6 October 2017
EMA/MB/660406/2017 Adopted
Management Board

Minutes of the 97th meeting of the Management Board

Held in London on 5 October 2017

The chair opened the meeting welcoming Marcin Kolakowski, new alternate member for Poland.

1. Draft agenda for 5 October 2017 meeting

[EMA/MB/158073/2017] 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 *"B.4 Amending Budget 01-2017, B.6.2 Amendment to the 2017 Work Programme; B.11 Revision on Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) / limited market".* 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 96th meeting, held on 14-15 June 2017 adopted via written procedure on 26 July 2017

[EMA/MB/383134/2017] The Management Board noted the final minutes, adopted by written procedure on 26 July 2017.

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A. Points for automatic adoption / endorsement

A.1 Withdrawal of the request for derogation from the Commission rules on appraisal for middle managers

[EMA/MB/552174/2017; Ares(2016)6965618; Ares(2017)3520119; EMA/460261/2017; EMA/460658/2017; EMA/MB/460753/2017] The Management Board authorised the Executive Director to withdraw the request to 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 and adopted the above mentioned Commission decision C(2016)7270 final. The decision was taken after clarification by the European Commission that the provisions apply also to agencies and that specific model decisions for agencies are not needed.

B. Points for discussion

B.1 Highlights of the Executive Director

Brexit

The weeks surrounding the deadline for the evaluation of the 19 bids to host the European Medicines Agency have seen a high level of activity by all parties. Due to the leakage of some documents, and in order to provide a full version complete with the methodology which had been used, the EMA decided to release documents which had been prepared in order to inform the Agency's Brexit Business Continuity Plan (BCP) and have been provided to the institutions. In particular a survey conducted to determine possible staff loss was plotted against staffing levels necessary to guarantee operational levels and released in an anonymised version. The subsequent leaked disclosure of the names of the cities in the various scenarios was unfortunate, and did not add any value. The information that has now been made available provides full transparency on the methodology used and will allow for the correction of misperceptions. The priority for all should not be on the decision on where to relocate an agency, but on how to maintain and protect its activities which are vital for public health.

EU Activities

The discharge procedure in the European Parliament for the Agency's 2016 accounts has started. EMA will have a meeting with the Rapporteur to clarify any questions and discuss the Agency's specific situation due to Brexit. The annual exchange of view at the ENVI committee will likely take place on 7 December.

International Activities

The EU-US Mutual Recognition Agreement on GMP inspections was signed in March 2017 and will enter into force on 1 November 2017. By 15 December discussion on inclusion of veterinary products will begin. For the implementation of the agreement it is necessary that confidentiality commitments are now signed also between the FDA and the Member States. A first Awareness Session on the EU Regulatory System at the Agency was attended by ca. 50 persons from International regulators and NGOs and was open online to the general public. The session was arranged by EMA to rationalise its activities and will be held again when necessary, involving speakers from NCAs as relevant.

Interactions with the European Ombudsman

On 17 July 2017 the European Ombudsman informed EMA of its own strategic inquiry into the interactions between EMA and medicine developers before the application for a marketing authorisation. EMA has met with the European Ombudsman's services to clarify the scope of this enquiry, which seems very broad and may cover activities which are already foreseen in the

legislation. To avoid an excessive workload which might impact adversely on the Agency in view of the Brexit contingency, while ensuring that relevant information is collected for the enquiry, the EMA has proposed random sampling methodologies instead of detailed statistical analysis of large data sets. An answer from the European Ombudsman on the proposed methodology is expected shortly.

Public hearing on Valproate

The first public hearing at the EMA was held on 26 September 2017 to review risks of malformations and neurodevelopmental problems in babies who were exposed to valproate during pregnancy. In the hearing, which was attended by 65 members of the public and by representatives of the industry, 16 individual interventions were heard. The experience was appreciated by the PRAC and CHMP members, as well as by the public. A summary report was published, and the contribution by the public will be used in the final assessment, while 'lessons learned' including the feedback from all participants are being prepared. Conclusions drawn from the preparation carried out in a dry-run conducted in July 2016 were widely confirmed.

Interactions with members of the public

Concerning interactions with members of the public, the board was informed of all the steps that the Agency is taking, to ensure that the potential issues raised by a patient, who has addressed a high number of communications to various persons within the EU Regulatory network and other authorities, are taken as part of a legally binding measure (LEG) currently under evaluation by the PRAC.

Update on SPOR

Following the delivery in June 2017 of the Referentials Management Service (RMS) and Organisations Management Service (OMS) two ISO IDMP standards can now be implemented. RMS and OMS will be integrated with the electronic application form (eAF) and with the Common European Single Submission Portal (CESSP) to deliver a number of benefits. Phase 1 for the Products Management Service (PMS) and Substances Management Service (SMS) has been approved and is in implementation phase by end of 2018. For full achievement of the expected benefits, the involvement of the NCAs will be needed for some changes in the national systems and processes.

