16 December 2016
EMA/MB/862367/2016 Adopted
Management Board

Minutes of the 94th meeting of the Management Board

Held in London on 14-15 December 2016

1. Draft agenda for 14-15 December 2016 meeting

[EMA/MB/488455/2016] 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.1 Programming 2017-2020 - Programming 2017-2019, including 2017 work programme, budget, establishment plan; - Draft programming 2018-2020; B.8 Multinational assessment team concept; B.9 Revised EU Telematics governance model".* The Secretariat informed the board that all concerned members had been informed before the meeting and that their names and restrictions would appear in the minutes. 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 93rd meeting, held on 6 October 2016 adopted via written procedure on 14 November 2016

[EMA/MB/489158/2016] The Management Board noted the final minutes, adopted by written procedure on 14 November 2016.

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A. Points for automatic adoption / endorsement

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

[EMA/MB/666915/2016; EMA/738889/2016] The Management Board endorsed the fixed flat hourly rate for 2017, unchanged from 2016. One member raised a question about the adequacy of compensation for some Member States.

A.2 Model rules on non-application of Commission decision on the maximum duration for the recourse to non-permanent staff in the Commission services

[EMA/MB/714995/2016; EMA/MB/480025/2016; (2016) D/7065] The Management Board adopted the Decision on the non-application of the Commission Decision on the maximum duration for the recourse to non-permanent staff in the Commission services. This is based on an ex-ante agreement and model rules by the European Commission that take into account the way agencies operate.

A.3 Decision of the Management Board on setting up a Staff Committee

[EMA/MB/714784/2016; EMA/MB/438127/2016] The Management Board adopted a Decision on setting up a Staff Committee based on model rules provided by the European Commission.

B. Points for discussion

B.1 Programming 2017-2020

- **Programming 2017-2019, including 2017 work programme, budget, establishment plan**
- **Draft programming 2018-2020**

[EMA/MB/799574/2016; EMA/583016/2016; EMA/MB/740755/2016; EMA/804060/2016; EMA/679864/2016; EMA/804132/2016] The Management Board adopted the 2017-2020 Programming document and the budget 2017. The Programming document 2017-2020 is presented as a single document and is made up of the Programming 2017-2019, which includes the 2017 work programme, budget and establishment plan, and of the Draft programming 2018-2020. After adoption by the board, the Agency will include any comments received, update the final 2016 figures and divide the documents presented into two separate ones, which will be circulated to the board before being mailed to the European Commission and other institutions by 31 January 2017. In order to facilitate the discussion of the Programming Document, the presentation to the board was structured according to the different components of the package: Work programme overview, draft budget 2017 and 2018-2020 overview, IT budget and strategy, Programmes and projects, Procurement. The Topic Coordinators Grzegorz Cessak, Catarina Andersson Forsman, Lorraine Nolan and Kristin Raudsepp took

part in the presentation to the board of the topics on which they had concentrated more intensely during the 3 month preparation with the Agency.

