17 June 2016
EMA/MB/421228/2016 Adopted Corr*
Management Board

Minutes of the 92nd meeting of the Management Board

Held in London on 16 June 2016

Christa Wirthumer-Hoche, Chair of the Management Board of the European Medicines Agency (EMA), opened the meeting welcoming the participants, and congratulated the new members appointed by the European Parliament Tonio Borg and Björn Lemmer (confirmed), as well as the Civil Society representatives appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission Wolf-Dieter Ludwig, representative of doctors' organisations, Nancy de Briyne, representative of veterinarians' organisations, Yann Le Cam and Ilaria Passarani representatives of patients' organisations. She also welcomed the new members Delfa Radic-Kristo, member for Croatia, Tomas Senderovitz, member for Denmark, Lorraine Nolan, member for Ireland, as well as Sylvia Fueszl, alternate member for Austria and Rita Purcell, alternate member for Ireland, wishing all a fruitful and successful cooperation.

The chair reminded the board that following her appointment the position of Vice-chair had remained vacant and that an election would take place at the October meeting of the board. The Secretariat would send a note inviting candidates to come forward for the position in the next month.

Two positions to be covered by Civil Society Representative Management Board members were vacant at the EU Telematics Management Board (EU TMB) and at the Steering Group of the Management Board data gathering initiative. Nancy de Briyne was appointed by the board for the EU Telematics Management Board and Ilaria Passarani for the Steering Group.

The chair further reminded the board that she had been designated as one of the two reporting officers for the appraisal of the Executive Director of the Agency, and in her capacity as new Chair she must now act as the appeal assessor, which is incompatible with the role held previously. The Management Board appointed Rui Santos Ivo as reporting officer.

Finally the board appointed Catarina Forsman and Lorraine Nolan as new topic coordinators for the budget and programming document of the Agency.

1. Draft agenda for the 16 June 2016 meeting

[EMA/MB/3373/2016] The agenda was adopted with no amendments.

*Correction on page 1. wording *March* replaced to read *June*

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2. Declaration of conflicts of 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 Multiannual Work Plan to 2020, B.6 Criteria for EMA involvement in externally funded projects (e.g. IMI, FP & H2020), B.7 Criteria to be fulfilled by Industry Stakeholders organisations involved in European Medicines Agency (EMA) activities, B.8 EMA Stakeholder Relations Management Framework, B.10 Principal elements for a vision for a European Medicines Web portal.* The Secretariat informed the board of the restrictions arising from the current policy in force as of 1 May 2016 and 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 91st meeting, held on 17 March 2016 adopted via written procedure on 3 May 2016

[EMA/MB/206400/2016] The Management Board noted the final minutes, adopted by written procedure on 4 May 2016.

A. Points for automatic adoption / endorsement

A.1 Management Board meeting dates 2017-2018

[EMA/MB/245471/2016] The Management Board adopted the following meeting dates for 2017 after agreeing the need for a second two-day meeting to take place each year to allow for in depth discussion of specific topics:

- Thursday 16 March
- Wednesday 14 June and Thursday 15 June
- Thursday 5 October
- Wednesday 13 December and Thursday 14 December

The board also noted the following proposed meeting dates for 2018:

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

A.2 EMA New Working time rules

[EMA/MB/294876/2016; EMA/56681/2016] The Management Board adopted the European Medicines Agency decision on working time. The Implementing rules concern working time at the Agency. They are based on the European Commission model rules for Agencies, and will come into effect on 1 October 2016.

A.3 Revision of the EMA Code of Conduct

[EMA/MB/308158/2016; EMA/385894/2012 rev.1;EMA/306912/2016] The Management Board endorsed the revised European Medicines Agency Code of Conduct. The revision was due to the recent revisions of several documents concerning the handling of competing interests and the subsequent need for a formal editorial revision of the Code of Conduct. Documents in Annex were replaced with a separate Appendix that can be maintained separately from the Code, nomenclature for internal organisational structures of the Agency and references to certain applicable provisions were updated.

B. Points for discussion

B.1 Highlights of the Executive Director

Update on the discharge 2014 procedure

On 28 April 2016 the European Parliament granted the discharge for the Agency's 2014 accounts. The decision is based on a review of the annual accounts, the Court of Auditors' annual report, the Annual Activity report and the MB assessment of the Executive Director's report.