European Union Civil Service Tribunal rejection of the application of annulment of the selection procedure of Guido Rasi as Executive Director in 2011

With the rejection on 28 September 2017 of its first judgement of 2014, the Court has confirmed the rigour of the first (as well as second) selection procedure for the Executive Director. This outcome is important also for future selection procedures as it largely confirms the correctness of the process followed by the European Commission in several similar procedures. The Executive Director thanked DG SANTE, the Commission's Legal Services and the EMA Legal Department for the excellent cooperation, and the Management Board for the unconditional support it had always provided.

In the overall discussion several members, among whom the representatives of the patients' organisations, expressed their concern on the effects that an adverse outcome of the enquiry by the European Ombudsman could have on public trust for the Agency and for all other regulators, and offered help and support. The Executive Director thanked the board and specified that he had hoped that assurance already provided in August together with explanations on how input by the Agency on early Clinical Trial design benefits patients, would have led to a satisfying clarification. The Agency is now trying to understand what other information might be helpful to the European Ombudsman.

B.2 Report from the European Commission

Brexit

The European Commission completed and published the analysis of the 19 bids to host the EMA on 30 September. The assessment took place within the boundaries of the procedure and criteria determined

in the procedure leading up to a decision on the relocation of the agency endorsed by the Heads of State or Government. The EMA was consulted on the technical requirements, and the Commission took note of the information provided for the purposes of its assessment. The approach used by the Commission was to examine only the information provided within the bids without checking its veracity, for which ultimately the Member States shall be responsible. The assessment was expressed as a short descriptive text without any value judgement. The technical assessment produced under the responsibility of the Secretariat-General of the Commission, with significant input by the Agency, DG SANTE and other Commission services, aims to facilitate a decision by the governments of the 27 EU Member States.

State of the Union

In his State of the Union President Juncker delivered his key messages on health that will determine legislative acts undertaken by June 2018. A joint action plan on vaccination policies is aimed at strengthening cooperation between the Member States in the area of demand, supply, exchange and research. The action plan will include a Joint Action on vaccination coordinated by INSERM including financial incentives of 3 Million Euro and will start in early 2018, involving EMA, ECDC, WHO and DG RTD. 24 countries, among which 20 Member States, will participate. A very fruitful workshop with other organisations and with industry took place in May.

Financial perspectives after 2020

The current financial framework 2014-2020 for a budget of 959 billion euros supporting the Union's political priorities will come to an end in 2020. The Commission has started work on a proposal for the next period to be submitted in May 2018. In the current uncertainty over Brexit many questions are open, but focus should be on providing specific added value at EU level when no other level is effective. There is a perception that the current crises recommend greater flexibility in order to tackle unforeseen challenges that can call for reallocation of funds across different legal bases.

Communication on digital transformation of health and care

A public consultation until 12 October was launched on 20 July. A communication is due by the end of the year and will address also the use of data in health research, disease prevention, treatment and personalised medicines. The debate should involve health experts and not only IT experts. A workshop on general data protection regulation, implementation and health data will be held on 23 October in Brussels and will be led by regulator in interior ministries. The presence of representatives of the healthcare sector would be helpful to provide a balanced view on the use of data concerning health.

Clinical Trials Regulation

With the publication on 16 September of the Delegated Act on GMP for IMP all legal obligation for the application of the Clinical Trials Regulation have been fulfilled. The Commission will continue to provide support to the EMA for the development of the Clinical Trial Portal and Database.

Study on marketing authorisation procedures

There is a legal requirement to submit to Parliament and Council every 10 years a report on the operation of the centralised, decentralised and mutual recognition procedures. As the last report was submitted in 2010, the Commission is now preparing to launch a study in 2017 with a view to issue the report in 2019 and analyse it in 2020.

Update on the external study supporting the evaluation of the EMA fee system

Targeted consultations with EMA, NCAs, industry and other stakeholders have been completed and the contractor is now working on cost modelling. A draft interim report is expected in November 2017, to be followed by a public consultation currently scheduled from December 2017 to February 2018. The external study project should be completed in spring 2018, hopefully allowing for a Commission Staff Working Document to be ready by Q4 2018/Q1 2019.

Meetings on Pharmaceuticals

DG GROW organised two meetings on 12 September 2017: The Transparency Committee met to discuss issues arising from the implementation of Directive 89/105/EC, which is still in force after a legislative proposal for revision was withdrawn. A multistakeholder meeting on pharmaceuticals followed on the same day to address matters concerning access to medicines, and was attended by representatives from Member States, European umbrella associations for industry, patients, hospitals, insurers, consumers and healthcare professional.

