16 June 2017
EMA/MB/383134/2017 Adopted Corr*
Management Board

Minutes of the 96th meeting of the Management Board

Held in London on 14-15 June 2017

Christa Wirthumer-Hoche opened the meeting welcoming the new alternate member for Spain, César Hernández.

1. Draft agenda for 14-15 June 2017 meeting

[EMA/MB/1884/2017] 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 interests relating to the day's agenda were identified concerning topics *"5.a Feedback from the information meeting - general principles and working methodology; 6.a EMA Brexit preparedness business continuity plan principles and methodology; B.7 The European Medicines Agency's strategy for using cloud services; B.8 European Medicines Web Portal (EMWP): Governance and high-level plan".* 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.

3. Minutes from the 95th meeting, held on 16 March 2017 adopted via written procedure on 28 April 2017

[EMA/MB/183915/2017] The Management Board noted the final minutes, adopted by written procedure on 28 April 2017.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

4. EMA Preparedness on Brexit – Update

The chair of the Operations and Relocation Preparedness Task Force (ORP) provided a status update on developments at the Agency since the last meeting. Work has been progressing for the 4 workstreams identified in the scope of the Task Force as an increasing number of staff is involved in subgroups working on specific initiatives. It is to be expected that the workload will further increase in the coming months. As deliverables become available, more information will be provided to the board, with some documents presented for endorsement. Among the activities carried out for relocation preparedness was the technical input provided to the European Commission for the objective criteria for the relocation of EMA in the context of the 2012 Joint Statement and Common Approach on EU decentralised Agencies. The Agency carried out staff surveys to capture readiness to relocate and site visits by EMA teams upon request from members states to provide advice on specific future locations and building options and support to expats. An information meeting with members of the Management Board and heads of the National Competent Authorities of the EU/EEA Member States was held on 27 April on the impact of Brexit on applications and variations to certain regulatory procedures and on EMA Scientific Committees and Working parties. Two working groups, (human and veterinary) on operational preparedness were set up. In the context of EMA Brexit preparedness, other work performed by the ORP Task Force relates to the finalisation of an impact assessment and budgetary consequences based on current knowledge. A dedicated Brexit Preparedness Business Continuity Plan (BCP) is being developed to allow staff to work on EMA preparedness and to address possible EMA staff loss which can no longer be compensated through the recruitment of replacement resource. A staff relocation package with a number of measures will be designed by EMA to facilitate the relocation of over 800 staff and their families. The resulting proposals will be translated into decisions by the Executive Director or will be brought to the board or the European Commission if needed. In the meantime, EMA staff and stakeholders are provided regularly with up-to-date information. The board was also updated on the status of the lease agreement for 30 Churchill Place, which was signed in 2014 on a mandate by the board, involved since early 2010, and upon receipt of a favourable opinion by the budgetary authorities in 2011.

The representative of the European Commission welcomed the assessment of the legal options available to EMA under the lease agreement, and referred to the inclusion of the issue in the overall Brexit negotiations to be conducted with the UK government.

5. Meeting of 27 April 2017

a) Feedback from the information meeting

[EMA/MB/357943/2017; EMA/336491/2017] The board noted a feedback on the information meeting of 27 April 2017 and endorsed the agreed general principles and methodology. The meeting was held after the Management Board at its March meeting had decided to provide an opportunity for members of the Management Board and heads of the National Competent Authorities of the EU/EEA Member States to discuss the impact of the UK leaving the EU as regards workload and resources. The meeting's objective was to raise awareness of the current workload distribution across the network for procedures dealt with by EMA, and of the need for the NCAs to make up for ca. 20% of the total workload in view of the UK withdrawal from the EU. Furthermore, opportunities to streamline and improve some activities through better planning, analysis of the EMA Scientific Committees' composition, targeted membership nomination and possible review of the Working parties should be considered. The data on workload presented at the meeting had been previously discussed on 24 April with the Scientific Coordination Board (SciCoBo), and the outcome of these discussions taken into

account when formulating general principles and a methodology to successfully develop a framework for the (re)distribution of the workload, to be presented to the board for endorsement. Further agreed actions were: conducting a survey, after a consultation of the CMDs, the CTFG and the heads of agencies, on resources in the NCAs for human and veterinary activities; drafting the mandates for a human and a veterinary EMA working group on Committees' operational preparedness; calling for candidates for appointment by the chair of the board.