Organisational adjustments at the Agency

Following the completion of the EMA reorganisation in 2014 some fine-tuning of the structure of the operational Human Divisions will take place, coming into force on 1 September 2016. Their number will be reduced from 4 to 3, with two Departments per Division. The objective is to continue to move towards a lean and streamlined organigram whilst improving coordination of the Committees. Nerimantas Steikunas has been appointed Acting Head of Administration and Corporate Management Division, whose organisational structure is also under review currently to strengthen the integrated planning process at the agency and to create efficiencies in its operations. More details will be presented to the board in October.

International Activities

EMA attended with the European Commission the annual EU-China regulatory dialogue on pharmaceuticals in Beijing on 9th March and will also support the Commission at a meeting with the Indian authorities in Brussels in July 2016. Collaboration and training on GMP and GCP continues to be a strong theme in these discussions while providing an opportunity to disseminate the European approach and increase assurance on the quality of medicinal products. Further reflection is necessary on how to strengthen these activities and expand their capacity. At the last ICMRA meeting in Mexico in November 2015 an ICMRA Drafting Group on Supply Chain Integrity led by EMA was formed. In April 2016 the CHMP adopted an Article 58 scientific opinion for Umbipro (chlorhexidine). This is a further example of positive collaboration and extension of EU influence globally.

EU Activities

Following the institutional agreement on the new regulation on Medical Devices additional opportunities for cooperation with NCAs are created. Reflection will be needed also with the network on how to access the necessary expertise in the future.

Update of first-in-man guidance for CT

After the incident in Rennes the EMA has started a review of the guideline intended to assist sponsors in the transition from non-clinical to early clinical development. The review began in May under the auspices of the CHMP within its remit to develop and revise scientific guidance on medicines and two groups of experts are carrying out the preparatory work. The Agency is working in close conjunction with the French authorities, the Commission services and the HMA Clinical Trial Facilitation Group, and hopes that, thanks to good collaboration with the network, the finalisation of the revised guideline will take place in early 2017.

Meeting on Availability

EMA organised a meeting on Wednesday 15 June with Leads on the HMA MAWP (Multiannual Work Plan) to discuss how to join forces in the area of availability of authorised medicines, which is a key theme of the common EMA/HMA Multiannual work programme 2020.

Multi National Assessment Teams (MNAT) post-authorisation

Building on the positive feedback from the NCAs involved in the MNATs in pre-authorisation, a request was made by some NCAs in Q4 2015 to extend the MNAT concept to post-authorisation activities for human medicinal products. The EMA is working on a framework for this next phase which caters for all possible post-authorisation scenarios and is setting up ground for both human and veterinary medicinal products. The Management Board will be presented with details of this next phase at a next Management Board meeting.

Stakeholders activities

A public consultation of academia launched with the objective of developing a framework of collaboration between EMA and academia was closed on 18 April 2016. A total of 1016 answers from all over the world were received, generally very positive and indicating the high interest of academia to work closer with regulators. On this basis, the framework of collaboration will be drafted and discussed at the Scientific Coordination Board in September prior to its submission for adoption to the Management Board, currently planned in December 2016.

HPV vaccines

The 2015 review of HPV vaccines continues to be criticised by some stakeholders. EMA strongly defends the conclusions of the PRAC on the outcome of the HPV review and our regulatory system. Vaccinations are vitally important for the health of our citizens and confidence in vaccines and in the regulatory system that assesses their safety, efficacy and quality and enables their authorisation is a matter of public health protection. The Agency is also committed to assist Member States in dealing with these issues wherever they need it and consider it useful.

PSUR Repository mandatory use

As of 13 June 2016, the use of the PSUR repository is mandatory for all Marketing Authorisation Holders in the EU submitting PSURs for human medicines. The last release of the PSUR repository was delivered on the 14 May 2016, on schedule and within budget. Leading up to the mandatory use there has been effective collaboration between NCAs and EMA, resulting in the creation of a network of

communication contact points at national level ensuring the consistent and coordinated communication of the mandatory use milestone throughout all the Member States. This group will remain active until the end of 2016 at which point their activity will be revisited.