B.3 EMA Preparedness on Brexit

The Executive Director informed the board on the approach taken by EMA to assess staff readiness to relocate and its possible impact on the Agency's activities. The Agency also assessed the number of FTEs necessary to carry out its activities under the categories of its Brexit BCP. Starting from February 2017 it ran three surveys to assess the number of staff willing to relocate. Although these surveys were progressively better informed as the Member States focussed their bids on specific cities and provided information, it also became clear that the likelihood of staff following the Agency is decreasing. It must be borne in mind that when indicating willingness to relocate to a specific city, staff members were not stating a liking, but expressing their estimation of how they will be able to recast their families life in an unknown location. Furthermore, the survey needs to be interpreted as a best case scenario, since the likely staff retention was compiled from both answers 'likely' and 'very likely' to relocate. The leaking in the press of the names of the cities in the staff survey was unhelpful, as it distracts from the main issue at stake, which is to assure the business continuity of the Agency.

B.3.1 Update on EMA preparedness

The Deputy Executive Director reported to the board on how the Agency has been preparing for Brexit in the last few months. The Agency's input into the Commission's assessment of the offers to host the EMA was limited to technical aspects in relation to the proposed building, facilities, and relocation plan, and relied solely, as requested by the European Commission, on the information provided in the bids themselves. Where several buildings were put forward, the Agency considered them all, unless a priority or preferred building was stated, in which case it limited its assessment to that. If temporary buildings were proposed, they were taken into consideration for the overall assessment but the adequacy of the temporary premises was not examined due to lack of sufficient information. Clarifications on specific aspects were provided to the European Commission as required. The Agency has further published its review of all other criteria, accompanied by a description of its working methodology. The Agency deems that a fit for purpose building in itself does not guarantee continuity of operations in the absence of adequate staff retention and connectivity for delegates. Some of the information that is of interest to staff for the decision to relocate, such as availability and pricing of housing, and capacity of schools in the years 2018 and 2019, was scarcely present in the bids. The Agency will do all it can to support best possible retention of staff through appropriate measures to be implemented during a minimum transition period from 1 July 2018 to 31 July 2020. The measures need to comply with applicable legislation and respect sound financial management, and will be subject to approval and endorsement respecting the current decision-making process. They will be designed to provide the highest possible degree of flexibility to all staff members and teams, building up from entitlements and allowances under the Staff Regulations and changes in EMA practices and implementing rules, as well as other dedicated measures supplemented by support measures offered by the new host Member State. Should a critical situation arise, depending on location, budget and environmental factors, Commission approval will be sought for extraordinary measures beyond what is currently foreseen. The package of measures to be applied during the transition period includes:

earlier notice of contract renewal, relocation visits, transitional working time arrangements, language training in the official language(s) of the new host Member State and education support. All staff retention support measures are being finalised and will be subject to the applicable decision making process. After the seat decision is taken and more location dependent information is available, measures will be further tailored.

B.3.2 Feedback from meeting of the working groups on committees' operational preparedness for human and veterinary medicines

Work in the working groups has been progressing with two joint human and veterinary meetings held and a further human only meeting held on 4 October. The surveys on the planned increase in resources of the Network (human and veterinary) provide assurance that capacity and increased expertise in the NCAs should assure compensation for the loss of UK expertise. As reiterated by the European Commission, the UK will not be a member of the EU after March 2019. This must be taken into account whenever there is a need to appoint a Rapporteur or lead for an assignment that may finish after that date. Concerning the reallocation of UK products' portfolio on the human side, the proposals presented at the meeting will be fine-tuned and discussed at the next meeting in October. The Working Groups will take into consideration proposals made by the heads of the UK human and veterinary NCAs and discuss how to work with UK colleagues as part of teams making use of best available expertise up to March 2019. Concerning knowledge retention and transfer of the UK products' portfolio it was agreed that the Rapporteurs will need to make sure that their teams are acquainted with the dossiers. The next steps will include holding further meetings of the Working Groups in November, and holding on 15 November 2017 a second information meeting in a EU27 setting with Management Board members and Heads of Agencies (both human and veterinary) who are not members of the board. The resulting proposals will be discussed at the meeting of the board in December.

The representative of the UK stated that the UK will support procedures and fulfil its duties as long as it remains a member of the EU. He invited to consider willingness for continued close cooperation on the grounds of public health, as negotiations are ongoing and their future impact is not known. The representative of the European Commission replied that EMA must prepare for the only possible current scenario of Brexit taking place in March 2019, and that there cannot be any excuses for not doing so. He warned from any ambiguity concerning the meaning of Brexit for EMA, which should be guided by the need for business continuity.

