22 December 2015
EMA/MB/858667/2015 Adopted
Management Board

Minutes of the 90th meeting of the Management Board

Held in London on 16 - 17 December 2015

The Chair of the Management Board opened the meeting by welcoming the new members Karl Broich and Klaus Cichutek, member and alternate for Germany, Svens Henkuzens, member from Latvia, Csilla Pozsgay member from Hungary and Andreja Čufar the member from Slovenia.

Sir Kent Woods informed the board of his decision to stand down as Chair at the end of December and that consequently this would be the last meeting under his chairmanship. When putting his name forward for a second term in June 2014 he had said that he would not serve for more than another 1-2 years. Last year's uncertainties around the Executive Director appointment and the need to maintain stability during a difficult period for EMA confirmed the necessity to stay on until the Agency was again in a strong position to move forward. The Vice-Chair, Christa Wirthumer-Hoche, will now take the role until the election of a new Chair takes place at the beginning of the next meeting of the Board on 17 March 2016. The secretariat will send Management Board members a request for nominations in the New Year.

The Board expressed sincere thanks to Sir Kent for more than four years of exceptional stewardship of the Management Board and wished him all the very best in his new position.

1. Draft agenda for 16-17 December 2015 meeting

[EMA/MB/169416/2015] The agenda was adopted with no amendments.

2. Declaration of conflicts of interest related to current agenda

The chair informed members of the Management Board that he had reviewed members' declared interests, together with the secretariat, in accordance with the Board's policy on conflict of interests. Some potential conflicts relating to the day's agenda were identified concerning topic B.1, Strategy for EU Medicines Network to 2020. Should the need for a vote on this topic arise, the chair would take up the matter again; all concerned members had been informed of the restrictions arising from the current policy on interests which is to be reviewed under Item 6.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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The chair invited members to further declare any specific interests that could not be drawn from their declarations of interests that could be considered prejudicial to their independence with respect to the items on the agenda. No conflicts of interests were declared.

3. Minutes of the 89th meeting, held on 2 October 2015 adopted via written procedure on 10 November 2015

[EMA/MB/313663/2015] The Management Board noted the final minutes, adopted by written procedure on 10 November 2015.

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/711738/2015; EMA/742260/2015] The Management Board endorsed the fixed flat-hourly rate for 2016, unchanged from 2015.

B. Points for discussion

B.1 Strategy for EU Medicines Network to 2020 – working together to improve health

[EMA/MB/778307/2015; EMA/MB/151414/2015; EMA/670072/2015; EMA/441188/2015] The Management Board noted the Outcome of the public consultation on the EU Medicines Network Strategy and adopted the EU Medicines Agencies Network Strategy to 2020 with two minor editorial amendments. The Strategy had been submitted to a public consultation until 30 June 2015, after endorsement by the Management Board at its March 2015 meeting. Subsequently all comments had been reviewed by the joint EMA/HMA Steering Group. The accepted comments resulted in amendments to the Strategy or will be taken on board in the context of the multi-annual work programmes of HMA (February 2016) and/or EMA (for 2017-2019 within the current Programming document for adoption at current meeting, for further years at the March 2016 meeting). Among the changes introduced to the Strategy following the consultation were a better differentiation between human and veterinary medicines, an increased emphasis of the importance of generic/biosimilar and non-prescription medicines for the healthcare system, and a clarification of the description of novel products, now defined as “added therapeutic, diagnostic or prophylactic value and/or new active substances”.

The representatives of the European Commission joined other board members in congratulating all on a considerable piece of work, stressing the importance of continuing cooperation to align with the Commission’s strategic priorities for the next 5 years (among which are Antimicrobial Resistance (AMR), Health Technology Assessment (HTA), Safe and Timely Access of Medicines for Patients (STAMP). It is important that all parties in the network continue to work together to achieve synergy and efficiency.

The Network Strategy, a common press release and the document summarising the outcome of the public consultation, together with the written contributions received, will be published on both the HMA and EMA websites.

B.2 Programming Documents

B.2.a) Programming Document

[EMA/MB/792303/2015-Rev.1; EMA/693305/2015; EMA/610297/2015] The Management Board adopted the Programming Document including the Multiannual programming 2017-2019, the Work Programme 2016, the Preliminary Work Programme 2017 and the annexes to the Multiannual programming.