A request for some in depth discussion on the new Medical Devices Regulation was made. This will be scheduled to take place after its final approval.

B.2 Report from the European Commission

The representative of DG SANTE referred to the previous points made as providing compelling reasons for close collaboration between the Commission, the Agency and the NCAs, as a solid and scientific basis to inform public and political discourse. A presentation on EU legislative and policy developments in the public health area had been circulated to the board, which was invited to focus on a few main topics:

HTA

The way the European Commission understands its tasks in the area of human health under its limited remit focusses on health policy and the fostering of resilience of health care systems. In this framework HTA is acquiring ever greater importance. Two Joint Actions (JA) on HTA took place in the last 5 years and a 3rd has just started. A number of challenges however need to be overcome: the limited uptake of actions from the initiative, the sheer complexity of HTA, and the sustainability and continuity of action all require wide synergies. The Commission in now working informally on the terms for an impact assessment on stronger collaboration on HTA, with a focus on scientific rather than economic/ethical aspects with a view to exploring the possible need for legislative action.

Innovation and access to new medicines

The Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its members set a strong priority on access and availability of new medicines. These priorities are to be found in the EU network strategy, and need to balance incentives to innovation with patient access. The European Commission intends to facilitate cooperation between Member States in this field, as shown by the excellent work carried out within STAMP.

Antimicrobial Resistance (AMR)

Antimicrobial resistance is an area characterised by a sense of urgency. As more Members States raise their concerns, at a global level WHO is calling for the establishment of national action plans. A Task Force on the One Health approach was set up and the Dutch Presidency has organised a conference on the subject of AMR. As the EU action plan draws to a close this year, three key priorities will need to be further considered for action: making the EU the 'best practice' region in the field of AMR, of which an example is prudent use; stimulating research and innovation for example in early diagnostics; promoting EU action at a global level, including G7, WHO, FAO and others.

Cooperation with ECDC

Cooperation between EMA and ECDC should be further strengthened to provide support to EU activities on crisis preparedness and response, and to address effectively serious cross-border health threats, also in partnership with EFSA.

TTIP

The trade negotiations with the US (TTIP) have seen some good progress with the last round in April 2016. First discussions on an EU and US proposal for a legal text are ongoing, and thanks to a

favourable attitude by the US FDA there has been major progress towards mutual recognition of GMP inspections. In this phase Member States must be relied on to strongly support the necessary auditing process in order to achieve the agreement in the timelines envisaged. The Commission has committed to continuing funding support of the audit process in 2017 and considers this process a high priority.

The representative of DG GROW informed that Commission representatives, Ambassadors (COREPER) and EP Committee have found a consensual agreement that would be presented at Health Ministers Council (EPSCO) in Luxembourg on the following day (17/6). Further to other administrative procedures e.g. translations, it is anticipated that the formal adoption will take place by the end of the year or early 2017. The Commission will further report at the next meeting of the Management Board.

In the discussion some members shared their concerns about the tensions between the regulatory and the HTA world, particularly on issues like adaptive pathways. Harmonisation on HTA will be a critical area, as well as the inclusion of real life data in the process. The HTA network reflection paper on the synergies between regulatory and HTA issues might contribute to put the issues in sharper focus. The representative of the Commission confirmed that the reflection paper should be ready in November. HTA cooperation is important but also complex, and an impact assessment might help to clarify where synergies can be achieved and where distribution of responsibilities could be optimised.

One member shared his concern about the recent inclusion of veterinary medicines in the TTIP and the fact that inspection systems of veterinary medicines have not been yet included in the audit. In USA immunological products are not controlled nor inspected by FDA but by the USDA. So the implementation of the TTIP in veterinary medicines could not be launched at the same time as human medicines and not before a complete audit of the American system. Concerning TTIP, the Commission indicated that, while the priority was on human medicinal products, the opportunity to recognise FDA inspections for veterinary products in a second phase were also under discussion.

The Executive Director informed the board that the Agency will organise a workshop on Adaptive Pathways, to address results achieved in the pilot and discuss proposals for the future direction. Key stakeholders and experts who could actively contribute to the topic will be invited to the workshop.