The board was also informed that pharmaceutical industry was asked in a recent meeting to plan adequately to cope with the deadline of March 2019, and to identify all possible supply issues, informing regulators in order to address possible shortages.

B.3.3 EMA Brexit Preparedness Business Continuity Plan

[EMA/MB/626542/2017; EMA/196585/2017] The Management Board noted the EMA Brexit Continuity Plan. At its meeting of June the board endorsed the principles and methodology for the BCP on the basis of which the presented document was developed. The BCP is needed for the scenario in which the Agency can no longer apply a 'business as usual' approach but must ensure that the necessary human resources to work on Brexit preparedness are available, and when it is no longer possible to compensate for an important staff loss through the recruitment of replacement resource.

B.3.4 Phase 2 of the Business Continuity Plan

Phase 1 of the BCP was launched on 1 May 2017 to free-up resources needed to prepare for the consequences of Brexit. Now the Agency needs to progress to phase 2 according to the same principles and methodology of phase 1, based on classification of EMA activities into 3 categories ranging from Category 1 (highest priority) to Category 3 (lowest priority) to be suspended or their output reduced starting with the category with the lowest priority. In phase 2 category 3 activities will be further reduced, while targeting reduction of category 2B and afterwards 2A. Category 1 should be addressed as last resort and within this category a distinction will be made between a purely legal obligation and the protection of public health, with the latter prevailing. All activities that continue should be carried out to the same high standards as previously. The current forecast for 2018 foresees that by Q4 ca 86 FTE will be needed for Brexit preparedness and implementation. This is a best case scenario in terms of anticipated staff loss that will need to be reviewed once the new host Member State is known. Managers will be able to monitor staff loss and reduction of activities by means of a dashboard, and the Management group will review the situation and redeploy resources where needed to maintain activities. For the 2018 Work Programme, the consequences envisaged are that 2017 temporary suspensions for category 3 and 2B activities will be maintained, with a further small reduction of additional category 3. Some proposals for further category 2B activities to be suspended or output to be reduced were presented to the board. A revised proposal taking into account preliminary comments by the board and the calculation of the number of freed-up FTEs will be presented to the board at the December meeting in the context of the discussion of the 2018 draft Work Programme.

In the discussion members offered support in areas which may be deprioritised, and considered that NCAs would indirectly be affected as well by the Phase 2 approach at the Agency. The Deputy Executive Director invited board members to familiarise with the classification of activities, particularly 2A and 2B, in order to acquire a deeper understanding of the decisions that will need to be adopted in December concerning the Work Programme. As for support to the Agency by NCAs, the Executive Director warned that at the present time it is impossible to foresee how and in which parts of the organisation a loss of staff will affect specific sets of skills.

B.3.5 Budget 2018 and Preliminary Draft Budget 2019

At the December meeting the board will be requested to endorse the 2019-2020 Programming Document, including the preliminary budget requirements for 2019 to be submitted to the Commission by 31 January 2018. This deadline is tight, considering that the expected relocation of the Agency in 2019 poses significant planning and budgeting challenges, concerning in particular the cost of the building and possible staff loss, that will only partially be clarified after a decision on the seat of the Agency is taken on 20 November 2017. Therefore the Agency is preparing the preliminary documents based on a set of assumptions which may need to be modified substantially. The EMA will therefore make the distinction, requested by the Commission, between 'business as usual' expenditure and 'Brexit' costs. These will reflect additional costs for the preparation of the relocation and staff turnover costs, as well as reduced costs from the slowing down or suspension of certain activities. The Agency will first attempt to cover 'Brexit' related costs from its own resources where possible, before requesting additional EU budget contributions. From the budgetary perspective, the Agency could maintain business as usual assessment and safety activities in 2018 and 2019. In addition, the Agency can cover some of the 'Brexit' related costs. Remaining costs will need to be financed through additional EU funding in 2018 and 2019. Current assumptions for Brexit related costs for 2018 amount to EUR 21 million due to the cost of additional interim staff to backfill Brexit related vacancies, staff reimbursement cost related to resignations or transfer to new duty station, relocation of the data

centres and other IT relocation activities, some provisional costs for fitting out and for move management. These will be partially offset by a reduced occupancy rate due to staff loss and by lower meeting costs due to reduced activity. For 2019 costs might be influenced by expenditure for further increased in interim staff as increased support in case of high attrition rate for staff, costs related to relocation and resignations of staff, costs for the building in the new location, partially offset by a reduced weighting coefficient. Possible scenarios will be determined by how high the staff loss will turn out to be, and by the possible costs of investment for the new building and for the lease termination. A significant staff loss would have an impact on the ability to process fees and deliver fee-generating activities, thereby leading to moderate to very high reduction of income, a corresponding budgetary deficit and reduction in payments for the remuneration of the NCAs. The Agency is taking several actions to mitigate the risk of staff loss, including the BCP and staff redeployment mechanism, staff retention measures and the short term increase of interim and trainees and up to 40 Contract Agents to support Brexit workload in the transitional period.