The UK delegate stated that the UK remains a full member with full rights and responsibilities until the moment when the country leaves the EU, and that it remains committed to support the EU regulatory network. As long as negotiations have not taken place, it is impossible to know whether a form of regulatory partnership or transitional agreement might be established, and while understanding the wish for contingency planning, it would be premature to consider specific scenarios that may affect companies and prejudice the possible outcome of negotiations. He informed the board of the intention to continue to put forward experts as chairs of Committees or Working Groups and as rapporteurs. He furthermore considered that inclusion of the UK in meetings where redistribution of portfolios is discussed would be helpful. The Executive Director acknowledged and welcomed the expression of commitment by the UK and assured that full participation by UK representatives in all formal meetings would be guaranteed. Information and planning meetings are necessary to discuss existent and future capacity of resources in the remaining 27 member states in view of the need to ensure business continuity beyond March 2019. Any proposal originated in such meetings would in any case need to be endorsed at the Management Board, where the UK retains full representation. The representative of the European Commission confirmed that the UK has full membership until it leaves the Union. He stated that there can be no uncertainty about the fact that with the triggering of article 50 the process for leaving the EU has begun and therefore it is of primary importance to ensure business continuity and prepare in view of the departure of the UK at the end of March 2019. Addressing legal concerns expressed by some members, he clarified that discussions and decisions that will have consequences beyond March 2019 are part of the preparation for Brexit, and should take place, on the example of the European institutions, in a EU27 setting. He invited members to address any outstanding doubts to the European Commission. The understanding by member states was confirmed, that no decisions will be taken in informal meetings, which merely provide guidance to scientific committees, and that decisions will be taken in formal fora where the UK is represented.

b) Mandates of the working groups on committees' operational preparedness for human and veterinary medicines

[EMA/MB/357655/2017; EMA/300951/2017, EMA/300988/2017] The Management Board endorsed the mandates of the EMA Working Groups on committees' operational preparedness for human and for veterinary medicines. The two advisory working groups were proposed as an outcome of the discussions at the information meeting of 27 April and will explore options for a reasonable and robust allocation of the workload across the network based on criteria such as: ensuring business continuity and proportionality in the distribution, ensuring knowledge retention, allow to comply with the legally required timelines and maintain the quality of output, maintain 'best available expertise' as determining factor in assigning lead roles and further encourage the MNAT concept. Taking into consideration the outcome of a mapping exercise on resources to be conducted, the two working groups will work on proposals for frameworks for distribution of workload for new procedures, and for redistribution of the UK product portfolio once the UK leaves the EU.

Some discussion took place concerning the criteria for the appointment by the chair of the board of NCA representatives to the two working groups, which had been handled on a "first come first served"

bases. Concerning the veterinary group, it was agreed to broaden the membership to add a further NCA member, as well as a further member of the CVMP and the chair or vice-chair of CMDv. While it is clear that the two groups will only be dealing with procedures under the responsibility of the EMA, it was felt that the CMDh chair is involved in the distribution of certain PRAC procedures, and at any rate it is desirable to maintain a strong link to the parallel work to be conducted with the CMDs for the decentralised activities. The NCA representatives appointed by the chair are Karl Broich, Catarina Andersson Forsman, Thomas Senderovitz and Xavier De Cuyper for the group for human medicines and Jean-Pierre Orand, Lorraine Nolan and Hugo Hurts for the group for veterinary medicines. Once again it was clarified that the group will not take decisions, but merely put forward proposals to help the Executive Director to take decisions in areas under his responsibility. These will then be presented for endorsement to the board. At no time will the working groups be involved in the direct appointments of rapporteurs, which continue to be carried out along long established procedures. Concerning the timing of procedures, it was stressed that they need to be addressed on a case-by-case basis, as business continuity issues apply for those extending beyond March 2019. The representative of the European Commission confirmed that the single working assumption at all levels of the institutions is that Brexit will take place. The reference to process improvements in the mandates of the working groups was appreciated, in the context of the need to maintain the current high standards of quality while continuing to operate to legal timelines.

6. EMA Brexit Preparedness Business Continuity Plan

a) Principles and methodology

[EMA/MB/358162/2017; EMA/322750/2017] The Management Board endorsed the EMA Brexit preparedness business continuity plan principles and methodology. The BCP has been developed to take the necessary measures when a 'business as usual' scenario is no longer possible. This applies both to the need to ensure that the necessary human resources are available to work on EMA Brexit preparedness and to the scenario where EMA can no longer compensate staff loss through the recruitment of replacement resource, acknowledging that both situations can exist in parallel. A further BCP for the purposes of the physical relocation will need to be launched at the time of the move of the Agency. The EMA Brexit Preparedness BCP has been developed on the basis of existing prioritisation of EMA activities. EMA activities have been classified according to three categories: Category 1 with highest priority concerning legal obligations, activities with a fee generating component or of a strategic nature, Category 2 with a medium priority for strategic activities or other core activities not captured in Category 1, and Category 3 with the lowest priority. As a consequence of the implementation of the BCP, activities may continue at the same high standards, be temporarily suspended or temporarily scaled back without lowering standards, resulting in a reduced output or a delay in achieving deliverables. These decisions will be taken by EMA senior management, starting with the category with lowest priorities, keeping in mind that priorities within Category 2 might need to be further sub-classified into 2A and 2B. Resources thus freed up will be directed in a 1st phase towards EMA preparedness, in a 2nd phase to activities with the highest priority to ensure continued operation of EMA's core activities.