B.3 Assessment of the Executive Director's Annual Activity Report (AAR) 2015

[EMA/MB/356802/2016; EMA/140840/2016; EMA/323238/2016] The Management Board noted the Annual Activity Report and adopted the Assessment of the Executive Director's Annual Activity Report (AAR) 2014, which had been drafted by the topic coordinators Hugo Hurts and Belén Crespo Sánchez-Eznarriaga. The topic coordinators complimented the Agency on its overall level of performance and on the clarity and detail of the AAR. They welcomed the fact that overall the targets had been met. The fact that the Agency has for the first time a common strategy with the Heads of Medicines was appreciated. The topic coordinators particularly appreciated that as a result of improved interactions and support to committees the average clock-stop for applications for new active substances and biosimilars had been significantly brought down. The efforts to improve timely access for patients to new medicines through the adaptive pathways approach was supported, as well as the establishment of the European Network Training Centre. Recognising the growing concerns on antimicrobial resistance, the Agency was invited to continue with its efforts to fight it, also in the framework of enhanced international cooperation. Timely implementation of the EU clinical trial regulation was considered of high importance, as it is expected to improve significantly the environment in which

clinical trials are conducted, including their transparency. The importance of the implementation of the Telematics strategy and of the ISO IDMP standard was stressed, and the organisational changes in the Information Management Division were supported. Satisfaction was expressed on the audit by the IAS on the Paediatric Regulation procedures, which confirmed that the Agency uses adequate systems, and on the results of the audit of the European Court of auditors confirming the reliability of the 2014 accounts.

As a further collateral reflection, the topic coordinators expressed the view that a discussion on outcome indicators, extending the board's discussion beyond qualitative indicators, would be welcome at a later date. It was decided to give the topic adequate discussion time during one of the 1.5 day meetings of the board.

B.4 Multiannual Work Programme to 2020 (MAWP)

[EMA/MB/388475/2016; EMA/319713/2016] The Management Board adopted the Multiannual Work Programme to 2020, which had been prepared on the basis of the Network strategy and mirrors the approach of the HMA MAWP. In order to follow the requirements of the Agency's financial regulation the MAWP will be incorporated in the Programming document to be submitted to the board in December and will no longer exist as a separate standalone document. As such, the MAWP will become a living document that is updated, as necessary, during the annual planning cycle. The topic coordinator Kristin Raudsepp, also on behalf of her colleague Karl Broich, not present at the meeting, provided an overview of the document, which she found to contain clear targets and performance indicators. The 'living document' nature of the MAWP will provide the flexibility and opportunities to update and further improve the document. The annual review would also give members the possibility to comment every year. The structure of the MAWP mirrors network strategy and follows four main themes, with 4 strategic objectives under each theme. Like the HMA MAWP, this plan describes many of the key initiatives and areas of work for the coming years, but does not cover the full spectrum of work undertaken by the Agency which will be found in the annual Work Programme. A specific detailed point was mentioned concerning availability of authorised medicines, which is an objective under both Theme 1 Contributing to human health and Theme 2 Contributing to animal health and human health in relation to veterinary medicines. A meeting on this rising problem had been held at the Agency on 15 June with the objective to take stock of initiatives already ongoing to avoid gaps and duplication of effort. Representatives of the Agency, of the Commission, of NCAs, CMDh and CMDv had taken part in the discussion and concluded that more systematic communication on the various initiatives is needed. Before deciding to establish a Task Force clear targets need to be set out in a Reflection Paper to be discussed at HMA and at the board in September and October respectively.

The board was appreciative of the MAWP, and some suggestions for improvement were made, such as ensuring alignment with budget and resource planning, ensuring all links and cooperation points with the NCAs are reflected, and further developing the theme devoted to animal health objectives. The programming document will incorporate a number of these proposals. On the example of the HMA MAWP the Agency might consider selecting some priorities among the objectives, to be embedded in the work taken forward. Further discussion on the need to establish success indicators took place. The Executive Director agreed to carry out further reflection at the strategy level, rather than the work plan, together with the topic coordinators, with a view to have a future dedicated discussion at the board.