As the first planning cycle presented in accordance with the new Framework Financial Regulation and taking into account the guidelines set out by the European Commission, a single programming document containing multiannual and annual programming had been submitted to the board. The programming document combines a number of previously separate planning documents and includes additional information. The document is for adoption by the Management Board and must be sent to the Commission, the European Parliament and the Council by 31 January every year. In order to facilitate the discussion of the Programming document, the presentation to the board followed the different components of the package: work programme, budget, staffing, IT budget, programmes and projects. The topic coordinators Grzegorz Cessak, Christa Wirthumer-Hoche and Kristin Raudsepp took part in the presentation to the board of the topics on which they had focussed more intensely during the 3 month discussions with EMA.

The Executive Director introduced the drivers shaping the Programming document. Workload evolution should be approached in both a qualitative and a quantitative perspective, as the complexity of scientific demands and stakeholder involvement will pose the greatest strains on scientific expertise. Other challenging factors are globalisation and the need for capacity building in new areas, AMR developing into a social driver, MUMS and vaccines as being recast in the ambitious Commission proposal for the veterinary legislation. These demands will not concern EMA alone, but the network as a whole.

The workload trends to 2017 appear stable, with some increase in the areas of innovation linked to the Horizon 2020 programme, such as Orphan designation and protocol assistance. Activities for post-authorisation procedures and monitoring and compliance trends are unvaried, although there may be some evolution for GCP inspections following a review of the fees in 2015. Pharmacovigilance legislation has now reached full implementation and work relating to PSUR Single Assessment (PSUSA) is expected to increase substantially for EMA and NCAs. Veterinary applications are expected to increase, while requests for MUMS classification will probably remain stable. Further non assessment related areas where workload is evolving are development and maintenance of additional IT systems as required by legislation, stepping up of training initiatives and capacity building, and the implementation of the publication of clinical data. The introduction of public hearings will require the extension of collaboration with stakeholders, as well as the development of new frameworks. International activities will address new cooperative mechanisms, while corporate activities, such as audits, evaluation activities of programme and projects and antifraud policy implementation will increase as a consequence of new requirements. Grzegorz Cessak described to the board how the Work Programme 2016-2017 converges in the forward planning of the Agency with the objectives set for all its four themes by the Network Strategy. Christa Wirthumer-Hoche provided an analysis of the budget: for 2016 revenue from fees is likely to increase, along with expenditure for payments to NCAs

for scientific services; full implementation of the Pharmacovigilance Fee Legislation has created a steady state; investment in the new building is no longer necessary for the time being, with the exception of an auditorium for public hearings; with a small staff increase of 8 FTE, within the overall limit of the draft 2016 budget, staff costs will further rise due to unfavourable EUR-GBP exchange rates and the introduction of payment of the employer's part of pension contributions previously paid by the Commission. For the preliminary draft budget 2017 it is expected that the moderate increase in fee revenue will continue, that the assigned revenue from the building will only pay for part of the rent costs and the full EU contribution will therefore resume. A staff increase of 12 FTE has been accepted by DG SANTE and will be reflected in the expenses accordingly. Funding of network activities will increase particularly in the areas of meeting activities and EU Training Network. Alexis Nolte presented to the board the new Information Management Strategy, which shifts the focus for Telematics and support to the Agency from the provision of technology to the provision of services for sharing information on medicines and their effective regulation in Europe. The role of systems is to acquire information, re-use and transform it by means of an organising logic, and deliver it to stakeholders and public. The Information Management strategy implementation plan 2016 to 2018 foresees the delivery of the solutions required by law for telematics, which make up 80% of the IT budget, sharing of information on medicines and establishing and improving the Agency's information services. Kristin Raudsepp completed the presentation with an overview on IT budget and programmes and projects in 2016-2017. These will continue to focus on delivering the objectives of the EU Telematics Strategy.

The representative of the European Commission informed the board that the presented work programme 2016 is in line with expectations by the Commission, whereas the official opinion on the 2017 part will be sent by July 2016. He commended on the fact that the multiannual programming aligns strategic priorities and spending. The draft 2016 budget is fully in line with the EU budget, while the preliminary 2017 budget will need to be presented to the budgetary authority by end of January 2016 but will receive feedback only in July 2016 once it has been considered within the overall EU budget. He looked forward to a dialogue with the board and the Executive Director to set the priorities to be reflected in the budget soon. For the future early dialogue will take place with the board and the Executive Director in order to deliver on common objectives. .