The principal drivers of the Programming document are the Network strategy to 2020 and the priority areas to fulfil the Agency's legal obligations in the context of evolving workload and an increasingly complex environment. They may however be influenced by the overarching factor of the possible impact of the outcome of the UK referendum on EU membership. The Agency continues to work under assumptions of 'business as usual', but depending on the evolution of the situation, shifts in priorities and focus may become necessary. The Agency is conducting impact assessments and general preparedness activities to identify the possible impact of loss of UK expertise, loss of current staff and currency volatility. Workload evolution trends indicate continuous growth in procedure volume, as well as in complexity of procedures, as more innovative products enter the Agency's portfolio. In this circumstance the Agency must focus on maintaining the high quality of assessments and prepare for the new and implement recent legislation, while delivering the Telematics system and implementing a number of requirements for compliance in the corporate areas. Other priorities will address public health issues, such as Antimicrobial resistance (AMR), supporting innovation and access to medicines, availability and innovation of veterinary medicines, and strengthening the regulatory capacity and capability, for example through the EU Network Training Centre (EU NTC), open also to candidate and potential candidate countries and international regulators, or the Multinational Assessment Team concept (MNATs). Grzegorz Cessak recommended adopting the Work Programme for 2017 and the preliminary Draft Work Programme for 2018, highlighting the Agency's priorities on access to new medicines, especially for unmet needs, emerging threats and challenges in public health, improving dialog with stakeholders, promoting the European regulatory model and capacity building as well as preparing for the possible relocation of the Agency, while mitigating as much as possible the impact of Brexit on all core activities. Concerning human resources, for 2017 the Agency will cut its establishment plan by 6 Temporary Agents to comply with the 2014-2018 staff reductions requested to all EU agencies, compensating with contract agents to address workload pressures. The agency also aims to increase the Seconded National Experts programme. For 2018 the Agency would like to adhere to the ongoing pilot established for EASA with the agreement of DG Budget, which allows for flexibility in adjusting the number of establishment plan posts on the basis of the development of solid workload, efficiency and quality indicators for fee related work. On this basis the Agency will request 11 fee-related Temporary Agent posts for 2018 taking into account workload increase and implementation of efficiencies. If increase in temporary agents would not be approved in the budgetary process, the same head count increase will be needed through contract agents. The draft budget 2017 is growing by 4.4% with an estimated increase of 5.4% in fee-financed activities. At the same time, following the budgetary authority decision to cut EMA's EU contribution by € 8,350,000, the Agency will not be able to create a proposed 'Brexit provision' of € 6.4 million, and € 2.2 million for IT project activity will need to be covered by further cross budget savings and by closely following the Euro – GBP exchange rate developments. Catarina Andersson Forsman provided an analysis of the draft budget and preliminary 2018 estimates. Income from fee-financed activities continues to rise, and should reach € 300 million by 2018. On the expenditure side the Agency spends ca. 70% of its budget on evaluation activities for human medicines and 5% for veterinary medicines, 13% for horizontal activities and 12% on corporate governance and support activities. Funding of network activities continues to increase, with expenditure for EU NTC having reached the top in 2017 and Pharmacovigilance evaluation activity having reached cruising levels. For 2017 an increase in salary costs (1.3%) is foreseen, due to higher than expected insurance and pension costs, and payment to NCAs for evaluation of medicines is expected to increase by 3.6%. The major shifts in the Euro – GBP exchange rate, together with the stoppage to investments on the building in the perspective of a possible relocation, will significantly reduce certain expenditure for 2017. The IT budget is overall

stable, with some increases for maintenance and support on the 2016 budget reflecting the go-live of various systems. An increase in business consultancy for 2017 is due to the need to support additional projects. Other IT costs in 2017 are linked to the transitioning of application maintenance and development from a time and means system to fixed price contracts, including also 'testing as a service', increase in information security and in enterprise architecture budgets and upgrades, and significant increase for some projects. Lorraine Nolan provided an analytical comparison between the 2017 preliminary draft budget and the draft budget 2017 summarising the changes to IT project costs, with business consultancy costs broadly in line with estimates. She further looked in detail at the evolution of project estimates from 2016 to 2018, inclusive of EMA staff effort expressed in FTEs. The 2017 IT budget reflects a best estimate, with some uncertainties caused by the transition to fixed price contracts, and significant changes due to a new service delivery model and architecture changes to prepare for the possible relocation of the Agency. Details on the procurement plan for 2017 concluded the presentation. Of these two procedures are needed to support IT projects, two to re-open or retender existing framework contracts in the area of effectiveness and pharmacoepidemiological studies, and two to address provision of travel management services and provision of hotels for delegates.

The board welcomed the detailed explanation of the Programming document. Looking at the uncertainties linked to a possible 'Brexit' scenario, topic coordinators and members expressed concern about the elimination of a budget reserve during the EU budgetary process. The suspension of investment in the building and the effect on procurement contracts was also discussed. The Agency acknowledged the budget risk, which it is managing by looking for further efficiencies. Maintenance of the building continues as planned, while non portable investments have been stopped. The cost of IT expenditure, which is concentrated on a limited number of projects, was mentioned. The representative of the European Commission recognised their extreme complexity as a cause and was pleased about the involvement of three members of the board and of the Commission's own IT services in the support and oversight of a project which will have an important financial impact. Concerning the perception by a member that expected increase in fee income for 2017 will not be matched by a corresponding increase in remuneration to rapporteurs, it was clarified that the mix of fees for procedures for which NCAs are involved produces an increase for both Agency and NCAs of 4.7%. Other variances do not concern NCAs as they occur in the form of incentives, which are carried by the Agency alone, or concern administrative activities with no NCA involvement.