B.3.6 Update on communication activities

Communication on Brexit at the Agency is focussed mainly on the relocation of EMA and the necessary business continuity arrangements, and on the impact on the regulatory operations and the work within the European Medicines Regulatory Network to prepare for when the UK will leave the EU. The Agency will strive to provide an improved understanding of EMA's role and work, as well of its needs and its business continuity planning, timely information on operational changes to partners and stakeholders, and full information on the impact of relocation decisions on staffing. The Agency is publishing Brexit related materials on a dedicated landing page on its website and has issued several press releases, leaflets and infosheets. The Agency will release a 2nd batch of Questions and Answers by the end of October, and will modulate its communications on the milestones that will lead to the decision on its new host city on 20 November.

B.4 Amending Budget 01-2017

[EMA/MB/163175/2017] The Management Board adopted the amending budget to recognise the increase in value of external assigned revenue, due to the continued weakening of the Sterling against the Euro and its resulting higher Euro value, and to earmark it for the payment of rent by the same amount.

B.5 Revision of budget structure from financial year 2018

[EMA/MB/573458/2017] The board endorsed the revision of the budget structure from the financial year 2018. In 2017 the budget structure was revised extensively, in particular with regards to expenditure, to reflect the new Financial regulation and to align it with the European Commission's guidelines. With the proposed amendments the revision was completed on the revenue side as well.

B.6.1 EMA Mid-year report 2017 from the Executive Director (January – June 2017)

[EMA/MB/635545/2017; EMA/413591/2017] The Management Board noted the mid-year report from the Executive Director. The report reflects progress and achievements of the Agency from January to June, and does therefore not take into account developments in the second semester. The Agency's performance overall has been very good, while Brexit preparedness work proceeded along various workstreams, from supporting operational preparedness of scientific committees, to informing

stakeholders, drafting procurement plans, and surveying staff to prepare the Brexit preparedness BCP, the first phase of which was launched in May. Highlights of key activities include the first year of the PRIME procedures, which led to granting 20 out of 96 requests; the completion and publication of the second ECDC/EFSA/EMA Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA); the preparations for the first public hearing; the publications under the EMA policy on publication of clinical data for more than 20 products, corresponding to over 700 documents; the continued success of the EU NTC, with 2,800 users and NCA experts registered on its platform, and 6 NCAs opening their training for inclusion in the learning management system; the adoption of a framework for interaction with academia and of a policy on how EMA handles allegations of improprieties received from external parties. On the operational side progress is positive, with increases in activity noticeable across the board, but particularly in the areas of human and veterinary Scientific Advice requests. International cooperation on inspections shows positive results, with 20% of routine GMP re-inspections addressed through exchange of information, while GCP inspections show a positive trend following the measures on fees adopted by the board in August 2015. From a budget perspective the overall revenue and commitment rates are on track. It is possible that the Agency might experience a surplus in 2017 due to some reasons, including such as the impact of favourable fluctuation in exchange rate, and the amending budget which increased revenue income. The Agency would request the Commission to use such surplus for a Brexit reserve in 2018 and/or 2019.

As a consequence of the BCP, in 2018 the Mid-year report will be limited to high level indicators.

B.6.2 Amendment to the 2017 Work Programme

[EMA/MB/640248/2017; EMA/583016/2016] The Management Board adopted an amendment to the 2017 Work Programme to accelerate IT activities linked to relocation preparations. A project for 'Application maintenance relocation', to transform and transition IT applications maintenance to a fixed price off-site operating model, will start in 2017 after approval by the board. The revised work programme will be republished on the EMA website.

B.6.3 Transfer of appropriations in budget 2017

[EMA/MB/617418/2017] The board adopted transfer of appropriation 7/2017 according to Article 27(2) of the Financial Regulation. The transfer of EUR 7.8 million from Title II, investment in immovable property, renting of buildings and associated cost, to Title III, operating expenditure, will fund both the updated forecast full cost of IT activities, including those related to data centre relocation preparedness, as well as the costs for the 'Application maintenance relocation' project.

