18 March 2016
EMA/MB/206400/2016 Adopted
Management Board

Minutes of the 91st meeting of the EMA Management Board

Held in London on 17 March 2016

Christa Wirthumer-Hoche, Vice-Chair of the Management Board of the European Medicines Agency (EMA), opened the meeting welcoming the participants, in particular the new members Rui Santos Ivo, member for Portugal, Nicolae Fotin, member for Romania, Catarina Anderson Forsman, member for Sweden, Ian Hudson, member for the United Kingdom succeeding Kent Woods, Siniša Tomić, alternate member for Croatia, Janis Zvejnieks, alternate member for Latvia and Jonathan Mogford, alternate member for the United Kingdom.

The Vice-Chair thanked the four Civil Society members of the board, Nikos Dedes, Christophe Hugnet, Wolf-Dieter Ludwig and Wim Wientjens, whose mandate was due to expire on 20 March, as well as the two European Parliament representatives, Bjorn Lemmer and Giuseppe Nistico' whose mandate also was due to expire on 30 April for their contributions and support to the board. While hoping for prompt nominations or renewal of the Civil Society and European Parliament members, hopefully ahead of the next meeting of the Management Board in June, the Vice-Chair thanked in particular Giuseppe Nistico' who was not able to attend this last meeting, as he would not seek a new nomination by the European Parliament.

1. Draft agenda for 17 March 2016 meeting

[EMA/MB/266/2016] The agenda was adopted with no amendments.

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 conflict of interests. Some potential conflicts relating to the day's agenda were identified concerning topics *B.6 Revised implementing rules to the Fee Regulation* and *B.10 Draft revised rules of procedure on the organisation and conduct of public hearings at the PRAC*. Should the need for a vote on these topics arise, the chair would take up the matter again. All concerned members had been informed of the restrictions arising from the current

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policy on interests, which will be replaced by the revised EMA Policy on the handling of competing interests of Management Board members, to enter into force on 1 May 2016.

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 interests were declared.

3. Election of the Chair of the Management Board (in camera)

The election was chaired by Xavier De Cuyper, as the longest serving member of the board.

In accordance with the election procedure the chair announced votes by proxy:

- Xavier de Cuyper (Belgium), proxy to Karl Broich (Germany) for agenda point 3 only.
- Björn Lemmer (European Parliament), proxy to Karl Broich (Germany)
- Giuseppe Nistico' (European Parliament), proxy to Grzegorz Cessak (Poland)
- Kristin Raudsepp (Estonia), proxy to Svens Henkuzens (Latvia)
- Despoina Makridaki, (Greece), proxy to Loizos Panayi (Cyprus)
- Csilla Poszgay (Hungary), proxy to Grzegorz Cessak (Poland)

The Board appointed Brigitte Batliner and Audun Hågå, observers from Liechtenstein and Norway, to act as tellers. The vote took place by secret ballot.

The Management Board elected Christa Wirthumer-Hoche, representing Austria, as the Chair. The newly elected Chair thanked the Management Board and assured the board of her ambition to ensure a strong partnership between EMA, the European Union national competent authorities and the European Commission, to guarantee that EMA is able to fulfil its important role of safeguarding human and animal health in Europe.

Following the election Christa Wirthumer-Hoche chaired the meeting.

4. Minutes from the 90th meeting, held on 16-17 December 2015 adopted via written procedure on 9 February 2016

[EMA/MB/858667/2015] The Management Board noted the final minutes, adopted by written procedure on 15 February 2016.

A. Points for automatic adoption / endorsement

A.1 New rules for promotion / re-classification

[EMA/MB/151877/2016; EMA/56968/2016; EMA/56978/2016] The Management Board adopted the European Medicines Agency decisions laying down general implementing provisions regarding Article 54 of the Conditions of Employment of Other Servants of the European Union and laying down general implementing provisions regarding Article 87(3) of the Conditions of Employment of Other Servants of the European Union.

B. Points for discussion

B.1 Highlights of the Executive Director

Zika virus

A Task Force was created by the EMA on the basis of the one established for Ebola 2 years ago. It is composed of experts from the EU network and will focus on regulatory activities with respect to development of vaccines and antivirals. EMA would like to support WHO and international regulators in this crisis. It is acknowledged that most medicinal products are at discovery stage and gaps in knowledge need to be filled to allow definition of plausible development pathways for vaccines and medicines. The areas of diagnostics and vector control will have priority at this stage as they can be deployed rapidly.