B.5 2015 Annual reports of Audit Activities at the Agency

a) Annual Internal Audit Report (IAS-EC) 2015

- **IAS Audit on Paediatric Regulation Procedures in EMA**

b) Annual Report of the Internal Audit of EMA 2015

[EMA/MB/337671/2016; Ares(2016)2309382 - 18/05/2016; EMA/278688/2016] The board noted the annual reports on Audit Activities. The 2015 Internal Audit Report was not issued by the Internal Audit Service for the EC (IAS) due to the fact that there were no open critical or long overdue very important recommendations. The IAS issued the Final report on the comprehensive audit on Paediatric Regulation procedures in the European Medicines Agency, which had the objective to address the adequacy of the design and the effectiveness of management and control systems and provide essential information in preparation of the new Paediatric legislation. The report was positive and did not contain any critical of very important recommendation. The Annual report of the Internal Audit of EMA 2015 provided information about the audits conducted, main audit findings and status of main audit recommendations. From previous years' audits no critical recommendations are open and all other recommended improvement actions are under implementation. The Agency's internal audit further provided information on other audits which took place and on the activities carried out by the Audit Function, such as cooperation with other European bodies and coordination of audit fieldwork, cooperation with the Anti-Fraud Office for the development of the Anti-Fraud strategy and self-assessment at the Agency.

The representative of DG SANTE commended the Agency on the favourable reports by IAS, and explained that the paediatric audit was legally due by 2017, and might not necessarily lead to a revision of the Regulation, as more regulation is not always the best way for regulators to keep up with innovation. A request for a more in-depth discussion of certain aspects of the paediatric legislation and its implementation will be satisfied once the Report on the Paediatric Regulation is ready at the end of 2017.

B.6 Criteria for EMA involvement in externally funded projects (e.g. IMI, FP & H2020)

[EMA/MB/294875/2016] The Management Board endorsed the criteria for the Agency's involvement in externally funded projects. The topic followed-on from the discussion at the previous meeting, which had been prompted by an invitation by DG SANTE to present information on ongoing activities of EMA for EU funded programmes, for which EMA can no longer be funded under the financial regulation. Further to this discussion and in the light of experience gained, priorities of the network, new legislation and a situation of zero growth, the Agency has updated the EMA process of engaging in external regulatory sciences and process improvement research activities for public and animal health. The proposal is meant to provide a set of clear and transparent criteria: whether the existing opportunities for interactions with the Agency suffice (e.g. Scientific Advice, innovation task force briefing meetings) or whether different involvement is needed, alignment of the project with the Agency's mission, Work Programme and Network Strategy 2020, benefit for the EU public and animal health, EMA and its Committees and the regulatory network, quality of the project proposal, absence of significant conflict of interest to be systematically and specifically considered, availability of a viable minimum of resources. The Executive Director further stressed the importance for the Agency of

having the possibility to engage early with IMI in order to be able to plan appropriate involvement and for sharing information with the NCAs for a consistent approach.

The representatives of patients' organisations stressed the importance of the presence of the Agency in European public projects, some of which would not be possible without EMA. It should however be made clear in the criteria that EMA engagement does not necessarily imply that the Agency is bound by its outcomes or endorses them. Concerning resources, a description of project deliverables and their timing should support planning and provision of resources. The board decided to endorse the principles with a few changes, inviting members to provide further comments by the end of July if desired.

B.7 Criteria to be fulfilled by Industry Stakeholders organisations involved in European Medicines Agency (EMA) activities

[EMA/MB/323682/2016; EMA/323235/2016] The Management Board adopted the Criteria to be fulfilled by Industry Stakeholders organisations involved in European Medicines Agency activities. The Framework for interaction between EMA and industry stakeholders was adopted in October 2015. Eligibility criteria were developed taking into account existing criteria for other EMA stakeholder organisations, criteria devised by other EU institutions and general principles outlined in the European Commission's Better Regulation package. These criteria will apply where an organisation seeks to be consulted and involved directly by the Agency or to co-operate jointly in specific areas. Any organisation can register with the EMA as an interested party to receive information and notice of written consultations in selective areas of interest.
The proposal was submitted for consultation to industry stakeholders who were supportive, and was endorsed by the European Commission.