B.7 Report to the Management Board on the implementation of the clinical trial Regulation (EU) No. 536/2014, in particular on the development of the clinical trial EU Portal and Database and related projects (EudraCT legacy and Safety Reporting)

[EMA/MB/471090/2017; EMA/443908/2017] The board discussed and noted the update on the Clinical Trial EU Portal and Database. The Management Board has been kept well informed by means of fortnightly reports that have been circulated by the Agency starting in June. Moreover, the day before the meeting of the board, Topic Coordinators were able to meet the developer to directly discuss progress since the last meeting. At the meeting of the Management Board in June it had been decided to postpone a decision on the adoption of the revised delivery timeframe for the EU Portal and

Database to October, but after discussion it seems advisable to wait until the December meeting in order to have a more informed discussion. The current draft project timeline aims for the system to go live second half of 2019. The next fixed price contract will address the delivery of the integrated system (EUPD and Safety Reporting functionalities) in release 0.9 and analysis and design for the development up to the production version. A third contract will include delivery of the go-live release. Release 0.6 was developed according to the revised schedule presented by the supplier in June but this required diverting effort from release 0.7 development and SAT completion was delayed by 10 working days due to the volume of bugs found as well as environment issues. The timing for the User Acceptance Testing (UAT) is maintained. The schedule for completion of release 0.7 is under review with the supplier. Since the detection of the delays in April-May, a set of measures to improve delivery were undertaken and resulted in the delivery of release 0.6 with implementation of all planned requirements. This includes 75% of all 'Must' requirements of the complete system and 76% of all 'Auditable Must' requirements, and for the first time allows the execution of end-to-end business scenarios across sponsors and Member States and includes a public view on the clinical trials database. Intensified communication and collaboration have resulted in a better alignment with expectations. Release 0.6 is the largest release in the project, and system functionality has more than doubled. A demo of release 0.6 to the Members States Group on 26 September provided an indication of a system on which they can work. It has been decided not to submit a revised delivery timeframe for endorsement in October to enable the completion of the Site Acceptance Test (SAT) and its follow-up, to collect the experience from the UAT and to obtain confirmation of the plan for the development of the release 0.7. The UAT of release 0.7 will likely take place end of Q1 2018 and the audit of the EU portal and database in Q2 2018. Before a decision on the revised delivery timeframe can be proposed at the next meeting of the Management Board in December, the Management Board sub-group members Xavier De Cuyper, Ian Hudson, Rui Santos Ivo, Thomas Senderovitz and the chair of the Management Board will meet again in the second half of November. They will consider progress made on the basis of a plan for the release 0.7, reviewed and validated by the EMA (a first review of the plan will take place during the EMA's Project Manager visit to the developer on the second week of October), a risk management plan with mitigation measures, as well as the draft report from the 0.6 UAT.

The topic coordinators reported the outcome of the meeting with the supplier on the 4th of October, which had provided some assurance on the development, but there is a need to further strengthen testing and in particular put in place a robust risk management plan for the next releases. This would not take into account other risks related to subsequent contracts, Brexit or status of implementation of the Regulation at a national level. The representative of DG SANTE underlined the importance of continuing to monitor the development closely and assured all of the continuing support by the Commission.

B.8 EudraVigilance Auditable Requirements Project

[EMA/MB/558545/2017; EMA/558542/2017] The Management Board noted the status update on the EudraVigilance Auditable Requirements Project. After an independent audit report was met with a favourable recommendation by the PRAC and by the confirmation and announcement by the EMA Management Board that full functionality of the new EudraVigilance database had been achieved on 22 May 2017, the date for the go-live of the new system was set for 22 November 2017. The Agency is now focussing on providing support to stakeholders by means of the necessary training for the experts in the NCAs and through monthly webinars. A testing environment has been available since June and has allowed for interoperability testing with the NCAs' pharmacovigilance systems, and with marketing authorisation holders and sponsors of clinical trials in the EEA. The launch of EudraVigilance on 22

November 2017 will be preceded by a downtime between 8 to 21 November during which some components of the system will not be available or only partially available. This is required in order to ensure the proper and accurate transfer of over 11 million Individual Case Safety Reports and the careful installation of the new components. The go-live planning was endorsed by the PRAC and the Clinical Trials Facilitation Group (CTFG) and communicated to all impacted stakeholders. After the go-live EMA will continue to organise ICSR submission training courses and support webinars. A further release with minimal downtime is planned for February 2018.