Further involvement in the discussion on prioritisation of some activities was requested, and will take place at the board, should the need for activation of Phase 2 move nearer. In the meantime for Category 1 the criterion that the protection of public health shall prevail on any other consideration, including meeting some legal obligations will be made more explicit.

b) Launch of Phase 1

[EMA/MB/370735/2017; EMA/336490/2017] The board noted the launch of phase 1 of the EMA Brexit Preparedness Business Continuity Plan. Phase 1 was launched on 1 May to free-up the EMA resources needed to prepare for the consequences of Brexit, estimated at 43 FTE by the end of Q4 2017. Activities classified in Category 3 and some in Category 2 have been suspended or scaled back. The board was invited to note that certain deliverables in the 2017 Work Programme might be affected. Where legislation explicitly foresees it, the formal adoption by the board of certain measures will be required. The implementation of the BCP will be continuously monitored and communicated to stakeholders.

There was interest expressed in how the Agency can make sure that freed-up resources are redeployed in activities where a need arises. In phase 1 of the BCP this does not constitute a problem, as the Brexit related work is mostly of an administrative nature like the activities that have been suspended or scaled back. It is however not possible at the current point in time to foresee which areas might be affected by staff loss, and although the Agency's time accounting system has a high granularity allowing to know which activities staff is contributing to, profiles which are not easily interchangeable may be affected. The situation will be closely monitored and reported to the board.

7. Communications Plan on Brexit

A draft communications plan on Brexit was presented to the board. Working closely with the European Commission, the Management Board, Experts, Committees and NCAs, the EMA intends to engage with stakeholders, listening and responding. A high degree of alignment throughout the network is necessary, using the EMA website as the main communications channel, complemented by a mix of other tools and channels customised to the needs of the target audiences.

A representative of the European Commission recommended close coordination with the Commission, in particular with the messages issued by the Task Force 50.

8. Revised annual audit plan for 2017

[EMA/MB/257332/2017; EMA/MB/244061/2017] The Management Board adopted a revised annual audit plan for 2017. The revision consisted in the cancellation of two non-legally required, but risk based audits planned for the second half of 2017. This decision was taken as part of the reprioritisation of the tasks of the Audit Function following the launch of Phase 1 of the BCP. By cancelling these and most of the Benchmarking of European Medicines Agencies (BEMA) and Pharmacovigilance Audits Facilitation Group (PAFG) activities, management will be able to reallocate 350 FTE days until the end of 2017. The risk implied in this revision is limited to the 3rd line of defences in the system.

The head of the Audit Function assured the Commission that IAS is fully informed of the cancellation of the two audits, and that the Agency will inform the Court of Auditors, as they both rely to some extent on the work done by the internal Audit Function.

A. Points for automatic adoption / endorsement

A.1 Management Board meeting dates 2017-2019

[EMA/MB/312375/2017 Rev. 2] The Management Board confirmed the following meeting dates for 2017:

- Thursday 5 October

- Wednesday 13 December and Thursday 14 December

adopted the meeting dates for 2018:

- Thursday 15 March
- Wednesday 6 June and Thursday 7 June
- Thursday 4 October
- Wednesday 12 December and Thursday 13 December

noted the meeting dates for 2019:

- Thursday 21 March
- Wednesday 12 June and Thursday 13 June
- Thursday 3 October
- Wednesday 18 December and Thursday 19 December

The board was informed that due to the need that may arise in the period leading up to the UK leaving the European Union, and the relocation of the Agency, it might be necessary to hold extraordinary meetings solely dedicated to Brexit-related topics. In such cases, the Executive Director and Chair of the Management Board will notify the Board as soon as possible.

A.2 Model decision for Agencies on the policy on protecting the dignity of the person and preventing psychological and sexual harassment

[EMA/MB/273876/2017; EMA/338802/2010; EMA/338797/2010; EMA/MB/854173/2016] The Management Board adopted the 'EMA policy on protecting the dignity of the person and preventing psychological harassment and sexual harassment' based on a European Commission's model decision for agencies. The adopted policy supersedes the Agency's Policy 0042.

A.3 Derogation from Commission rules on appraisal for middle managers

[EMA/MB/325723/2017; C(2016)7270; EMA/301141/2017; EMA/MB/244091/2017] The Management Board adopted a decision authorising the Executive Director to request the European Commission to grant a derogation from Commission decision C(2016)7270) final of 17 November 2016 amending Decision C(2013)8985 laying down general provisions for implementing Article 43 of the Staff Regulations and implementing the first paragraph of Article 44 of the Staff Regulations. This is due to the fact that currently the rules to be amended do not apply to the Agency. The Agency therefore would propose that model rules applicable to agencies are developed. The Agency agrees with the substance of the proposal and currently implemented provisions on evaluation of managerial duties within its own appraisal procedures.

B. Points for discussion

B.1 Highlights of the Executive Director

Update on the discharge 2015 procedure

On 27 April, the European Parliament voted positively on the discharge for EMA's 2015 accounts.

This is the final approval of the budget implementation for 2015 and was based among other on a clean unqualified opinion with regard to the 2015 annual accounts and implementation of the 2015 budget.

EU Activities

A delegation from the European Parliament's ENVI committee visited EMA on 19 and 20 April, to learn more about the activities of the Agency and get an update on the latest developments in areas such as transparency, PRIME and antimicrobial resistance. The usual annual hearing on the draft budget (for 2018) will also take place at the Parliament's BUDG committee meeting in July.

