018 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2018
- [EMA/MB/101123/2019; EMA/101122/2019] Report on ex ante and ex post evaluation of projects for the period 1 January to 31 December 2018
- [EMA/MB/112294/2019] Outcome of written procedures finalised during the period from 24 November 2018 to 22 February 2019
- [EMA/MB/129665/2019] Summary of the transfers of appropriation
- [EMA/MB/56107/2019] Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2018
- [EMA/MB/130004/2019; EMA/145199/2019] Revised Executive Directors decision on rules governing the secondment of national experts to the EMA

List of participants at the 103rd meeting of the Management Board, held in Amsterdam, 21 March 2019

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	Bogdan Kirilov *(member)* [1]
Czech Republic	Irena Storová *(member)*
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)* Mette Aaboe Hansen *(alternate)* Tina Engraff *(observer)*
Germany	Karl Broich *(member)* Wiebke Loebker *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	*Apology received from Ioannis Malemis*
Spain	María Jesús Lamas Diaz *(member)* César Hernández *(alternate*) María Jesús Alcaraz Tomas *(observer)*
France	Dominique Martin *(member)* Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Luca Li Bassi (member) Gabriella Conti (observer)
Cyprus	Loizos Panayi *(member)*
Latvia	Janis Zvejnieks *(alternate)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Mátyás Szentiványi *(member)* [1]
Malta	John-Joseph Borg *(member)*
Netherlands	Hugo Hurts *(member)* Michiel Hendrix *(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	Marius Daniel Șișu *(member)* [1] Roxana Stefania Stroe *(alternate)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Momir Radulović *(member)* [1]
Finland	Eija Pelkonen *(member)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points 5.4, B.5, B.12 and B.13.*

Sweden	Catarina Andersson Forsman *(member)* Åsa Kumlin Howell *(observer)*
United Kingdom	Jonathan Mogford *(alternate)*
European Parliament	Björn Lemmer Tonio Borg
European Commission	Anne Bucher (DG SANTE) Carlo Pettinelli (DG GROW) Aude L'hirondel DG SANTE (*observer*)
Representatives of patients' organisations	Yann le Cam
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdottir Hvannberg (Iceland) Brigitte Batliner (Liechtenstein) Audun Hågå (Norway)

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