The discussion that followed touched on some points needing further clarification. This concerned the apparent contradiction between stable numbers of applications and an increase in fee income. It is basically the result of the full implementation of the pharmacovigilance regulation and of the cumulative effect of other post-authorisation activities. Overall the payments to NCAs will increase at a similar rate as the estimated fee income. Other comments concerned matters of process. Some members wished for more time to consider the large document (ca. 120 pages), the provision of outcome indicators and a comparative approach to certain information. The key role of the topic co-ordinators in scrutinising the evolving documents on behalf of the Board was acknowledged with thanks. The programming document was adopted with the provision to further consider these suggestions in the future, and in particular in relation with the Multiannual Work Plan implementing the Network Strategy, to be submitted to the board at the March meeting.

B.2.b) Budget and Establishment Plan 2016

[EMA/MB/577439/2015; EMA/MB/596380/2015] The board adopted the Budget and Establishment Plan 2016.

B.2.c) Non-automatic carryover 2015 to 2016

[EMA/MB/615629/2015] The Management Board adopted the non-automatic carryover 2015-2016. Some services could not be contracted out before year end due to unforeseen circumstances. Contract signature had therefore to be postponed to January/February 2016. In order to make these allocations from the 2015 budget, the board adopted non-automatic carry forwards for Clinical Trials – EU Portal and Database, Data integration – OMS/RMS (Organisation Management System/Referential Management System), scientific research studies and the EU Network Training Centre.

B.2.d) Delegation of non-substantial amendments to the Work Programme to the authorising officer

[EMA/MB/768568/2015] The Management Board adopted the Delegation of non-substantial amendments to the Work Programme to the authorising officer. Article 32(4) of the new Financial Regulation foresees that substantial amendments to the Work Programme should be adopted by the Management Board, while the board may delegate to the authorising officer the power to make non-substantial amendments. The adopted decision will allow the authorising officer to make amendments to the work programme that entail amendments of activity based budget from one chapter of the annual work programme to another not exceeding the 2% materiality threshold of the adopted operational budget. The authorising officer shall inform the board of any non-substantial amendment during mid-year and annual reporting. Amendments to the work programme that go beyond the 2% materiality threshold as well as addition of a new activity area or discontinuation of an activity area shall be submitted the Management Board for a decision.

B.3 Audit strategy 2016-2018 and annual Audit Plan for 2016

[EMA/MB/718643/2015; EMA/363099/2015] The Board noted the audit strategy 2016-2018 and adopted the annual audit plan for 2016. Seven topics for audit have been selected following the 2015 risk assessment, and five further topics are to be undertaken on the basis of legal or regulatory requirements in 2016. The audits will be conducted by the EMA audit function and by external bodies. Further activities of the EMA audit function address the needs for coordination and harmonisation of audit tasks, the needs for cross Agency consultancy and for internal and external training.

There was interest by some board members in the possibility to audit overall performance in running the business. Assurance was provided that the audit function examines the performance and not just the compliance, as an example it was mentioned one recent audit in the area of the building blocks of assurance, as well as planned audits for 2016 in the field of governance of IT and performance of governance in projects.

B.4 Highlights of the Executive Director

Upcoming organisational changes

The current Deputy Executive Director, Andreas Pott, will retire in 2016. Noël Wathion, EMA Chief Policy Adviser, has been appointed as his successor. As of 1 February 2016 they will be working closely together in order to ensure a smooth transition in a role which has proven to be of critical importance to the Agency. Among other responsibilities, Noël Wathion will be in charge of policy development and preparation for new legislation, emergency/crisis management, liaison with EU

Institutions, access to documents and proactive publication of clinical data, as well as fostering integration of EMA activities across the Agency.

Technical issue with the EU Clinical Trial Register (EUCTR)

The Board was informed on 2 October 2015 of an incident in the software of the EU CTR which led to the withdrawal of access for sponsors to enter results or edit existing results in EudraCT, and to the removal from public view of results summaries already posted. The Agency has now resolved the problems which led to the suspension of these information services and plans to release them back into production in the week of 11 January 2016.