Update on the technical issue in the EU Clinical Trial Register (EUCTR) results module

At the December 2015 meeting the board was informed that the software issue in the EU Clinical Trial Register had been resolved. The system was relaunched on 13 January 2016 as planned, and by 14 March already 959 sets of summary results have been published. EMA would like to thank the stakeholders with whom it has worked closely in solving the problem. The EUCTR, in which sponsors publish summary trial results under the existing clinical trial and paediatric legislation, is one of the three pillars of the Agency's transparency on clinical trial results and will continue to be important for a number of years.

Implementation of the Clinical Data publication policy

The work to implement the Clinical Data Publication policy is progressing as scheduled. EMA has published guidance for Industry on procedural aspects and will now start to liaise with the first companies who received CHMP opinions in September 2015, with a view to start the submission of clinical reports for publication as of mid-September 2016. EMA is supporting SMEs with a helpdesk through the SME office and by providing SMEs with a software licence for a redaction tool that EMA also uses. This is an administrative service with no cost to the SMEs and minimal financial impact for EMA, estimated at EUR 3000 per year.

EU Activities

EMA received a positive opinion from the Committee on the Environment, Public Health and Food Safety and a positive draft report from the Committee on Budgetary Control of the European

Parliament on its 2014 accounts for the 2014 Discharge. The vote at the European Parliament plenary is scheduled in April.

Further to the Phase I Clinical Trial incident in France a debate took place at the plenary EP meeting. Reference was made to the new clinical trial regulation, and several MEPs asked for the new CT Database and the Regulation to be implemented as soon as possible. It was acknowledged that there is no link between the implementation and the incident, and the Agency noted the expectation that there will be no slippages.

The process for the appointment of the civil society representatives at the EMA Management Board is ongoing at the level of the European Parliament and Council and should hopefully lead to their mandate starting at the June meeting of the board.

Launch of the Priority Medicines Scheme (PRIME)

On 7 March the Agency launched PRIME, a scheme to strengthen support to medicines that target unmet medical needs. PRIME was developed in consultation with the Agency's scientific committees, the European Commission and its expert group on Safe and Timely Access to Medicines for Patients (STAMP) as well as the European medicines regulatory network. PRIME builds on the existing regulatory framework and available tools such as scientific advice and accelerated assessment.

Telematics Governance

There is an increasing awareness by NCAs of the importance of Telematics and in particular of Substance, Product, Organisation and Referential data (SPOR), as the Rolling plan of activities for NCAs for SPOR was endorsed at HMA in February 2016. Over the last year the Agency had strengthened communication with all stakeholders. In February it hosted the “Telematics Forum”, a two-day workshop with IT and business colleagues from all NCAs as well as the Annual EU Telematics Management Board meeting with industry representatives. These meetings are felt by stakeholders to be very valuable to achieve the best possible telematics system.

A review exercise was conducted on the Telematics governance. No major changes were identified apart from improving the reporting lines and streamlining the maintenance structure to have a single change management board (CMB). The revised Governance model was adopted by the EU TMB in February 2016 and will be presented for adoption to HMA in May with more details on the proposed CMB.

The mandates of the EMA representatives at the EU TMB, David Mackay and Noël Wathion, were renewed. The board agreed to the renewal of the Management Board representatives Andrzej Rys and Luca Pani. The third representative of the board should be a civil society representative, and will be nominated or renewed once the civil society representatives are re-nominated to the board.

Update on structured approach to interactions with Academia

Academia is an important source of expertise and of innovation. The Agency prepared a consultation of academia with the objective to develop a EMA framework of collaboration. A survey was launched and has so far had a high number of respondents. The results of the survey will be discussed with the Scientific Coordination Board and Healthcare Professionals Working Party. The outcome of these discussions will further inform the development of the framework of collaboration.

Visit of the Italian Minister of Health Beatrice Lorenzin

On 1 March 2016 the Italian Minister of Health Beatrice Lorenzin visited EMA. Meeting Agency's senior management, she was particularly interested in initiatives that stimulate innovation in medicines development, such as PRIME, in common negotiations by Member States to achieve better pricing of medicines, and closer interaction between the regulatory world and HTA.