B.8 EMA Stakeholder Relations Management Framework

[EMA/MB/331273/2016; EMA/48651/2016] The board adopted the European Medicines Agency stakeholder relations management framework. This has been developed to streamline the interaction with the Agency's main stakeholder groups, by setting out the fundamental principles that apply: transparency, independency and integrity, accountability, appropriate and relevant interaction, board representation, effective communication and continuous improvement. The working methodology is based on the EC Better Regulation Guidelines that foresees four levels of interactions: 'inform', 'consult', 'consult and involve' and 'cooperate and participate'. The framework's overarching principles apply across the key stakeholder group: patients, healthcare professionals, industry and academia (currently under development.)

B.9 Pharmacovigilance Programme: EudraVigilance high level audit plan update

[EMA/MB/321035/2016; EMA/452911/2015] The board noted the EudraVigilance high level audit plan update. In December 2015 the board had noted the high level audit plan to be carried out by an independent auditor in Q3 2016. The move to centralised reporting in EudraVigilance for the pharmaceutical industry is based on the Management Board announcement of the successful audit and becomes mandatory six months later. The company that will perform the audit was selected from the main EMA framework contract for audits in consultation with volunteers from the PRAC. The

EudraVigilance auditable requirement project however has undergone re-planning due to the need to further strengthen the performance of the new EudraVigilance system prior to its go-live. The rescheduling impacts some key project milestones, and the new timeline now foresees that the audit takes place in February 2017. The board agreed that in order to enable the system to come into use as soon as possible, that updated information to be presented to the board in March 2017 and a final report will be presented for adoption by written procedure in May 2017 after consultation with the PRAC, if needed an extraordinary board meeting may be organised by teleconference. The go-live date would therefore move by four months and take place in mid-November 2017.

It was observed that the selection process for the independent auditor had been impeccable. Answering questions of a more detailed nature, members were informed that the EU Expert Working Group will be informed, that time when MAH will need to report to NCAs will be extended and that testing will take place as foreseen but four months later. The Agency was aware of inconvenience for the NCAs, but trusted that this would be understood considering the need for a robust system, which should be able to handle a very high volume of transactions.

B.10 Principal elements for a vision for a European Medicines Web portal (EMWP)

[EMA/MB/385463/2016; EMA/385484/2016] The board endorsed the principal elements for a vision on developing a European Medicines Web Portal for medicinal products for human use. Discussions on how to best develop the EMWP started in July 2014 with follow-up discussion in November 2014 and in February 2015 when an agreement on a vision was reached at HMA, with focus on how to best provide information for non-centrally authorised products (NAPs). Since February 2015 comments on a draft reflection paper calling for a more ambitious vision had been received by the IT Directors and by the EU TMB. At the June HMA meeting in Rotterdam there was agreement that the EMWP will be the common window to information on medicines for citizens. A stepwise approach will be applied and will initially provide information on NAPs through links to national websites on the basis of validated information available from the Article 57 database. Broadening of the provision of information to other stakeholders, such as pharmaceutical industry, will take place in a second phase. As a next step a reflection paper will be developed, which will take into account the agreement by HMA, and will be discussed at the next HMA and Management Board meetings. An implementation plan will be drafted as a successive step.

B.11 Clinical Trial EU Portal and Database

The board noted a status update on the development of the EU Portal and Database. The project is on track and is currently in its 2nd iteration and undergoing User Acceptance Testing (UAT). The Agency is mindful of the board's recommendation for a strong focus on communication with all stakeholders and business partners, and is informing Member States regularly by means of a Clinical Trial programme microsite containing regularly updated documentation on key business requirements, technical documentation, planning and scheduling documents, templates and more. The discussion on classification of requirements as auditable or non-auditable continued with a proposal by Member States in January 2016. An agreement was reached for most requirements after review by the Agency and the process for resolution of the remainder is in hand and agreed. The first UAT was very successful with 457 testers from 43 diverse organisations participating. Satisfaction scores were high as testers had a chance to get a first feel of the system and identify desired improvements or changes. Over 500 testers have registered for UAT 2, which will end on 20 June 2016 with a report to be sent on 1 July 2016. It has to be born in mind that every UAT adds to the scope of the preceding with a

cumulative effect. The Agency is committed to develop the interfaces to national systems by Q2 2017 for those Member States who will not solely use the EU Portal and Database. A workshop with IT Directors to discuss interface development is planned for Q4 2016.