International Activities

The review of the Article 58 procedure with the Bill & Melinda Gates Foundation has been completed and the EMA together with the European Commission is exploring how to enhance the liaison with WHO and local regulators. EMA attended the 10th Summit of International Heads of Medicines Agencies and the International Coalition of Medicine Regulatory Authorities (ICMRA) which took place in Mexico City from 10th to 13th November. Three new ICMRA action areas were proposed based on mapping prepared by the EMA: supply chain integrity mapping of track and trace systems, crisis management – preparation of a best practices SOP and actions in the areas of pharmacovigilance. India was present for the first time, and will be engaged in the three identified work streams. After 4 years of preparatory work, the International Council for Harmonisation (ICH) reforms have been completed and will allow for a global initiative, expanding beyond the current ICH members.

Director General of DG SANTE

The Agency welcomed the new Director General, Mr Xavier Prats Monné, to his first meeting as the new DG SANTE management board member. Mr Prats Monné had already met with EMA senior management in October and had been introduced to EMA staff. Future cooperation between EMA and DG SANTE was discussed with a view to renew the commitment to focus on main common objectives with an integrated approach, including also Member States.

EU Innovation Network (EU-IN)

The EU-IN was initiated informally in 2011 jointly by the EMA Innovation Task Force (ITF) and a number of senior officials from National Competent Authorities (NCAs). At the HMA meeting in October 2015 it was considered useful to explore whether the current informal activities of the EU Innovation Offices Network (EU-IN) need to be formalised and strengthened. The FIMEA Director General Sinikka Rajaniemi was given the leadership in this initiative and she called a meeting on 25 November at FIMEA in Helsinki which was attended by representatives of 15 EU agencies, as well as the CHMP Chair Tomas Salmonson. The initiative has the objective to promote collaboration with SME and academic enterprises which produce innovation, providing support at a national and at the central level to develop products, involve patients wisely and achieve success.

Pilot on Parallel Distribution

At the end of September 2015 the Agency received a request from Malta to explore ways to improve availability of medicines on its territory. The Maltese Medicines authority provided a detailed analysis demonstrating that 61% of centrally authorised active substances are not available in Malta. The Agency was requested to explore the possibility of reducing the parallel distribution fees in order to

increase availability in Malta by means of parallel trade. The Executive Director has therefore initiated a 1 year pilot initiative involving a fee reduction for notifications for parallel distribution in the Maltese language. By March 2017 the Maltese authorities will provide detailed data on the impact of this pilot scheme to be evaluated and carefully considered by the Agency, especially under the perspective of improving availability of medicines also in other small Member States.

Structured approach to Academia

At the beginning of January the Agency will circulate to the NCAs for information and input the outline of a survey designed to better understand the needs and expectations of academia.

IMI research project engagement of EMA

A paper on this topic will be presented in March. Some major projects have not started yet and some aspects of the role of regulators need to be clarified with DG SANTE and DG Research.

B.5 Report from the European Commission

The representative of the European Commission thanked the Agency for the warm welcome and addressed the board on topics concerning constructive collaboration, strategic issues and the upcoming consultation on the evaluation roadmap.

STAMP

The Safe and Timely Access of Medicines for Patients (STAMP) is an excellent example of good collaboration on innovative initiatives such as the PRIority MEdicine scheme (PRIME) and Adaptive Pathways. Progress in these areas could not be achieved by the Agency, the Commission or Member States alone.

ICH

The first face to face meeting of the reformed ICH took place and included new associates. Brazil, China and Russia are among further countries who are showing an interest. EMA's contribution was fundamental, and shows how good collaboration leads to a greater impact.

Veterinary legislative proposal

The Commission is pleased that the Dutch Presidency sees the strengthening of the action on Antimicrobial Resistance (AMR) within the Veterinary medicines legislation proposal as a top priority, and is interested in progressing it during their Semester. It is expected that the European Parliament will be aligned on this so as to achieve the objectives in the area of AMR.

Antimicrobial Resistance

It is also critically important that at national level it is recognised that AMR needs to be upgraded in the governments' agendas. In the effort to push the AMR issue globally, the Commission and EMA can contribute to the EU response along with other DG SANTE partner agencies, such as ECDC and EFSA, to make the EU into a best practice region. The Action plan for AMR will expire this year. An assessment is ongoing and the likely outcome may be that the next action plan should be more ambitious. The Council of Ministers meeting in Amsterdam will cover important topics such as research

and innovation, early diagnostics, veterinary topics, and policy issues concerning the use of antibiotics in food producing animals.

Health Technology Assessment (HTA)

HTA will be very high on the strategic agenda in the next few years. While the EU does not have a remit for the national Healthcare systems, it can support national efforts to increase their performance. Access to healthcare, resilience and effectiveness cannot be achieved without HTA which, just as AMR, is part of the single market agenda. eHealth is not only about technology, but must be understood as a tool to boost the performance of healthcare systems.