B.2 Highlights of the Executive Director

Brexit preparedness

As the UK Prime Minister has announced that a notification according to Article 50 to withdraw from the European Union will be launched before the end of March 2017 the Agency continues to run its business as usual, while performing the necessary work on preparedness. There is a need to ensure continuity of operations, and some higher than normal loss of staff has been observed recently. In order to respond to the numerous requests by cities and governments who have asked about the operations of EMA the Agency has prepared facts and figures on operations and logistic features.

EU Activities

The EMA, together with PDCO, has produced a detailed report on the experience gained with the Paediatric Regulation published as part of the European Commission's public consultation in preparation for its second report after 10y of implementation. The report shows that paediatric medicine development has improved in the European medicines regulatory network over the last ten

years but also highlights challenges to be addressed. The Executive Director's annual "Exchange of Views" with the ENVI committee took place on 8 November. The 2015 discharge process has started at the European Parliament; a draft positive opinion was presented last week to the ENVI committee.

International Activities

The Summit of Heads of Agencies and the ICMRA meeting (International Coalition of Medicines Regulatory Authorities) took place 10-14 October 2016 in Interlaken Switzerland. At the bi-annual WHO ICDRA meeting (International Conference of Drug Regulatory Authorities) in Cape Town, 27 November to 2 December, there was a strong European presence raising much interest in the European model and on how it can be shared with other regulators around the world. EMA hosted an informal dinner with regulators from African national authorities and regional organisations to prepare for a meeting that will be held in Malta in early March 2017. The meeting will be jointly organised by the EMA and the Maltese EU Presidency, with the support of the Gates Foundation and WHO and has the purpose to raise awareness and use of the Article 58 procedure.

Publication of first clinical data under Policy 70 on 20 October

The website for the publication of clinical data for human medicines was launched on 20 October 2016 and clinical data for the first two medicines were published, with 382 documents, containing 260,143 pages of which only 8 pages with redacted CCI (Commercially Confidential Information). The reaction from stakeholders has been very positive.

Workshop on Adaptive Pathways

The workshop had been requested by the European Commission and took place on December 8th. Two thirds of participants were from civil society, patient and consumers organisations, payers, HTAs, academia etc. It provided an opportunity for a frank exchange of ideas on the concept and the feasibility of the adaptive pathways approach, and for clarification that not all products are suitable for this approach. Further reflections will be shared with the board on offering a platform within Scientific Advice for multistakeholder discussion.

Workshop on Big Data

The workshop was held on 14-15th November and included 33 speakers/panelists. 160 participants comprising regulators, industry and representatives of academia attended, with ca 650 other persons following on line. The workshop was very well received and earned an editorial in Nature entitled "Daunting Data". It is now important to harness the momentum and enthusiasm generated by the meeting.

Implementation of MAWP HMA/EMA joint Task Forces

At the HMA meeting in Bratislava on 29-30 November 2 mandates for HMA/EMA Joint Task Forces were adopted: the HMA/EMA Joint Task Force on Big Data and the HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use. At a time of strained resources the Agency has limited capacity, but would like to participate in activities where it can provide value.

During the discussion some members were interested in better understanding the Agency's collaboration with HTA bodies. The Agency is active in the area of parallel scientific advice with HTA authorities. The success of this activity is dependent on the number of participating organisations, and on the reliance by all on data generated within post-authorisation safety as well as efficacy studies, foreseen by the Pharmacovigilance legislation. The Synergy group proposed by the European Commission provides an occasion to explore scope and opportunities for collaboration between

regulators and HTA bodies. Given the high levels of interest at the board, a dedicated topic will be on the agenda at the March meeting.

EMA preparedness following the UK referendum on membership of the EU

A first set of information prepared by the Agency's Operation and Relocation Task Force (ORP) looking at the impact of a Brexit on the operation and functioning of EMA was presented to the board. Based on gathered information, including results of an EMA staff readiness survey, it is estimated that in a worst case scenario up to 50% of staff members may decide not to relocate, and that this decision is largely dependent on the future location of the Agency. A second information set related to impact assessment for the scenario in which the UK were to leave the Union without joining the EEA. The UK contribution in the two areas of regulatory procedures and of contribution to EMA scientific committees, working parties and experts was examined. The impact on applications, products and procedures was presented to the board, also in the context of a reflection on assignment of rapporteurships.