The board expressed satisfaction with the progress of the project. Concerning the still open question on whether information on Clinical Trial applications can be made accessible to non CMS, the representative of DG SANTE remarked that IT tools can facilitate access, but Member States must decide whether to grant it according to their own national legislation. A survey is being conducted (by CTFG) to ascertain whether and which Member States, in accordance with their national law, can share the clinical trial application dossier and data, and assessments with other Member States who are not CMS. The representative of DG SANTE reminded all of the importance to continue to work towards a possible advancement of the timeline. Concerning a specific implementation date however, it was the Agency's view that more UATs will need to be completed before the final timetable can be set.

B.12 Report by the Steering Group on the Management Board data gathering initiative

[EMA/MB/344089/2016] The board noted the ninth interim report of the Steering Group. For fee-generating activities all data collection work streams have been launched, with the exception of Type I variations on the human side. They are expected to be concluded by the end of October in order to allow for the preparation of a report to be provided by the end of the year to the contractor chosen by the European Commission for the Evaluation of the fee system. Most collections concerning non-fee generating activities have been launched in PDCO and COMP as well as in the Working Parties, with workstreams on SME work, Herbals, the remaining Committees and CMDx set to take place after summer.

On the human side, sample size of procedures and iteration of collection cycles should provide robust data, as long as compliance by NCAs remains good. It would be particularly desirable that high performing NCAs all contribute, as their experience is very valuable, and the Agency will follow-up in cases where data appear to be missing. The overview of Type II procedures also seems to provide a healthy dataset. An interim analysis of the first available data concerning the Initial Marketing Authorisations and Type II procedures is set to take place in June and will provide information also on solidity of data samples. The veterinary-only effort is proceeding along the same line, with some procedures started ahead of human procedures in order to compensate for lower frequency of submission.

The Chair opened the discussion by thanking DG SANTE for having in the past week allowed board members to provide comments in an extended timeframe to the Terms of Reference drafted by the European Commission to select a contractor to carry out the evaluation of the EMA fee system. A teleconference held on 10 June and chaired by the Commission was very helpful to discuss the approach taken in an open and collaborative conversation. The representative of DG SANTE informed the board that the consultation was an unprecedented initiative, put in place by the Commission in order to foster transparency and good partnership. It is expected that the Terms of Reference will be published in July, so that the contractor can start working in 2017. With regard to expectations that future fee systems could be based on value of service, he further clarified that fees should be based on cost of service, as this is established in the legislation and has in the past been the subject of observations by the European Parliament and the Court of Auditors.

B.13 Annual report on the performance of the Agency's scientific procedures

[EMA/MB/3373/2016; EMA/271473/2016; EMA/384685/2016] The Management Board endorsed the Annual report on the performance of the Agency's scientific procedures: 'Key Performance Indicators for medicinal products for human and veterinary use', as well as the 'Key Performance Indicators and performance information for the calendar year 2015' for the Pharmacovigilance Fee Regulation. The first of the reports is based on the cooperation agreement and is presented to the board each year. 2015 did not present any significant highlights, and no KPI was breached. For the first time indicators on inspections were included in the report. No impact on the critical path of authorisations was reported. The second report was presented for the first time and was compiled in the context of the Pharmacovigilance Fee Regulation which sets out reporting requirements in part V of its Annex. Five KPIs are based on the fees for procedures received and provide high level metrics of volume of work which generates income. Some of the performance information defined in Part V of the Annex was provided by the NCAs, and was collected retrospectively at the end of 2015. NCAs provided information on number of hours spent by the rapporteur and the co-rapporteur(s) per procedure for PSUR, PSUSA and PASS assessment, as well as on referrals. For 2016 the collection of data will be done prospectively and will be part of the report to be provided to the contractor of the European Commission for the evaluation of the fee system. The Steering Group on the Management Board data gathering initiative will start discussing the findings at its next teleconference.

The chair pointed out that variability within the data provided by the NCAs is very high and invited NCAs to reflect whether this might depend on different ways of working which could be addressed with targeted training.