Fee system

The Juncker Commission puts a distinctive emphasis on evaluation of the existing legislation prior to considering putting forward any legislative proposal. In the case of the revision of the Agency's fees, a detailed evaluation is necessary, as all subsequent actions derive their credibility from a thorough and independent approach. A roadmap for an independent evaluation has been launched and stakeholders will have a month's time to provide comments. Once an independent contractor has carried out the evaluation, a report will be prepared on the performance of the existing fee system. If a legislative proposal is considered, an impact assessment will have to be carried out separately. It can be expected that the legislative process might be finalised by 2020. A good cooperation with all agencies and a reasonable approach are key factors for success.

Concerning HTA some doubts were expressed by some members on the involvement of patients' organisations. The Commission representative's views were that more transparency is needed, as well as greater certainty on rules of engagement, so as to involve patients in a representative manner. Some members requested further information on how Member States will be involved in the process leading up to the revision of the fee system. The Commission representative explained the role of the Commission in initiating and carrying out the different steps, starting with a thorough and independent evaluation, and reassured that a public consultation at key steps is part of the Commission's approach. Concerning specifically the Terms of Reference for the evaluation contractor, the Commission will go one step further by sharing them as soon as available with the Steering Group of the data gathering initiative to allow for comments. It is necessary that all agencies cooperate fully with the contractor during the actual evaluation.

B.6. EMA policy on the handling of competing interests of Management Board members and Breach of trust procedure

[EMA/MB/774793/2015; EMA/MB/715362/2015; EMA/MB/309079/2012 Rev. 1] The Management Board adopted the EMA policy on the handling of competing interests of Management Board members and the Revised EMA breach of trust procedure on declarations of competing interests for Management Board members. Guiding principles for a revision of the policy had been discussed at the June and October 2015 meetings of the Management Board. The Management Board Chair and the topic coordinators Wolf-Dieter Ludwig and Pekka Kurki were involved in all phases of the revision of the policy, which took into account the outcome of all discussions held. The revision aimed at finding the best possible balance between managing conflicts of interest (now termed competing interests) versus the specific roles and responsibilities of Management Board members, achieving alignment with the policy for experts, where relevant, e.g. with respect to the common definitions. The mitigating measures proposed for board activities take into account the nature of the declared interest, the timespan since the declared interest ended, the type of board activity and likely impact of decision on

industry, and the action requested from members. The possibility to participate in the discussion to enrich the debate is safeguarded in all cases.

The board welcomed the revised policy and the consequent revision of the breach of trust procedure. It was felt that rules and mitigation measures have been simplified and clarified, and will be reflected in the amended form. A yearly review of the experience with the policy will be undertaken within the context of the Agency's annual review of its independence policy. Revised rules in relation to staff will be presented to the board during the next year. The revised breach of trust procedure will be in force as of 1 January 2016, while the revised Policy for Management Board members will be applied as of 1 May 2016.

B.7 Report by the Steering Group on the Management Board data gathering initiative

[EMA/MB/774793/2015; EMA/MB/841279/2015; EMA/841290/2015] The Management Board noted the report by the Steering Group and endorsed the planning of data gathering for human and veterinary activities for 2016. The pilot on Scientific Advice procedures was concluded and the final report will be circulated to the board shortly. The data collected in the course of three cycles proved robust enough to inform future decisions regarding Scientific Advice fees and to support the use of the per procedure/per delegation methodology for all other regulatory procedures, whether remunerated or not, with appropriate adaptations. Veterinary time collection has begun with Scientific Advice and Type II procedures using the same methodology, adapted by a veterinary satellite group. Another satellite group was set up to adapt the existing methodology to PDCO and COMP procedures, as well as to discuss the approach to other Paediatric and Orphan activities. A further expert group will work in Q1 2016 on a methodology to collect data on the generation of guidelines. Among the lessons learned so far was the importance of appointing well informed national contact points responsible for coordination, who can participate in the webinars organised by EMA. The proposed high-level planning for the complete exercise foresees the launch of collection of data for several human and veterinary procedures in December 2015, extending to the others in early 2016, as well as for regulatory procedures related to COMP and PDCO. For other non-fee generating procedures, human and veterinary, there will be staggered starting dates through 2016. The European Commission has taken into account the planning that is compatible with the timelines for the evaluation, so that the collected data can feed into it.