The UK delegation stated their commitment to continue to provide resources and support to the procedures in order to ensure a smooth transition. There was concern over provisions to be made by the Agency in case of a substantial loss of staff, and on the time needed to select and train new staff members. The Agency will work to streamline its selection procedures, but must think also about other alternative solutions. Concerning availability of scientific expertise in the network, it was considered that increasing complexity of procedures might be a hurdle to engagement by NCAs in centralised procedures, as some resources might start to be under strain also in the decentralised procedures. NCAs might need to plan investments in scientific resources to face not only possible challenges, but also opportunities, which a significant change in working dynamics might bring. The board expressed appreciation for the work of the ORP, and looked forward to future updates.

B.3 Report from the European Commission

The report by the European Commission concentrated on selected highlights.

Follow up of Council conclusions of June 2016

The methodology and timelines for the EC studies on impact of pharma incentives on innovation, availability and accessibility and on paediatrics, to be conducted following the June Council conclusions, were presented at the EPSCO Council of 8 December. Member States participation in these studies will be essential Terms of Reference have been approved and will be published shortly.

STAMP delivery and interactions with EMA/HMA

The two years of the operation of STAMP has informed the development of early access initiatives and the reflection paper on HTA and has explored, compassionate use, registries, repurposing of established medicines, and off-label use of medicinal products. The EU Medicines Agencies Network Strategy to 2020 and STAMP share common activities on which both EMA and NCAs need to work while avoiding duplication of action.

Synergies between regulators and HTA networks

Following the unanimous adoption by the HTA network of the Reflection Paper on synergies between regulatory and HTA issues, a temporary Synergy Group will be created to facilitate interactions between key players and avoid duplication and uncertainty. HTA and regulators will be represented in equal numbers, and the European Commission will take on the role of facilitator. EMA/EUnetHTA collaboration continues with two work packages, Joint assessments and Evidence generation, in

progress. A first meeting of EMA and EUnetHTA took place on 7 December with the objective to develop a joint work plan. In the context of the HTA initiative on strengthening EU cooperation on HTA beyond 2020, an Inception Impact Assessment was published on 14 September. After a public consultation and meetings with stakeholders and bilateral meetings with Member States an impact assessment planned for 2017 might lead to a non-legislative or legislative proposal.

EU-US Mutual recognition of GMP inspections

With the ambition to achieve Mutual Recognition Agreements by 20 January 2017, a key element of the ongoing discussions is to ensure that all inspectorates that will not be recognised at the time of entry into force (mid 2017) will be assessed within a time period that is as short as possible (a period of approximately 2 years is currently considered). Concerning a question on whether the US Freedom of Information Act could hinder sharing of information among inspectorates, EMA indicated that discussions were well advanced on a draft administrative arrangement allowing the exchange of confidential information and trade secrets between FDA and EMA/SANTE. This arrangement, once finalised, will provide a robust basis for developing arrangements between FDA and MS inspectorates that will have to be adapted to each national legislation.

Implementation of the Clinical Trials Regulation

Work on the legal obligations is on track as several Implementing and Delegated acts will be adopted by April 2017. A meeting of the expert group on Clinical Trials is planned for 26 January 2017.

Cooperation with WHO on Art. 58

A strong interest was shown by some NGOs in promoting the use of Art. 58 procedure for products to be marketed outside the EU. The European Commission and EMA want to clarify that the same standards for clinical data and GMP apply, regardless of procedure. The Commission welcomed the EMA work program to promote cooperation with WHO in stimulating the use of Art. 58, and the upcoming event by the Maltese Presidency to address cooperation with third countries, in particular African regulators.

A representative of patients' organisations stated the urgency for patients of cooperation on HTA, the importance of a wider involvement of stakeholders in STAMP and the need to reduce uncertainties on pricing and reimbursement by establishing a dialogue between EMA, the HTA network and Pricing & Reimbursement authorities. While reminding that pricing and reimbursement are national competencies, the European Commission informed about the Network of competent authorities on Pricing & Reimbursement (CAPR) which meets under the rotating Presidencies of the Council, with financial and administrative support by the European Commission. The next meeting of this network is scheduled for 14-15/3/2016 in Malta.

B.4 a) Audit strategy 2017-2019 and annual Audit Plan for 2017

[EMA/MB/759063/2016; EMA/541719/2016] The Management Board adopted the Audit Strategy 2017-2019 and Annual Audit Plan for 2017. Four topics for audit have been selected on the basis of an assessment of risk and assurance map and seven further are to be undertaken to fulfil legal or regulatory requirements in 2017. Additionally, the European Court of Auditors and the Internal Audit Service of the EC will conduct one audit each. The audit strategy is subject to annual review and outlines also the rolling audit plan related to 2018-2020, which takes into account the outcome of the 2016 risk assessment leading to the update of the Agency's risk register, the assurance map prepared

by the Audit Function and the outcome of discussions with all Heads of Division. In 2017 the Audit Function itself will be the object of an external audit in order to comply with quality standards.