International activities

The spring meeting of ICH took place 29 May – 1 June in Canada and was attended by a strong EU delegation, with experts from the network taking leading roles in the discussion. Six Heads of agencies from the East African Community came to the Agency on 18-19 May to study how to organise a networking agency as they intend to establish one for themselves. Continued cooperation with Japan MHLW/PMDA is deepening, and both MHLW and PMDA have sent a number of staff to the EMA over recent years. A small-scale staff exchange programme has been agreed with MHLW/PMDA, sending one person in 2017 with plans to send another in 2018 if possible.

PRIME Workshop

A meeting was organised in May 2017 with a broad range of the Agency's stakeholders to review the experience gained during implementation of PRIME and receive feedback from users of the scheme. The meeting provided further insight on the scheme to two key stakeholders, patients and HTAs. With PRIME, EMA aims at focussing resources to provide the extra support to those candidate medicines that are likely to make a real difference to a patient's life. Up to date two marketing authorisations are expected in the near future for products that have been included in the PRIME scheme. In addition PRIME has already triggered more than 17 procedures of scientific advice where different aspects of development have been discussed.

First-in-human, revision of the guideline meeting

A technical workshop held at EMA on the 28 March was attended by approximately one hundred representatives of Industry, CROs, Academia and Ethics committees that had submitted comments on the guideline, together with NCA representatives and Swissmedic. The new guideline, which aligns with current scientific practice of performing first-in-human administration in the context of integrated Clinical Trials protocols, is planned to be adopted at the July CHMP.

Future participation to MB meetings by Chairs of Committees and Working Groups

The cycle of presentations to the MB by the various Scientific Committee Chairs regarding the operational challenges and achievements of their respective Committees has been considered a useful awareness exercise for all parties. It is proposed to extend the next cycle with the addition of some key working party presentations from both the Human and Veterinary area e.g. the CHMP Biologics Working Party, the joint CHMP/CVMP Quality Working Party and the CVMP Efficacy Working Party.

ATMP

Conversation between different actors is progressing slowly as the constant development of new technical aspects causes the need for continuous readjustments.

SPOR

The Referential Management Service (RMS) and Organisations Management Service (OMS) of the SPOR project are planned to go live on 19 June and this is a major step towards implementing ISO IDMP (common identification of medicinal products) and building the medicines product database for Europe. RMS and OMS will provide a single source of data to NCAs and stakeholders and will start supporting an increasing number of medicines regulatory activities.

Parallel distribution fee reduction: new initiative

In 2016 the Agency conducted a 1-year pilot initiative for fee reductions for notifications of parallel distribution in the Maltese language to improve availability of medicinal products on the Maltese marketplace. Based on the perceived positive outcome, the Maltese authorities have requested an extension of the initiative. Following the request in March this year by the Latvian NCA this was opened to all Member States fulfilling the requirement of having less than two million inhabitants. A new initiative is due to be launched on the 1st of July 2017 for one year. It will be concluded with an assessment based on detailed reporting of the impact parallel distribution has on the availability in smaller Member States.

Delegates from two other member states expressed an interest in taking part in the pilot and were invited to liaise with the relevant Division at the Agency.

B.2 Report from the European Commission

Brexit

The procedure leading up to a decision on the relocation of the Agency has started with the proposal from the President of the European Council and the President of the European Commission for a set of objective criteria for the relocation of EMA in line with the 2012 Joint Statement and Common Approach on EU decentralised Agencies, and a timeline leading up to a decision on the future location of the Agency to be taken by the General Affairs Council on October 19/20[1]. The European Commission supports the mapping exercise of capacities in the NCAs which will enable the planning of increase in capacity through a multiannual process. There has been good progress in provision of information to stakeholders with the notice and Q&A published in May by the European Commission and the EMA. Good collaboration with CMDh and Member States is necessary to tackle concentration of procedures in the transition period.

Digital health communication

With the mid-term review of the overall Digital Single Market adopted by the Commission on 10 May, e-health is included for the first time. The Commission is working with EMA to make use of opportunities for synergies between the work of the institutions and initiatives such as the EMA/HMA task force on big data as part of the vision for a digital single market.

Clinical Trials Regulation

[1] Post meeting note: the decision is likely to be taken on 20 November.

The legislative work to complete the legal obligations for the implementation of the Clinical Trials Regulation has been completed with the Commission Implementing Regulation on GCP inspection procedures, the Delegated Act on GMP for IMP and the Guidelines for GMP for IMP to be adopted for September.

EU/US confidentiality commitment ('Super-CC')

The Super-CC for the exchange of information as part of the implementation of the EU-US Mutual Recognition on GMP inspections is being finalised between the European Commission/EMA and the US FDA.

EC report on Product information

A study on SmPC and Package Leaflets commissioned by DG SANTE was adopted in March 2017, published and submitted to the European Parliament and to the Council. The Commission will work with the Agency and the NCAs on the implementation of recommendations in close collaboration with stakeholders.