B.2 Report from the European Commission

The representative of DG SANTE congratulated Christa Wirthumer-Hoche on her election as Chair of the EMA Management Board. He referred to a presentation on EU legislative and policy developments in the public health area, which had been circulated to the board, and focussed on areas of particular interest:

Clinical Trial Portal and Database

At the December meeting the board after a thorough debate had endorsed the later of the proposed timeframes for the delivery of the Clinical Trial EU Portal and Database, with the firm commitment by all members to work towards an earlier implementation within this maximum timeline if possible. The recent attention and discussion at the European Parliament confirm the need to maintain this resolve.

Antimicrobial Resistance (AMR)

The time has come for the issue of antimicrobial resistance to increase actions at international level, by supporting WHO on a global agenda. Progress has been achieved under the NL Presidency, with a Ministerial Conference on AMR (Health and Agriculture) raising its visibility as a threat to the health and wealth of nations. From the European Commission's evaluation of the Action plan for AMR the need for a strengthened global action is emerging, along with nationally strengthened surveillance and prudent use of antibiotics, as well as the implementation of the One Health approach. At a global level awareness is increasing, as AMR has been put by China on the agenda of the upcoming G20 meeting. DG SANTE has set up a task force, and is planning to continue working with EMA, ECDC, EFSA and WHO.

Budget 2017

In December the preliminary draft budget was adopted by the board, but is subject to further feedback by the budgetary authority. At a hearing with the Directorate-General for Budget the requested staff increase of 12 FTE compared to 2016 was approved, as well as an EU contribution of 37.2 million EUR, slightly lower than the 40 million EUR requested. In the current 'zero growth' economic climate this has to be seen as recognition of the work done at the EMA.

The representative of DG GROW informed the board on the status of the revision of the EU Medical Devices Legislation, which is currently undergoing intensive trialogue discussions, with a view to potentially reaching a political agreement by June.

Two meetings were organised on 22-24th March by DG GROW in collaboration with the Dutch Presidency in Amsterdam: 1) a Multistakeholders Workshop dealing with access to medicines and pricing /reimbursement policies and 2) the network of competent authorities responsible for pricing and reimbursement of pharmaceuticals. The Commission will keep the MB updated on any other relevant activities.

The relevant legal basis for these meetings is Directive 89/105/EEC on the transparency of administrative measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems. A meeting of the Consultative Committee for the implementation of this Directive was held on 8 February with MS representatives to discuss their national practices.

Concerning the implementation of the Clinical Trials Regulation, members asked for an update on the issue whether Member States who are not concerned in a procedure will have access to information in the database. The European Commission confirmed that legislation cannot be disregarded. The Commission, however, supports the work done at HMA level to share information on a voluntary basis, as well as the survey conducted by CTFG to ascertain what national constraints may exist.

Some concern was expressed that the veterinary legislative proposal may set different regulatory requirements compared to those applicable for human medicines and not go in the direction of the One Health concept. According to the European Commission, convergence on AMR must be tackled in a single perspective by bringing together different stakeholders from the concerned sectors.

B.3 Annual Report 2015

[EMA/MB/173103/2016; EMA/57635/2016] The Management Board adopted the Annual Report 2015. The report is drafted in a similar style to the 2014 and 2015 reports with a number of key improvements, such as stakeholder views presented in an interview style authored by representatives of the Agency and important stakeholders, more metrics and analysis of core activities, certain annexes provided in a format allowing analysis, and improved lay-out and links to EMA webpages to be provided in the final published version. Among the major key projects and initiatives delivered in 2015 were the entry into force of a landmark transparency policy on publication of clinical data, action on public health challenges such as AMR, Ebola and medicines shortages, initiatives to facilitate the developments of medicines or early access, and international collaboration. Highlights in the human sector show 93 medicines recommended for marketing authorisation of which 39 are new active substances. Requests for Scientific Advice have levelled at 510, but include 30 parallel advice with HTA bodies (11 in 2014). ADR reporting has increased by 8.5%, of which a significant number were provided by patients. In the veterinary field 14 new medicines were recommended, of which 7 were new active substances and 5 vaccines to prevent viral of bacterial infections in food-producing animals. ADRs have increased by 10.8%. A dedicated report on SMEs will be annexed to the final Annual Report.

On request by some members the Agency will provide more detailed statistics to the board for planning purposes.