It should be noted that some pharmacovigilance activities are not included in the data gathering exercise, as the corresponding collection of time data by NCAs and their reporting is already foreseen in the legislation and in the Cooperation Agreements. The Steering Group thanked the co-chair Sabine Juelicher and the Management Board chair, both outgoing members, for their engagement and contribution in the group, and invited the vice-chair of the board to join until the election of the chair.

The Agency provided some clarification requested on specific procedures and on non-procedure related work to be captured. Part of the planning concerns activities that are carried out at EMA alone, since the collected data are meant to support evaluation of legislation concerning the fees payable to the Agency. So called horizontal activities such as those carried out in the ca. 70 Working Parties and Working Groups will be captured.

B.8 Timelines for the implementation of the EU Portal and Database and Clinical Trial Regulation

[EMA/MB/744249/2015; EMA/760345/2015] The Management Board discussed and endorsed the timelines for the implementation of the EU Portal and Database with an extended time frame. The draft time frame had been developed in September 2015 in collaboration with Member State experts and the European Commission and presented to the board for discussion at the October meeting. Detailed business requirements were subsequently mapped against the time frame, shared with the Member States and the European Commission and reviewed in extensive discussions in subgroups and in expert groups. A key step in the legislation is an independent audit of the functionality of the EU portal and database, on which the Board will base an information to the Commission that the Regulation can come into effect. Challenges and dependencies emerged on the scope of auditable requirements, the need for Member States and sponsors to have a system meeting their requirements, and the capacity of the development team to deliver these prior to the audit. In addition the Agency (under procurement rules) has to finalise its tender procedure for a new contract with vendors in 2016. Simplifying the auditable requirements of the system to achieve implementation of the Regulation in December 2017 would carry risks; only a proportion of the 'must'[1] business requirements could be included in the audit with the intention of delivering the remainder between audit and go-live. The final timelines must balance earliest delivery of the benefits of the Regulation for researchers and patients with full functionality of the system to be used.

Two scenarios were considered by the Board: Time frame A maintaining the proposed timeline with Regulation (EU) No 536/2014 becoming applicable in December 2017, and Time frame B with the audit of a release containing a more comprehensive set of 'must' requirements taking place in Q3 2017. The latter would enable users to achieve the ambitions and meet the requirements of the Regulation with a more complete and fully operational release, and the Regulation would become applicable in October 2018 at the latest.

There was a general agreement on the need not to delay the implementation of a piece of legislation one of whose key objectives is to strengthen the attractiveness of the European clinical trial environment, benefit researchers and patients in Europe and foster innovation, as emphasised by the European Commission representative.

All interventional Clinical Trials in the future will have to pass through the Portal and Database, therefore any impact of suboptimal functioning of the system could undermine this key objective. The board recognised that the various stakeholders involved have been working towards the expected timelines and could prepare for using the new system, while work on implementation of non-auditable 'must' requirements could take place up until the go live of the final production version. There was however concern about the fact that only almost half of 'must' requirements would then be included in the audit, giving the Board inadequate assurance on the future functionality of the system at the point of their approval. It was recognised that the EU portal and database is not only an IT system, but is part of a sophisticated and complex business solution aimed at implementing the clinical trials regulation. The risk of not providing the required benefits to the multiple stakeholders without the system being fully functional was debated. There had been substantial reflection on earlier integration, prior to the audit, of a reduced set of essential 'must' requirements, but it was considered that these are difficult to single out and untangle from the rest. Scaling up of IT resources was considered not to be a feasible option taking into account the optimal size of a development team. The board examined the risks of an inconclusive or unsuccessful audit, or of the premature release of a system not

[1] According to MOSCOW criteria (Must, Should, Could, Won't)

providing full functionality, and considered the consequential risk of delivering the system even later than the time frame proposed as B. For these reasons it settled on endorsement of time frame B, as a maximum time frame, with the firm commitment of all members to make every effort to implement the EU portal and database within the maximum timelines proposed under this option. In the meantime there will be a continuing strong focus on developing business processes and on communication with all stakeholders and business partners. A rigorous monitoring system will provide information on actual progress of development. The Management Board will be regularly updated, and will seek to bring forward the maximum timelines if there are opportunities to do so as the work progresses.