Update on the Transparency Directive (Council Directive 89/105/EEC) and Multistakeholders meeting

These are meetings for the competent authorities of Member States responsible for pricing and reimbursement of pharmaceuticals. The Transparency Directive was adopted in 1989 with the purpose to ensure that pricing and reimbursement decisions in the Member States are made in a transparent and not discriminatory manner without disruption of the internal market. A proposal for a revision of the directive was withdrawn in 2015 after failing to attain a compromise. Consequently the "1989 Directive" remains in force and the Commission is committed to implement it taking into account the evolving practices both from industry and NCAs as well as the outcome of case law. To achieve the proposal's objectives the Commission is organising meetings of a consultative committee called the Transparency Committee. Furthermore, the Commission facilitates the multistakeholder platform, bringing together all players, including NCAs, industry, patients, health professionals, consumers and hospitals.. On 12.9.2017 meetings of both bodies will take place at different times.

Concerning a request by a member on further information on the Second AMR Action Plan, the representative of the European Commission informed that the plan is likely to be adopted on 29.6.2017 and will focus on establishing the EU as a best practice region, implementing a One-health approach, supporting research, development and innovation against AMR, and contributing to the global agenda. The Executive Director provided further information on the mapping exercise of capacities in the NCAs which after consultation of the NCAs has now been launched in a revised simplified version. He invited all to provide information to the best of currently available knowledge. Successive surveys may be carried out to help fill identified gaps.

B.3 Assessment of the Executive Director's Annual Activity Report (AAR) 2016

[EMA/MB/328312/2017; EMA/141860/2017; EMA/234192/2017;] The Management Board noted the Annual Activity Report and adopted the Assessment of the Executive Director's Annual Activity Report (AAR) 2015, which had been drafted by the topic coordinators Hugo Hurts, Belén Crespo Sánchez-Eznarriaga and Nancy de Briyne. The topic coordinators welcomed the results presented in the AAR as well as the work programme 2016, noting that the Agency had achieved its targets for most of its performance indicators. Brexit was recognised as introducing significant uncertainties in the Agency's work. In appreciating the work by the EMA ORP task force to ensure operational preparedness, it was

recommended that the Agency continues to monitor real-time data relating to staffing levels and encourages the use of multinational assessment teams to allow a broader involvement of NCAs in scientific assessment work. Recommendation of new medicines for marketing authorisation maintained similar volumes to the preceding year. In the first 9 months of operation of PRIME an impressive number of 84 requests for eligibility were presented. The Agency continues its vital contribution in the global response to AMR, encourages research and innovation in veterinary medicines and promotes availability of veterinary vaccines. Other sources of satisfaction concern the progress achieved with the Mutual Recognition Agreement on GMP inspections with the FDA, the adoption of a multiannual work programme linked to the HMA multiannual work plan, the work done for the data gathering exercise, as well as the first 'big data' workshop organised. They stressed the importance to continue the implementation of the Telematics strategy, and noted that projects had been deprioritised or delayed mainly due to insufficient resources. The topic coordinators were satisfied of the results of the audit of the European Court of Auditors confirming the reliability of the 2015 accounts and noted the declaration of assurance of the Executive Director.

Members took up the suggestion for further discussion by topic coordinators to enquire about how cooperation between NCAs and HTA bodies could be made more concrete, also with the participation of the EMA. The representative of the European Commission informed that a process of public consultation on strengthening of the EU cooperation on Health Technology Assessment had been carried out and an impact analysis of policy options beyond 2020 was being prepared. A proposal could be available by the end of the year. Although the competence of the Commission does not extend beyond supporting member states on HTA, it is to be hoped that the Commission will be able to propose a structure for more permanent cooperation than in the Joint Action.

B.4 Item deferred

The item was deferred after the first mailing of documents to the board.

B.5 Revised Internal Audit Charter of the Audit Capability of the European Medicines Agency

[EMA/MB/257563/2017; EMA/209787/2017] The board adopted the revised Internal Audit Charter. The charter was amended following some changes to the International Professional Practices Framework and template for audit charter. The main changes are related to new standards clarifying the roles and responsibilities of the Head of Internal Audit and the area of quality assessment and improvement programmes.

B.6 Annual report of internal audit and advisory activities at the European Medicines Agency 2016

[EMA/MB/257389/2017; EMA/290360/2017] The board noted the Annual report of internal audit and advisory activities 2016. The Head of Audit is required to report to the Management Board as set out in the Financial Regulation. The 2016 report provided information on the 8 audits conducted, on audit findings and on the status of implementation of the recommendations from previous years. Of these there were no critical, 11 very important recommendations have been implemented and 10 are in the process of being implemented. The report provides information also on other activities performed by the Audit Advisory function.

A board member wished to know how Business Continuity Systems are audited in relation to interconnections with NCA activities. More information on this topic will be provided in a future meeting. Some findings, concerning f. ex. skill analysis and project management at the Agency, were considered of particular interest, given their relevance for Brexit related planning. The Agency assured that audit findings had been thoroughly examined by Management, and addressed through a review of methodologies applied at the Agency.