Concerning information requested on audits on IT development, systems and process, the audit function recalled that IT had been a main focus for the last five years, covering aspects of outsourcing, security, governance, value for money of projects, business continuity and more.

B.4 b) Report on Pharmacovigilance Audits carried out at EMA from 1st July to 30th June 2016

[EMA/MB/759561/2016; EMA/506638/2016] The board endorsed the report which is required on a 2-year basis to inform on regular independent audits performed on the Agency's pharmacovigilance tasks. The report presented is the second of this kind. The report outlines 13 audits performed on Agency's tasks and activities that impact directly or indirectly on the operation of the EMA pharmacovigilance system. All audits include systems and operations of the whole cycle. The conclusions show that all corrective actions related to the external audit of the PSUR repository conducted in March 2015 have been fully implemented. The implementation of corrective actions is ongoing for audits conducted in April and June 2016, with all critical findings already closed. All corrective actions related to previous reporting period have been implemented with the exception of two actions outstanding due to projects reprioritisation and introduction of new tools.

B.5 Framework of interaction with Academia

[EMA/MB/752841/2016; EMA/753033/2016; EMA/578639/2016] The board discussed a framework of collaboration between the EMA and academia. The framework is meant to complete the overall framework of interaction with stakeholder in addition to the already existing frameworks of collaboration with patients, healthcare providers and industry. A survey of academia was conducted in Q1 2015 after consultation of the Heads of Medicines Agencies. A workshop of the Healthcare Professionals Working Party was held in Q2 2016 to discuss the framework of collaboration and highlighted consensus on the opportunities of leveraging and enhancing existing activities in the fields of education and training, and on the crucial importance of putting in place a communication strategy to allow bidirectional exchanges. The objectives of the collaboration are raising awareness of the mandate and work of the Agency within the network to increase academia's engagement, promoting and develop support to foster the translation of academic research, and ensuring that the best scientific expertise and academic research are available. The working methodology is based on the four elements of the EMA stakeholder relations framework: inform – consult – consult and involve – cooperate/participate. An action plan and yearly reporting to the Management Board are foreseen. As a first action the Agency would like to establish contact points in the NCAs to act as hub of all activities involving academia.

Members of the board recognised the importance of collaboration with academia as a means to transfer knowledge on regulatory aspects of development, but some questioned the balance of roles between EMA and the NCAs or suggested a joint-up approach that would link with work done at national level. The NCA contact points will play an important role in the context of avoiding duplication of work done by the EU Innovation Network. The Executive Director clarified that the scope of the framework is not to engage in the development of products, but to provide clarity on definition of academia, handling of competing interests, and establish a better mutual understanding. EMA interacts through its frameworks with stakeholders at a European level. The board agreed to provide written comments to the framework within a month, and to adopt the revised document at the March meeting.

B.6 Revised framework of interaction with healthcare professionals

[EMA/752887/2016; EMA/677917/2016; EMA/705066/2016; EMA/89918/2016] The Management Board adopted the revised framework for interaction between EMA and healthcare professionals and their organisations. A first formal framework had been adopted by the board in 2011. A revision is now necessary to incorporate experience gained, align with regulators' strategic objectives, ensure consistency with the other EMA stakeholder frameworks, provide closer focus on healthcare professionals' fields of activity and areas of interest, and improve interaction.

B.7 Revised Access to Documents Policy

– Release for Public Consultation

[EMA/MB/750780/2016; EMA/729522/2016, EMA/183710/2016, EMA/127362/2006, Rev. 1] The Management Board endorsed the release for public consultation of the revised EMA policy on access to documents. The Policy and an Output Table have been in effect since December 2010. The current revision takes into account experience gained and new, revised or upcoming legislation since 2010. The main proposed changes concern the extension of the scope of the policy to include also corporate documents, the addition of a new specific principle of transparency on the requests and beneficiaries of the access to documents, the merger of the Policy and rules for its implementation into a single document, the revision of the existing output table and the creation of an additional output table for corporate documents. The Members of the Management Board agreed to maintain the current position that names of assessors in the Rapporteur and Co-Rapporteur teams shall not be released in response to requests for access to documents in accordance with Article 4(5) of Regulation (EC) 1049/2001. In 2017, after review of the outcome of the public consultation, the policy will be revised and submitted for adoption to the Management Board.