B.14 Draft Management Board decision on derogation from Commission Decision on the implementation of telework in Commission Departments

[EMA/MB/375574/2016; C(2015) 9151 final; EMA/368608/2016] The Management Board empowered the Executive Director to request a derogation from the Commission Decision on the implementation of telework in Commission Departments pending the adoption of model rules for Agencies reflecting their specific working conditions. At present telework at the Agency is disciplined by pilot rules. European Commission rules were issued in December 2015 and they will apply automatically to Agencies after nine months unless a derogation is requested. The EMA Staff Committee asked for the future rules based on the Commission's model rules not to be less favourable than the current pilot rules.

List of written procedures finalised during the period from 20 February 2016 to 11 May 2016

- Consultation no. 03/2016 on the appointment of Jana Schweigertova as CHMP Alternate, proposed by Slovakia, ended on 10 March 2016. The mandate of the nominee commenced on 11 March 2016.
- Consultation no. 04/2016 on the appointment of Fatima Ventura as CHMP alternate, proposed by Portugal, ended on 29 March 2016. The mandate of the nominee commenced on 30 March 2016.
- Written procedure for adoption of the 91st Management Board meeting minutes, ended on 3 May 2016. The minutes were adopted.

Documents for information

[EMA/MB/335100/2016, EMA/334790/2016] Report on EU Telematics

Feedback from the Heads of Medicines Agencies

[EMA/MB/294536/2016] Summary of transfer of appropriations in the budget 2016

[EMA/MB/335826/2016; EMA/774549/2015] European Medicines Agency's Interaction with Industry Stakeholders – Annual Report 2015

[EMA/MB/330352/2016; EMA/155560/2016] Report on the 10th Anniversary of the SME Initiative

[EMA/MB/305561/2016] Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2015

[EMA/MB/330379/2016; EMA/242286/2016] Outcome of SME office survey on the implementation of the SME regulation - Commission Regulation (EC) No 2049/2005

[EMA/MB/337783/2016; EMA/727872/2015] Annual report on the EMA interactions with patients, consumers and healthcare professionals and their organisations (2015)

[EMA/MB/336448/2016, EMA/338964/2016] Framework Strategy for Corporate Communications 2016-2020

Tabled documents

- Agenda for the 92nd meeting of the Management Board (version 4)
- Documents relating to Agenda point B.6 – Criteria for EMA involvement in externally funded projects (e.g. IMI, FP & H2020)
- Feedback from the Heads of Medicines Agencies

List of participants at the 92nd meeting of the Management Board, held in London, 16 June 2016

Chair: Christa Wirthumer-Hoche

Member State	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	Assena Stoimenova *(member)*
Czech Republic	Jiri Bures *(alternate)*
Croatia	Delfa Radic-Kristo *(member)*
	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)*
	Mette Aaboe Hansen *(observer)*
	Matilde Kyst Behrens *(observer)*
Germany	Klaus Cichutek *(alternate)*
	Ansgar Schulte *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)*
	Rita Purcell *(alternate)*
Greece	Despoina Makridaki *(member)*
Spain	Belén Crespo Sánchez- Eznarriaga *(member)*
	Laura Franqueza *(alternate)*
France	Jean Pierre Orand *(alternate)*
	Miguel Bley *(observer)*
Italy	Gabriella Conti *(alternate)*
	Pietro Erba *(observer)*
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Csilla Pozsgay *(member)*
Malta	John Borg *(member)*
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	*Apology received from N. Fotin*
Slovakia	Ján Mazag *(member)*
Slovenia	Stanislav Primožič *(alternate)*
Finland	Pekka Kurki *(alternate)*
Sweden	Catarina Forsman *(member)*
	Asa Kumlin Howell *(observer)*

United Kingdom	Jonathan Mogford *(alternate)*
	Claymore Richardson *(observer)*
European Parliament	Björn Lemmer
	Tonio Borg
European Commission	Xavier Prats-Monné (DG SANTE) Carlo Pettinelli (DG GROW) Olga Solomon DG Sante *(observer)* Chloe Spathari (DG GROW) *(observer)*
Representatives of patients' organisations	Ilaria Passarani
	Yann le Cam
Representative of doctors' organisations	*Apology received from Wolf-Dieter Ludwig*
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdottir Hvannberg (Iceland) Brigitte Batliner (Liechtenstein) Audun Hågå (Norway)