B.7 The European Medicines Agency's strategy for using cloud services

[EMA/MB/330200/2017; EMA/330193/2017] The Management Board endorsed the Agency's strategy for using cloud services. A decision on the use of cloud services is timely, as decisions on important new systems about to go live like the EudraVigilance system need to be taken, and as the need to relocate the Agency makes location independent services more attractive. The strategy was drafted after extensive consultation with partners and stakeholders, the EU TMB, and the European Data Protection Supervisor (EDPS). A Cloud Security Consultative Group was created, composed of security experts from industry associations as well as experts representing patients/consumers and healthcare professionals, and is chaired by EMA's Information Security Officer. The Agency has considered aspects relating to Information Security and Data Privacy Implications, as well as legal, commercial, public confidence, quality and service continuity risks. EMA has identified the greatest business benefit in the short to medium term by initially using 'Software as a Service'. It will adopt cloud services in a flexible, incremental and controlled manner only where there is value and the right controls are in place. It will therefore operate for some time a hybrid IT by maintaining traditional on-premises hosting environments.

The board supported the step by step approach to the use of cloud services and the Agency was invited to share experiences with the NCAs, as many are considering using cloud options. The Commission requested more information on the selection of the provider in one of the highlighted use cases and recommended not only focussing on protection from cyberattacks, but also to give consideration to the protection of confidential data ensuring that it is stored in the EU and that it will not be accessed by other countries. The Agency confirmed that it will take into account this recommendation during the implementation of the cloud strategy and clarified that the selection of the provider followed the Agency's processes and guidelines for selecting and procuring technology. Furthermore, where sensitive or operationally important information or processes are involved the Agency has adopted a cautious approach to only select technological solutions which are also available for deployment in the Agency's data centre or for operation via a managed or private Cloud service, should the need emerge. This was one of the selection criteria which led to the choice of the selected cloud provider. On this basis the Agency has concluded that, for the data in question (i.e. ICSRs), sufficient controls are in place for using the selected public cloud solution. If, in the future, for other data such controls should not be deemed sufficient, the Agency will continue to make use of solutions provided through the Agency's own data centre.

B.8 European Medicines Web Portal (EMWP): Governance and high-level plan

The Management Board noted the preliminary high-level plan for the European medicines web portal project and endorsed the Governance model. Following adoption of the reflection paper outlining the vision for the portal by HMA and EMA in the second half of 2016, the Online Programme team has developed the high-level plan and a governance model, which were endorsed by the EU TMB on 26

April 2017. As a consequence of the project reprioritisation exercise and business continuity planning linked to the relocation of the Agency, the EMWP project will be suspended as of 3 July 2017. Having an agreed governance model will enable to put in place a structure as soon as work on the project resumes. The proposed governance model for the EMWP is based on the methodology used at the Agency and foresees the standard reporting lines through the Telematics structure. Its unique features are the appointment of an NCA representative in the Online Programme Steering Committee to support oversight of the project, and the creation of a dedicated Partners and Stakeholders Group, including a veterinary observer, to provide experience for future similar veterinary projects. The high-level plan for the EMWP project foresees splitting the project into 4 shorter projects to better manage the challenges posed by its complexity and the dependency on the SPOR project.

B.9 Report by the Steering Group on the Management Board data gathering initiative

- **Pharmacovigilance fee regulation KPI report 2016**

[EMA/MB/327768/2017; EMA/325900/2017] The board noted the report by the Steering Group on the data gathering initiative, including the annual information on the key performance indicators and performance information as set out in the context of the Pharmacovigilance Fee Regulation. The data gathering initiative ended its main body of work in March, when it issued its report. It was however decided to allow for additional time for the collection of data on inspections until end of June 2017, to be presented in an addendum to the report. The Steering Group will hold a teleconference in early July to endorse the addendum, before a written procedure of the Management Board is launched with a deadline in late July. The board was provided with provisional data collected on GCP, GVP and GMP inspections for the EMA secretariat and NCAs, including information on the proportion between different roles and travel time. Early in the data gathering initiative, it was decided to rely for pharmacovigilance activities on the performance information on Pharmacovigilance which is legally required in the Pharmacovigilance Fee Regulation. Datasets in the performance information for pharmacovigilance included procedures finalised in the year, number of FTEs involved in pharmacovigilance activities specifying staff allocated to activities corresponding to each of the fees, average number of working hours spent by the rapporteur per procedure for PASS, PSURs and referrals. High variability in the datasets was apparent and was in the past interpreted by the Steering Group as due to multifactorial causes, although a trend for efficiency being linked to high volume of procedures is clearly apparent.