B.9 Revised EudraVigilance Access Policy

[EMA/MB/748121/2015 Rev.1; EMA/759287/2009 Rev 2] The Management Board adopted the revised EudraVigilance access policy. The policy was first adopted by the Management Board in December 2010 and came into force in July 2011. The revision has the objective to extend access levels to fulfil the legal requirements of broadening stakeholder access to EudraVigilance data and is in line with EU data protection legislation. A draft revision was released for public consultation in 2014, all comments were consolidated and the revision finalised based on the extensive feedback received. Changes will come into effect in Q3 of 2017 in parallel with EMA implementing a series of technical improvements to the EudraVigilance system. The revised EudraVigilance Access Policy underpins the delivery of the new EudraVigilance functionalities, for which an audit is planned in Q3 2016.

B.10 Pharmacovigilance Programme: Eudravigilance high level audit plan

[EMA/MB/727947/2015; EMA/452911/2015] The Management Board noted the EudraVigilance high level audit plan. In December 2013 the Management Board and the PRAC agreed the required functionalities of the new EudraVigilance system which will need to undergo an independent audit before the move to centralised reporting. The audit by an independent auditor is now foreseen to take place in Q3 2016. The audit report, along with a PRAC recommendation, will then be presented to the board who would then be able to announce at its meeting of December 2016 that the system has implemented the functionalities agreed in December 2013. The move to centralised reporting in EudraVigilance for the pharmaceutical industry, is based on this Management Board announcement, and would become mandatory in July 2017, six months after the announcement. The final audit dates will be confirmed after the independent auditor has been selected.

The new release of the system will not only implement the new reporting requirements, but also the new ICH ISO compliant data structure, which will allow easier exchange of information between world regions and more sophisticated search functions. Concerning requests by Member States for auto-forwarding mechanisms from EudraVigilance to national systems, once the direct reporting is in place, the enhanced EudraVigilance system will enable Member States to have all their national cases automatically forwarded to the national database.

B.11 Member State access to Art 57 data on medicinal products: functionality for Qualified Person for PhV (QPPV) and location of PhV master file (PSMF)

[EMA/MB/632566/2015; EMA/MB/730957/2015] The board adopted the proposal to discontinue variations for QPPV and PSMF as of 1 February 2016. The Article 57 database of products authorised in the EU was set up in 2012 according to Article 57 of Regulation 726/2004/EU and is now established and operational. With ca. 500,000 medicinal products, it is the most comprehensive database of medicinal products authorised on the European market. The Agency has established a robust quality assurance process to ensure high quality of data, the most up to date version of which are now made available to the NCAs and the European Commission. Training to NCA staff was provided by means of webinars in Q4 2015 and will be further available in 2016. As part of the data required, Marketing Authorisation Holders are submitting to the Article 57 database the name and contact details of the QPPV as well as the location of the PSMF. Changes to these data are currently also subject to type IA_{IN} variations. The Commission guideline on details of categories of variations foresees that no variations will need to be submitted for changes to QPPV and PSMF once the Article 57 database is functional. As a result of reliance on the Article 57 database, EU regulators will be able to access information in a single point and the regulatory burden on pharmaceutical companies will be reduced. The simplification will apply from 1 February 2016. From that date, type IA variations for QPPV and PSMF location will no longer need to be submitted by marketing authorisation holders, who will then ensure this information is always updated in a timely manner via the Article 57 database.

B.12 EMA Anti-fraud strategy: progress report

The Management Board noted a progress report on the implementation of the EMA Anti-fraud strategy, which was adopted by the board together with its Action Plan in December 2014. The strategy was set up following a call by the European Commission and OLAF to all EU agencies. All nine actions scheduled in the action plan to be implemented during 2015 have been completed. A tenth action is ongoing as it relates to the yearly assessment of the adequacy and effectiveness of the system of internal controls. The focus of action for 2015 was prevention of fraud. This was achieved also by means of a compulsory e-learning training to all staff of the Agency. EMA works closely through its Anti-Fraud Office with other EU agencies and OLAF, taking into account new developments and exchanging best practices. For 2016 efforts will continue to be devoted to prevention but will mainly focus on fraud detection.

B.13 EMA Information Management Strategy

[EMA/MB/764735/2015; EMA/768940/2015] The Management Board noted the EMA Information Management Strategy which had been treated under B.2.a).

List of written procedures during the period from 2 September 2015 to 2 November 2015

- Consultation no. 08/2015 on the appointment of Patricia Silva as CHMP member, proposed by Portugal, ended on 17 September 2015. The mandate of the nominee commenced on 18 September 2015.