B.8 Multinational assessment team concept (MNAT)

[EMA/MB/765224/2016; EMA/619544/2016] The board endorsed the Multinational assessment team concept. The MNAT concept, launched in 2012, has been so far applicable to (Co) Rapporteurs for initial human and veterinary MAAs, rapporteurs for MRL applications and coordinators for human and veterinary scientific advice procedures. It provides the option for an assessment team to be formed from different NCAs and aims to allow a broader involvement of NCAs in the work of EMA scientific committees, optimising resources while maintaining the high quality scientific work of the committees. In Q4 2015 some CHMP delegates with experience in MNAT requested an extension of the concept to the post-authorisation phase. Considering the positive experience with MNAT in the pre-authorisation phase some ground rules were developed: allowing flexibility while achieving a sustainable solution, ensuring knowledge transfer by retaining the same NCA composition of the MNAT pre- and post-authorisation, efficient and transparent process and also strive for a more robust planning of post-authorisation applications. The proposed approach will be applied stepwise, starting with phase 1 in Q2 2017 extending to existing pre-authorisation MNAT teams (Co)-Rapporteurs for both human and veterinary medicines, in case of extension of indications (additionally non-food target species for veterinary medicines) and line extension in the post-authorisation phase.

B.9 Revised EU Telematics governance model

[EMA/MB/796830/2016, EMA/MB/790083/2016; EMA/795871/2016] The Management Board endorsed a proposal for a revision of the Telematics governance model. Over the last year the Telematics Governance has been streamlined by moving the reporting line of the EU Network Data Board from the

EU TMB to the IT Directors Group and the IT Directors Executive Committee in February 2016. A further revision was proposed to create a new governance body, the Telematics Change Management Board (CMB), to replace the existing three Change Management Boards (Human, Veterinary and eSubmissions). The proposal and rationale were discussed at the Telematics Forum. The EU TMB adopted the revised Telematics Governance including the proposal for a single CMB in November, and the HMA endorsed it by written procedure on 9 December. A document on the approach on for prioritisation of requests by the CMB will be circulated to board members.

B.10 Pharmacovigilance Programme: Member State access to Art 57 data on medicinal products

[EMA/MB/729634/2016] The board endorsed the anticipated release of the Article 57 reports to the NCAs, which was originally planned for November 2017. In December 2015 the Management Board had decided that the Article 57 database was functional for pharmacovigilance and supported reliance on Article 57 for industry notifications of change to the Qualified Person for Pharmacovigilance (QPPV) and the Pharmacovigilance System Master File (PSMF) location, effectively eliminating the need for corresponding variations and reducing administrative burden. The expanded set of reports will allow the retrieval of information which might support further simplification of regulatory processes and facilitate identification of products in other countries. The reports will be released in Q1 2017 together with the user manual and e-learning.

B.11 Pharmacovigilance Programme: Update on EudraVigilance Auditable Requirements Project

[EMA/MB/725773/2016; EMA/452911/2015; EMA/325783/2016; EMA/835422/2016] The board noted an update on the EudraVigilance Auditable Requirements Project. Following the approval by the Management Board in June 2016 of an updated schedule for the implementation of the new EudraVigilance (EV) system, the board received an update in October. The current status shows that the EV Auditable Requirements Project is on track to deliver the enhanced EV system in 2017, with activities ongoing on audit preparations, EudraVigilance system development, system testing, training development, transition to a new supplier and release of additional Art. 57 publication reports. A minor technical revision of the EV Access Policy was undertaken to further strengthen personal data protection (see C.5 Pharmacovigilance Programme: revised Eudravigilance Access Policy).

B.12 Clinical Trial EU Portal and Database

[EMA/MB/757803/2016; EMA/753750/2016] The board noted a status update on the development of the Clinical Trial EU Portal and Database, which is on schedule to deliver the auditable version in July 2017. This is a very tight schedule and all concerned parties need to work together to ensure strict focus on 'Must' requirements for the audit and to closely monitor and mitigate identified risks. The auditable version will contain all 'Must' (auditable and non-auditable) requirements and meet the requirements of the Regulation and functional specifications. Key enhancements for sponsor and MS functionality are being prioritised for post audit implementation and their specification will be finalised in Q2 of 2017. As of October the Coordination group has been joined by three Management Board representatives who have taken part in two teleconferences. A subgroup of ca. 10 MS has been formed under BfArM leadership to define and present to EMA by mid-January the specifications for the Member States application programming interface (API) to meet the 'Must' API requirements, which EMA will then provide to the developer for inclusion in the auditable version for release in July 2017. Meetings on user management were organised by EMA on 28 November with stakeholders, on 29 November with MS and on 8 December with the MS Expert Group.