B.9 EMA co-operation with EUnetHTA

Following the high levels of interest previously expressed at the board, a presentation addressed the ways in which EMA co-operates with EUnetHTA. The need for collaboration arises from the observation that the evidence needed for the national decisions leading to access to medicines in different member states can be rather different from the data generated for regulatory decision, leading to time delays and potentially diverse outcomes. The collaboration with EUnetHTA has started over 7 years ago based on a recommendation from the High-level Pharmaceutical Forum. Currently the collaboration is structured through cooperation in distinct work packages of EUnetHTA's Joint Action 3 as well as an EMA/EUnetHTA work plan 2017-2020, which is about to be finalised and involves cooperation with CHMP, SAWP, PRAC, PDCO, CAT and COMP. Significant experience has been gained over the years with parallel regulatory/HTA advice and early dialogue procedures aiming at achieving a higher level of alignment on evidence generation plans. EMA started providing parallel scientific advice in co-operation with HTA bodies in 2010 and has seen over time an increasing number of requests. This experience has led to the recent launch of the Parallel Consultation platform together with EUnetHTA, as part of JA3 work package 5 Evidence generation through a life-cycle approach addressing early dialogue and post-licensing evidence generation. Furthermore, the Agency is contributing to work package 4 Joint Production, which aims at facilitating the immediate national uptake of Marketing Authorisations through the joint production of relative effectiveness assessments. Collaboration between regulatory and HTA assessors must be based on a mutual understanding of the output of each decision making and within the respective remits and confidentiality arrangements. It was noted that the Ad-hoc Synergy Group with HTA representatives and regulators is currently mapping all activities in the collaboration between regulators and HTA bodies that support the areas identified in the "Synergy paper" from the HTA Network. The EUnetHTA work plan 2017-2020 aims at underpinning the overarching strategy developed within the Synergy paper. This includes areas such as horizon scanning, advice on studies, real world evidence and market entry and allows for linking these to existing initiatives or leading to new concrete collaboration. EMA's collaboration with EUnetHTA strives to contribute to initiatives that can improve access to medicines by patients within the existing legal framework, and in the context of a European strategy.

Several members supported regular updates to the board on the HTA topic, which was considered of strategic importance to regulators to streamline processes and contribute to resolving differences and inefficiencies. The representative of doctors' organisations urged to conduct post licencing studies in a timely manner, and a representative of patients' organisations recommended reinforcement of horizon scanning and evidence generation all along the lifecycle of products.

B.10 Report from COMP Chair

Bruno Sepodes, Chair of the Committee for Orphan Medicinal Products (COMP) presented his views on the state of play and future perspectives of the Committee. Throughout its history from 2000 to now the Committee has traditionally elected a patients' representative as vice-chair. The COMP is different from other EMA committees as members do not have alternates, and its composition includes three

members to represent patients' organisations, as well as three members nominated by the Commission on the basis of a recommendation from the Agency. The absence of alternate members can sometimes contribute to difficulties reaching a quorum, for which 23 members have to be present. The history of the European orphan drug legislation is a success story, and its original objectives of providing incentives that stimulate research and development were met, as also shown by the number of protocol assistance, orphan designation and market exclusivity procedures. The legislation continues to attract investment in the development of therapies for diseases which have no treatment or no satisfactory treatment. Since 2000 the committee has issued 1886 orphan designations, leading to 143 authorised orphan medicinal products. Orphan status expires 10 years after marketing authorisation; this has already applied to 42 products, which are now marketed without orphan status. The high numbers of designated orphan products point to a success of the legislation over its 17 years. 70% of products require demonstration of significant benefit over existing methods of diagnosis, prevention or treatment of a condition, which is perceived by patients as an added value. Maintaining orphan status for a product in the EU is not directly linked to the success in obtaining a designation, as a higher level of evidence is needed for demonstration of significant benefit at the time of the marketing authorisation. Parallel scientific advice procedures with HTA have involved 15 protocol assistance procedures of orphan medicinal products since 2010. Good communication is important to dispel misconceptions about orphan medicinal products and clarify key concepts to different audiences. As of the end of this year COMP will start publishing the Orphan Maintenance Assessment Report (OMAR). Upcoming challenges in the field of orphan medicines include the discussion on proportionality of incentives raised in the Council Conclusions in June 2016, the good implementation of Art 8(2) allowing review of the orphan status 5 years after the marketing authorisation on request of at least one member state, and analysing the causes for infrequent applications based on insufficient return on investment. Bruno Sepodes concluded stating the willingness of COMP to embrace change and thanking EMA and the board for their continued support.

Questions by members of the board to Mr Sepodes addressed the issue of whether the so called Orphan Regulation is still fit for purpose, considering for example the high share of oncological products with an orphan status. Mr Sepodes suggested further reflection on the use of article 8(2), and on the possibility to reassess significant benefit more than once. He suggested that a future revision of the legislation should clarify the difference between orphan status and rare conditions, and further advocated the creation of alternate members in the COMP.

B.11 Revision on Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) / limited market

[EMA/MB/526899/2017; EMA/CVMP/388694/2014-Rev.1] The board adopted the Guidance on the classification of veterinary medicinal products for minor use minor species (MUMS) / limited market. The guidance had been updated in agreement with the CVMP to provide consistency with the recent revision of the CVMP guidelines on data requirements for veterinary pharmaceutical and immunological products intended for MUMS / limited market in 2016-2017. Changes are of minor administrative nature and no impact on financial incentives is expected.