- Consultation no. 09/2015 on the appointment of Ulrike Heissenberger as CVMP alternate, proposed by Austria, ended on 30 September 2015. The mandate of the nominee commenced on 30 January 2016.
- Consultation no. 10/2015 on the appointment of Bjørg Bolstad as CHMP alternate, proposed by Norway, ended on 30 September 2015. The mandate of the nominee commenced on 1 October 2015.
- Consultation no. 11/2015 on the appointment of Sylvie Louet as CVMP alternate, proposed by France, ended on 1 October 2015. The mandate of the nominee commenced on 2 October 2015.
- Written procedure for adoption of minutes of the Extraordinary Management Board meeting of 1 October 2015, ended on 23 October 2015. The minutes were adopted.
- Written procedure for adoption of 89th Management Board meeting minutes ended on 10 November 2015. The minutes were adopted.

Documents for information

- [EMA/MB/752101/2015; EMA/712432/2015] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/653272/2015] Outcome of written procedures finalised during the period from 2 September 2015 to 2 November 2015
- [EMA/MB/776950/2015] Summary of the transfers of appropriation 2015
- [EMA/MB/762330/2015-Rev 1; EMA/756676/2015-Rev 1] An action plan to improve the perception and use of the Article 58 procedure
- [EMA/MB/737283/2015] Overview of Staff Regulation implementing rules signed by the MB Chair during the period from 13 February 2015 to 2 October 2015

List of participants at the 90th meeting of the Management Board, held in London, 16-17 December 2015

Chair: Sir Kent Woods

	Members	Alternates	Other participants
Belgium	Xavier De Cuyper		
Bulgaria	Assena Stoimenova		
Czech Republic	*Apology received from Zdeněk Blahuta*		
Croatia		Viola Macolić Šarinić	
Denmark	Mette Aaboe Hansen		Matilde Kyst Behrens
Germany	Karl Broich	Klaus Cichutek	Anna Afentaki
Estonia	Kristin Raudsepp		
Ireland	Rita Purcell	Lorraine Nolan	
Greece	*Apology received from Despoina Makridaki*		
Spain	Belén Crespo Sánchez-Eznarriaga		
France		Jean-Pierre Orand	Miguel Bley
Italy		Gabriella Conti	
Cyprus	Loizos Panayi		
Latvia	Svens Henkuzens		
Lithuania	Gintautas Barcys		
Luxembourg	Laurent Mertz		
Hungary	Csilla Pozsgay		
Malta	John J Borg	Gavril Flores	
Netherlands	Hugo Hurts		Birte van Elk Hubert Leufkens
Austria	Christa Wirthumer-Hoche		
Poland	Grzegorz Cessak		Magdalena Pajewska
Portugal	Hélder Mota-Filipe		Rita Bastos
Romania	*Apology received from Nicolae Fotin*		
Slovakia	Ján Mazag		
Slovenia	Andreja Čufar		David Obranovič
Finland		Pekka Kurki	
Sweden		Johan Lindberg	
United Kingdom		Ian Hudson	Jonathan Mogford
European Parliament	Giuseppe Nisticò Björn Lemmer		
European Commission	Xavier Prats-Monné (DG SANTE)	Christian Siebert (DG GROW)	Miroslav Griva (DG SANTE) Olga Solomon (DG

	Members	Alternates	Other participants
			SANTE) Chloe Spathari (DG GROW)
Representatives of patients' organisations	W.H.J.M. Wim Wientjens *Apology received from Nikos Dedes*		
Representative of doctors' organisations	Wolf-Dieter Ludwig		
Representative of veterinarians' organisations	Christophe Hugnet		
Observers	Runa Hauksdottir Hvannberg (Iceland) *Apology received from Brigitte Batliner (Liechtenstein)* Audun Hågå (Norway)		

European Medicines Agency	Guido Rasi Andreas Pott Noël Wathion Stefano Marino Nerimantas Steikūnas Fergus Sweeney David Mackay Anthony Humphreys Alexis Nolte Zaide Frias Melanie Carr Agnès Saint Raymond Marie-Agnes Heine Agneta Brandt Anabela Marçal Wim Nuyts Emer Cooke Isabelle Moulon Monica Dias Peter Arlett Hilde Boone Edit Weidlich Silvia Fabiani Sophia Albuquerque