B.4 Multiannual Work Plan implementing the Network Strategy (MAWP)

The Management Board noted the approach and format for the preparation of the Multiannual Work Plan which will be presented to the board for adoption at the June meeting. The MAWP will provide information on the work of EMA to implement the Network Strategy, and must take into account the Financial Regulation's requirements concerning resource programming. A Multiannual programming 2017-2019 was adopted by the board at the December 2015 meeting as part of the Agency's programming document. The MAWP will cover the period until 2020, but will be in subsequent years incorporated into the programming document of the Agency, therefore effectively becoming a rolling work plan. In drafting the MAWP to 2020 the Agency will need to consider resource planning, the wish

expressed by the board in December to use whenever possible Key Performance Indicators based on outcome, and take a coordinated approach to the HMA MAWP to avoid gaps or overlaps.

The Chair called for expressions of interest for Topic coordinators for the MAWP and the Assessment of the Annual Activity Report (AAR) 2015 to be presented in June.

Post meeting note: Hugo Hurts and Belén Crespo Sánchez-Eznarriaga will act as topic coordinators for the AAR, and Karl Broich and Kristin Raudsepp volunteered for the MAWP.

B.5 EMA involvement in EU funded projects (IMI, FP & H2020)

[EMA/MB/56383/2016; EMA/141592/2016; EMA/195780/2016] The Management Board noted and discussed an overview of all ongoing activities of EMA for EU funded programmes. Following correspondence among EMA, DG SANTE and DG Research regarding reimbursement for IMI activities, which are no longer allowed under the financial regulation, DG SANTE had invited the Agency to present this information to the board. The summary included a description of the specific role of EMA in the programmes (as part of a consortium or in an advisory role), references to corresponding actions in the work programme and to the statutory tasks according to the basic act of the Agency, information on resources and financial contribution, deliverables, collaboration with Network partners and phase in the life-cycle. Further information was provided on the reasons for the cessation of the funding.

The representative of DG SANTE considered that the information provided was very useful to appreciate the extent of the important work carried out by the Agency. As further reflection is necessary on the direction to take for future involvement of EMA in IMI and similar projects, he proposed to the board to continue the discussion at a future meeting with a view to agree on a set of clear and transparent criteria.

B.6 Revised implementing rules to the Fee Regulation as of 1 April 2016

[EMA/MB/417927/2015; EMA/MB/170804/2015] The Management Board adopted the revised implementing rules to the Fee Regulation as of 1 April 2016. In accordance with legal provisions on adjustments to inflation all fees increase by 0.2%, rounded off to the nearest EUR 100, or EUR 10 for administrative charges. Further amendments concern Annex VII to terminate fee reductions due to changes in processing of certain pharmacovigilance Type IA variations (medicinal products for human use) and clarifications in Annex V on applicable fees for pharmacovigilance referrals. All proposed changes had been given a favourable opinion by the European Commission.

B.7 Revision of the Rules of Procedure of the Management Board

[EMA/MB/147961/2016; EMA/MB115339/2004/en/Rev.6] The Management Board adopted the revised Rules of procedure of the Management Board. Following the adoption by the Management Board in December of the *EMA Policy on the handling of competing interests of Management Board members* and of the Revised *EMA breach of trust procedure on declarations of competing interests for Management Board members*, the Rules where amended to replace partial, redundant and obsolete

wording under Article 11, Code of Conduct, with the references to the relevant documents which contain the applicable operational arrangements.

B.8 Update on the implementation of handling competing interests, revised rules for Management Board members: practical arrangements

The board noted an update on the practical arrangements for the implementation of the Policy on the handling of competing interests of Management Board members. The revised policy will enter into force on 1 May 2016, but a new form for the Declaration of Interests will be available on 1 April 2016.

B.9 Guiding principles for the revision of the MB Decision concerning the handling of declared interests of EMA staff

[EMA/MB/154358/2016; EMA/150971/2016] The Management Board endorsed the guiding principles for the revision of the MB Decision concerning the handling of declared interests of EMA staff. Following the revisions of the policies for the handling of the declarations of interest of scientific committees' members and experts and of Management Board members, the Management Board Decision concerning EMA staff needs to be revised and aligned with both policies. Changes are further proposed in order to streamline the process. Once endorsed by the Management Board, the guiding principles will be further developed and a revised MB Decision will be prepared and presented for adoption by the board at the June meeting.

The board welcomed the proposed alignment. Further information was requested on the nature of the differences between the policy for scientific committees' members and experts and the proposals concerning EMA staff. These concern nuances due to the different role of staff members and to the provisions arising from the Staff Regulations and will be presented in detail when the revised Management Board decision is discussed.