B.10 Clinical Trial EU Portal and Database (EUDP)

[EMA/MB/327139/2017 Rev 1; EMA/222592/2017] The Management Board discussed and noted the update on the Clinical Trial EU Portal and Database. On the previous day members of the board had been provided with the opportunity to meet and question the developer of the system who had presented their root cause analysis and a revised plan. Members had later discussed the information received and the next steps among themselves. The development of EUPD is severely delayed and affected by significant quality defects. The supplier is taking measures to improve the delivery for both aspects. The Agency will closely monitor with an enhanced level of oversight. The supplier has prepared a new development schedule that would delay the audit of the system by at least 9 months, with legislation becoming applicable in 2019. The timeframe, circulated, prior to the meeting, for endorsement was withdrawn and a new one will be resubmitted to the board in October, based on the experience with the delivery of release 0.6. Measures to improve delivery and reliability of the planning include increasing the development team and strengthening the architecture function,

scheduling fortnightly face-to-face meetings between EMA and the development team, and strengthening the project management function of the developer. Re-estimating all remaining work with different and more reliable methods is believed to lead to a more achievable timeline, including additional formal testing cycles ahead of demos and before end of the release. Tighter monitoring will be achieved by highlighting areas for improved, more granular monitoring and planning daily, weekly and fortnightly interactions at the appropriate levels. In a revised timeline the same releases would take place as in the original planning, but with wider gaps between the end of the site acceptance tests (SAT) and the start of the user acceptance tests (UAT), UAT 7 and audit, and between audit follow up and the Management Board decision. Functionalities included in release 0.8, such as the API 1, would be looked at by auditors at the time of its release, when full end-to-end testing would become possible. The Agency had taken into consideration the main concerns raised by Members States through the Expert Group, the Coordination Group, the Management Board represented by four members, and the EUTMB and believed that the measures taken by the supplier will improve the speed of delivery and alignment with quality targets. The EMA project team therefore recommended close monitoring of the development of release 0.6 with short periodic updates on progress circulated regularly before release 0.6 in September 2017. On that basis a revised time frame will be submitted to the Management Board for endorsement in October. Stakeholders will be informed that the EU Clinical Trials Regulation will come into application during 2019 and not in October 2018 as previously scheduled.

Several members expressed disappointment at the delay, which does not seem avoidable. However, it is important that once delivered the system provides all the functionality that is needed to provide value, and supports the full implementation of the Regulation. It was appreciated that the audit will take into consideration in a follow-up also functionality of the 0.8 release, and that end-to-end testing will be possible. By carefully monitoring and considering release 0.6, enough information should be available in September to take a sound decision on timelines in October. Should there be no confidence in the ability of the developer to deliver on the new proposed timeline, a contingency plan would need to be rapidly devised. It was also suggested that a contingency plan could be based on limiting the scope of the system to a minimum viable product. The Agency stated however that any substantial re-planning activity would be unlikely to bring the expected benefits and would not deliver time gains. One way in which member states are actively supporting the project, and which is very much appreciated, is by allocating own staff as Seconded National Experts (SNE). It was also recommended to take into account how Brexit might affect the project. The European Commission saw postponement of the audit as inevitable. Further delays should however be avoided by impressing the importance of the overall project in the developer, and by exercising a high degree of supervision and monitoring of commitments. The Commission has invested in the project with own IT staff and will continue to provide support.

B.11 PV ADR project status update

The board heard an update on the EudraVigilance auditable requirements. Following an independent audit report of 31 March and an addendum report of 19 April, PRAC issued a favourable recommendation on 5 May. After a written procedure, on 22 May 2017 the Management Board confirmed and announced that full functionality of the new EudraVigilance database had been achieved, allowing the enhanced system to go live six months later on 22 November 2017. Testing activities are set to begin on the EudraVigilance test environment as of 26 June, and will be complemented by training activities and support webinars. The Agency will continue to closely engage with experts and report to PRAC and IT Directors to ensure a successful launch of the enhanced EudraVigilance system.

The chair thanked all parties who had contributed to the success of the project.

B.12. Annual report 2016 on the performance of the Agency's scientific procedures: Key Performance Indicators (KPIs) for medicinal products for human and veterinary use (piloted procedures only)

[EMA/288781/2017; EMA/MB/294900/2017;] The board endorsed the Annual report on the performance of the Agency's scientific procedures: 'Key Performance Indicators (KPIs) for medicinal products for human and veterinary use' under the agreed pilot project started in 2011 with the aim to provide transparent reporting of the performance of NCAs under the Cooperation Agreement (CA) between NCAs and EMA for services provided. Overall the report shows satisfactory results for both human and veterinary procedures across the product life cycle. Positive trends are seen for assessment reports received on target for post-authorisation procedures (Type II, Workshare, Renewal, and Annual Reassessment) and QRD comments for human and veterinary procedures. On the veterinary side, the report shows excellent results for the number of assessment reports on target for scientific advice, and a positive trend for reports for initial MAA and Annex I procedures. Some signs of stress are observed at the human side. For initial MAA and Annex I procedures, there is a trend that more reports are received shortly after target (≤4 days) instead of on target, which means committee members have less time to comment. This should be monitored on a rolling basis rather than annually. A similar trend is observed for scientific advice assessment reports, in particular for the joint assessment reports. Those trends did, however, not result in a delay of the legal timelines. Data on performance indicators relating to inspections were included for the second year, and showed a continued good performance for all types of inspections.