Some members pointed out that much work still needs to be done, at the Agency in the development of the Portal and Database, and in the MSs who have to prepare on the basis of clear definitions and information on the systems. Overall coordination of the implementation of the legislation is needed, as the portal and database are only a part of it. The mentor of CTFG considered that the Coordination group is the right forum for discussion and informed that the Group proposed to hold a workshop on the implementation of the Clinical Trial Regulation on 14 February 2017 with representatives of all Member States, the Commission and the EMA. The objective of the workshop will be to provide the status update of all work streams of the implementation. A mix of experts representing business and IT, but also members of the board and heads of agencies should be invited, to achieve alignment at all levels, including the national level.

B.13 Report by the Steering Group on the Management Board data gathering initiative

[EMA/MB/813572/2016] The board noted the 11th interim report of the Steering Group on the Management Board data gathering initiative. The data collection phase, which was launched exactly a year ago, required a great effort by all parties involved and is now nearing completion. Key datasheets and high level graphic representations, based on human interim data collected before 31 October 2016 were presented to the board. These will be included in a draft statistical report to be prepared by the end of 2016 and completed in March 2017 with a full narrative report, updated data and the veterinary report. While all detailed information had been made available to members ahead of the meeting, the analyses showed overall averages of working hours by EMA and NCAs and the resulting effort levels for the main regulatory procedures, also broken down by different actors and by scientific or administrative role of staff involved. Standard deviations and variability were considered, also in relation to procedure type and phase in the procedure. Non-fee generating procedures relating to paediatrics and orphan medicines were included in the analysis, providing previously not available data, as well as information on time spent on average per month on different activities for Committee work by COMP and PDCO members. It is to be hoped that ongoing efforts will allow reaching a compliance rate of 80-85% as achieved for the pilot on Scientific Advice. The final report will also include data on inspections, and on the remaining Working Parties and Committees. Pharmacovigilance procedures will be captured separately in the legally required reporting stream relying on retrospective data for 2015 and prospective data for 2016.

Information was provided on progress with the study supporting the external evaluation of the EMA fee system. A kick-off meeting for the 15 month engagement was held on 12 December 2016 with the selected contractor and representatives of EMA and HMA as observers. It is foreseen that NCAs will be involved between February and April 2017, when the contractor will conduct a survey to collect cost data and approach a sample of individual agencies for interviews. NCAs were invited to ensure that their financial services are aware of the need to provide financial data in that timeframe. It was suggested to the Commission to organise a meeting of the NCAs with the contractor ahead of the survey, in order to ensure an understanding of the complexity underlying the system. The European Commission will keep the board informed of timelines and report on further developments.

B.14 ADVENT mandate renewal

[EMA/MB/734937/2016; EMA/CVMP/ADVENT/630299/2014 – Rev.2] The Management Board noted the mandate renewal for a period of three years for the CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT).

B.15 Update on the implementation of the Anti-Fraud Strategy

The Management Board noted a report on the implementation of the Anti-Fraud Strategy for 2016 and endorsed the Action Plan for 2017. Cooperation with OLAF on a number of cases has been very good. All three actions scheduled for 2016 have been completed, with some implementation measure still ongoing, specifically in the area of the revision of the internal access rights to the Agency's documents. The Action Plan for 2017 will focus on continuing to foster an anti-fraud culture, on follow-up actions further to two scheduled internal audits and on a review of the Agency's guidelines on sensitive posts from a more targeted anti-fraud perspective. The Anti-Fraud Strategy was adopted in 2014 and needs to be reviewed every 3 years. The Executive Director will set new objectives for the following 3-year period and an updated Action Plan will be prepared accordingly. The revised Anti-Fraud Strategy and the related Action Plan for 2018-2020 will be submitted to the Management Board for adoption at the December 2017 meeting.

Concerning a question on actions foreseen on handling of fraud allegations concerning regulatory documents submitted to the Agency, the board was informed that discussions with the European Commission and OLAF on a draft policy on external sources informing EMA about possible improprieties of that kind are at an advanced stage. The final policy might be submitted to the board at the next meeting.