B.12. Report on changes to GCP inspection fees

[EMA/MB/581959/2017; EMA/581984/2017] The board noted the report on the impact of the amendment of the Implementing Rules to the Fee Regulation for a revised definition of a 'distinct' Good Clinical Practice (GCP), adopted by the Management Board in August 2015. The envisaged

objectives of ensuring sufficient GCP inspection resources and increase the numbers of GCP site inspections for CAPs appear to have been achieved, even if a definite conclusion cannot be drawn that is due to the revision of the definition of "distinctive" inspection. The Agency will continue to monitor the impact of the amendment, specifically on availability of inspectors.

List of written procedures finalised during the period 12 May 2017 to 12 September 2017

- Consultation no 13/2017 on the appointment of Tomas Boran as CHMP alternate, proposed by Czech Republic ended on 23 June 2017. The mandate of the nominee commenced on 24 June 2017
- Consultation no 14/2017 on the appointment of Ewa Balkowiec-Iskra as CHMP member, proposed by Poland, ended on 28 June 2017. The mandate of the nominee commenced on 29 June 2017.
- Consultation no 15/2017 on the appointment of Simona Badoi as CHMP member, proposed by Romania, ended on 18 July 2017. The mandate of the nominee commenced on 19 July 2017.
- Consultation no 16/2017 Svjetlana Terzic as CVMP alternate, proposed by Croatia, ended on 21 July 2017. The mandate of the nominee commenced on 22 July 2017.
- Consultation no 17/2017 on the appointment of František Drafi as CHMP member, proposed by Slovakia, ended on 6 September 2017. The mandate of the nominee commenced on 7 September 2017.
- Consultation no 18/2017 on the appointment of Jayne Crowe as CHMP member, proposed by Ireland, ended on 6 September 2017. The mandate of the nominee commenced on 7 September 2017.
- Consultation no 19/2017 on the appointment of Peter Kiely as CHMP alternate, proposed by Ireland, ended on 6 September 2017. The mandate of the nominee commenced on 7 September 2017.
- Consultation for adoption of the Agency's final accounts 2016, ended on the 28 June 2017. The accounts were adopted.
- Written procedure for adoption of the 99th Management Board meeting minutes, ended on 28 of July 2017. The minutes were adopted.
- Written procedure for the endorsement of the Addendum Report on Inspections for MB Data Gathering exercise, ended on 18 July 2017. The document was endorsed.

Documents for information

- [EMA/MB/600544/2017; EMA/573994/2017] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/574504/2017] Outcome of written procedures during the period 12 May 2017 to 12 September 2017
- [EMA/MB/573435/2017] Summary of transfers of appropriations in the budget 2017
- [EMA/MB/547813/2017; EMA/MB/548040/2017] Report on ex ante and ex post evaluations (January – June 2017)
- [EMA/MB/650295/2017; Ares(2017)4590716 - 20/09/2017] New IAS Mission Charter

List of participants at the 97th meeting of the Management Board, held in London, 5 October 2017

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	Assena Stoimenova *(member)*
Czech Republic	Zdenek Blahuta *(member)*
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)*[1] 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)* Niamh Herlihy *(observer)*
Greece	Despoina Makridaki *(member)*
Spain	Belén Crespo Sánchez- Eznarriaga *(member)* César Hernández *(alternate*)
France	Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Mario Melazzini *(member)* Gabriela Conti *(alternate)* Monica Cattani *(observer)*
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Beatrix Horvath *(alternate)*
Malta	Gavril Flores *(alternate)*
Netherlands	Hugo Hurts *(member)* Birte van Elk *(observer)*
Austria	Sylvia Fuezl *(alternate)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)* Magdalena Pajewska *(observer)*
Portugal	Rui Santos Ivo *(member)* Maria Joao Morais *(observer)*
Romania	Nicolae Fotin *(member)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Andreja Čufar *(member)*[1]
Finland	Esa Heinonen *(alternate)*

1 Competing interest declared resulting in no participation in decision with respect to agenda points B.4; B.6.2 and B.11.

	Participants
Sweden	Catarina Forsman *(member)* Sara Rosenmuller *(alternate)* Annick Wennberg *(observer)*
United Kingdom	Ian Hudson *(member)* Jonathan Mogford *(alternate)*
European Parliament	Björn Lemmer Tonio Borg
European Commission	Xavier Prats-Monné (DG SANTE) Carlo Pettinelli *(DG GROW)* Jerome Boehm DG Sante *(observer)* Chloe Spathari (DG GROW) *(observer)*
Representatives of patients' organisations	Ilaria Passarani 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 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 Michael Lenihan Michael Berntgen Marie-Agnes Heine Hilde Boone Silvia Fabiani Sophia Albuquerque