In the EMA's view, these small signs of decline in time keeping should be looked into by the EMA Working Groups on committees' operational preparedness for human and for veterinary medicines, which will also address how to increase efficiency. A request for more detailed information on performance related to MNATs was made, and will be looked into by the Agency. Concerning small delays with timekeeping, a member state attributed them to some misunderstanding concerning submission deadlines. No conclusive answer could yet be provided to a question on the reasons for an observed decline in veterinary scientific advice procedures over the past few years, however EMA together with CVMP is planning a user survey to obtain information.

List of written procedures finalised during the period from 14 February 2017 to 11 May 2017

- Consultation no 08/2017 on the appointment of Svein Rune Andersen as CHMP member, proposed by Norway ended on 10 March 2017. The mandate of the nominee commenced on 13 March 2017
- Consultation no 09/2017 on the appointment of Maja Turk as CVMP alternate, proposed by Slovenia, ended on 10 March 2017. The mandate of the nominee commenced on 13 March 2017.
- Consultation no 10/2017 Jorge Camarero Jimenez as CHMP alternate, proposed by Spain, ended on 17 March 2017. The mandate of the nominee commenced on 20 March 2017.
- Consultation no 11/2017 Gesine Hahn as CVMP member, proposed by Germany, ended on 20 March 2017. The mandate of the nominee commenced on 21 March 2017.
- Consultation no 12/2017 on the appointment of Adriana Adameova as CHMP member, proposed by Germany, ended on 8 May 2017. The mandate of the nominee commenced on 10 May 2017.
- Consultation for endorsement of Final Report on MB Data Gathering exercise, ended on the 29 March 2017. The report was endorsed.

- Written procedure for adoption of the 95th Management Board meeting minutes, ended on 28 April 2017. The minutes were adopted.
- Written procedure for adoption of Confirmation and announcement of full functionality of the Eudravigilance database, ended on 19 May 2017. The report was adopted

Documents for information

- [EMA/MB/325702/2017;EMA/282408/2017] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/122153/2017; EMA/9942/2017] 2016 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2016
- [EMA/MB/109400/2017] Outcome of written procedures during the period 14 February 2017 to 11 May 2017
- [EMA/MB/288567/2017] Summary of transfers of appropriations in the budget 2017
- [EMA/MB/308950/2017; EMA/26003/2016; EMA/494077/2016] Annual report on the EMA interactions with patients, consumers and healthcare professionals and their organisations (2016)
  - Principles on the involvement of young patients/consumers within EMA activities
- [EMA/MB/343117/2017; EMA/812253/2016] Annual Report on EMA's interaction with industry stakeholders (2016)

List of participants at the 96th meeting of the Management Board, held in London, 14-15 June 2017

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	*Apologies received from Assena Stoimenova*
Czech Republic	Zdeněk Blahuta *(member)*
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)* [1] Mette Aaboe Hansen *(alternate)* Tina Engraff *(observer)*
Germany	Karl Broich *(member)* Birgit Naase *(alternate)* Anna Afentaki *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	Despina Makridaki *(member) partial*
Spain	Belén Crespo Sánchez- Eznarriaga *(member) partial* César Hernández *(alternate*) *partial* Sara Ares Santos*(observer)*
France	Dominique Martin *(member)* Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Gabriela Conti *(alternate)*
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	*Apology received from Laurent Mertz*
Hungary	Csilla Pozsgay *(member)* [1] Beatrix Horvath *(alternate)*
Malta	John-Joseph Borg *(member)*
Netherlands	Hugo Hurts *(member)* Birte van Elk *(observer)*
Austria	Sylvia Fuezl *(alternate)*
Poland	Grzegorz Cessak *(member)* Magdalena Pajewska-Lewandowska *(observer)*
Portugal	Rui Santos Ivo *(member)* Maria Joao Morais *(observer)*
Romania	Nicolae Fotin *(member)*
Slovakia	*Apology received from Zuzana Baťová*
Slovenia	Andreja Čufar *(member)* [1]

Corr* [1] Competing interest declared resulting in no participation in decision with respect to agenda points 5.a, 6.a, B.7 and B.8.

Finland	Esa Heinonen *(alternate)*
Sweden	Catarina Andersson Forsman *(member)* Annick Wennberg *(observer)*
United Kingdom	Ian Hudson *(member)* Jonathan Mogford *(alternate) partial*
European Parliament	Björn Lemmer Tonio Borg
European Commission	Xavier Prats-Monné (DG SANTE) Carlo Pettinelli *(DG GROW)* Jerome Boehm DG Sante *(observer)* Chloe Spathari (DG GROW) *(observer)*
Representatives of patients' organisations	Ilaria Passarani Yann le Cam
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdóttir Hvannberg (Iceland) Brigitte Batliner (Liechtenstein) Audun Hågå (Norway)

European Medicines Agency	Guido Rasi Noël Wathion Stefano Marino Fergus Sweeney Nerimantas Steikūnas Melanie Carr Agnes Saint-Raymond Alexis Nolte Enrica Alteri Anthony Humphreys Fia Westerholm Zaide Frias Sabine Brosch Anabela Marcal Monica Dias Marie-Agnes Heine Hilde Boone Silvia Fabiani Sophia Albuquerque