B.16 Revision of rules for reimbursement of expenses for delegates attending meetings

[EMA/MB/811697/2016] The Management Board was informed that a written procedure for the adoption of revised rules for reimbursement of expenses for delegates attending meetings will be launched in January 2017 to take into account the European Commission's revision of daily allowances and hotel ceilings, the roll-out of public hearing and various alignments and streamlining of text.

List of written procedures finalised during the period from 7 September 2016 to 16 November 2016

- Consultation no 10 /2016 on the appointment Nikola Moravcova as CHMP member, proposed by Slovakia, ended on 3 October 2016. The mandate of the nominee commenced on 4 October 2016.
- Consultation no 11 /2016 on the appointment Assena Stoimenova as CHMP alternate, proposed by the Bulgaria, ended on 11 October 2016. The mandate of the nominee commenced on 12 October 2016.
- Consultation no 12 /2016 on the appointment Selma Arrapovic Dzakula as CHMP alternate, proposed by the Croatia, ended on 27 October 2016. The mandate of the nominee commenced on 28 October 2016 2016.
- Consultation no 13 /2016 on the appointment Laimis Jodkonis as CVMP alternate, proposed by the Lithuania, ended on 15 November 2016. The mandate of the nominee will commence on 1 December 2016.
- Written procedure for adoption of the 93rd Management Board meeting minutes, ended on 14 November 2016. The minutes were adopted.

Documents for information

- [EMA/MB/756656/2016; EMA/731292/2016] Report on EU Telematics

- [EMA/MB/716724/2016] Outcome of written procedures finalised during the period from 7 September 2016 to 16 November 2016
- [EMA/MB/707314/2016] Summary of the transfers of appropriation 2016
- [EMA/MB/707899/2016; EMA/759287/2009 Rev. 3] Pharmacovigilance Programme: Revised Eudravigilance Access Policy

Tabled documents

- Draft agenda for 14-15 December 2016 meeting v.4
- HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use
  Priority: Availability of appropriately authorised medicines
  Terms of Reference
- Mandate HMA / EMA Joint Task Force Big Data
  Priority: Reinforce the scientific and regulatory capacity and capability of the network, Innovation and access to new medicines, Optimisation of the regulatory operations

List of participants at the 94th meeting of the Management Board, held in London, 14-15 December 2016

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member) attendance on 15 December 2016*
Bulgaria	Assena Stoimenova *(member)*
Czech Republic	Zdenek Blahuta *(member)*
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)*[1]
	Mette Aaboe Hansen *(observer)*
Germany	Karl Broich *(member)*
	Klaus Cichutek *(alternate)*
	Ansgar Schulte *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)*
	Rita Purcell *(alternate)*
Greece	Despina Makridaki *(member)*
Spain	Belén Crespo Sánchez- Eznarriaga *(member)*
France	Dominique Martin *(member)*
	Miguel Bley *(observer)*
Italy	Luca Pani *(member)*
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)*
	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	Pekka Kurki *(alternate)*
Sweden	Catarina Forsman *(member)*
	Asa Kumlin Howell *(observer)*
United Kingdom	Ian Hudson *(member)*
	Jonathan Mogford *(alternate)*

[1] Competing interest declared resulting in no participation in decision with respect to agenda points B.1, B.8 and B.9.

	Participants
European Parliament	Björn Lemmer
	Tonio Borg
European Commission	Xavier Prats-Monné (DG SANTE) *attendance on 14 December 2016* *Apology received from Carlo Pettinelli (DG GROW)* Jerome Boehm (DG SANTE) *(observer)* Chloe Spathari (DG GROW) *(observer)*
Representatives of patients' organisations	*Apology received from Ilaria Passarani*
	Yann le Cam
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
EEA-EFTA states	Runa Hauksdottir Hvannberg (Iceland) Brigitte Batliner (Liechtenstein) *Apology received for Norway*

European Medicines Agency	Guido Rasi Noël Wathion Stefano Marino Nerimantas Steikūnas Enrica Alteri Anthony Humphreys Alexis Nolte Melanie Carr Fia Westerholm Zaide Frias Agnes Saint-Raymond Isabelle Moulon Edit Weidlich Monica Dias Michael Lenihan Georgy Genov Paolo Alcini Hilde Boone Silvia Fabiani Sophia Albuquerque