B.10 Draft revised rules of procedure on the organisation and conduct of public hearings at the PRAC

[EMA/MB/154584/2016; EMA/363479/2015; EMA/144909/2016] The Management Board endorsed the draft revised rules of procedure (RoP) on the organisation and conduct of public hearings at the PRAC. Following a 3 months public consultation in 2014, the proposed responses to comments were discussed in various fora including the Management Board and HMA. The draft RoP were subsequently revised and sent to the European Commission together with an impact assessment. This has been prepared on the basis of a retrospective analysis of all safety referrals between July 2012 and September 2015 using the elements identified in the RoP to evaluate the need for a public hearing. Impact on all stakeholders, as well as on resources was considered. Further small changes in the draft RoP were introduced after minor comments by the European Commission and a presentation to the PRAC at the March meeting. Following the endorsement by the Management Board the PRAC will be invited to adopt the RoP at the April meeting. A "mock-up" public hearing will be organised in July 2016. Public hearings can then take place as of September 2016.

B.11 EU Portal and EU database

– Update on development of CT Portal and Database

The Management Board noted an update on the development of the EU Portal and Database. Since the December meeting of the board a number of teleconference and webinars, as well as face to face meetings took place with Member States and stakeholders to agree on the way forward in managing auditable and non-auditable must requirements. After the endorsement by the board of a delivery timeframe with October 2018 as the latest date for the Clinical Trial Regulation to become applicable, Member States and stakeholders need a fixed date to enable their planning, and have agreed to take a decision on it at the end of Q3 2016 once three or four iterations of the software development have taken place. User Acceptance Testing (UAT) will take place every three months at each iteration, and all Member States and a wide range of stakeholders can participate using remote access. A first UAT was taking place at the time of the meeting of the board and will provide a real sense of how the system works. The EMA is reviewing a proposed upgrade of non-auditable requirements to auditable status and further discussion on revisions will take place with the Member States over the coming two months. In conclusion a video system walkthrough and system screenshots were shown to the board.

The board expressed appreciation for the work done by the Agency and for its effort to balance complexity of requirements with timely delivery of the system. The representative of DG SANTE reminded the board of the expectations by the public surrounding this system and warned about the risk of excessive sophistication which could further delay the process.

B.12 Report from PDCO Chair

Dirk Mentzer, Chair of the Paediatric Committee (PDCO), presented to the board an overview of the achievements of the committee as well as the challenges that lie ahead. The EU Paediatric Regulation came into force 10 years ago with the aim to improve the health of children in Europe by stimulating high quality research, promoting the development and authorisation of paediatric medicines in the EU and by improving information. A further aim is to avoid unnecessary studies in children while not delaying authorisation of medicines for other populations. The output by the Committee has been significant, with a steady state of Paediatric Investigation Plans (PIPs) and PIP waivers of ca. 90 procedures a month. The number of Paediatric clinical trials including children has significantly increased over the last ten years, causing a workload increase also for the CHMP. As a result the therapeutic landscape for children has significantly improved over the past few years in certain areas, but there is still significant room for improvement concerning medicines development in areas such as neonatology, congenital defects and paediatric oncology. This is due to factors such as low return of investment, limited research funding and difficulties in the feasibility of clinical trials in paediatric populations. The increasing workload at PDCO is causing time-pressure for the committee, which is composed largely of experts from academia, and is currently lacking two members and several alternates. Discussions are ongoing over the need to add a day to the monthly meeting, currently lasting 2.5 days. The PDCO's work plan for 2016 foresees the contribution to the 10-year report by the European Commission, integration of innovative clinical trial methodology in PIP opinions, strengthened collaboration with other committees and SAWP. In years ahead the PDCO also intends to increase the involvement of patients in PIP decisions and continue to assure that authorised paediatric medicines and age appropriate formulations become and remain available.

Members of the board thanked Dr. Mentzer for the work done by the Committee and for the information provided. Answering questions by members Dr. Mentzer assured the board that the

impact of the work of PDCO on paediatric research is increasing, also thanks to the work of the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA), and that the integration of innovative clinical trial methodology, such as modelling, simulation and extrapolation of data, in the PDCO's decisions will contribute to avoid unnecessary studies in children.

B.13 Update on PSUR repository

The board noted an update on the mandatory use of the PSUR repository. On 11 June 2015 the Management Board had confirmed, on the basis of the independent audit report and of the PRAC recommendation, that the PSUR repository met the full functional specifications and that the system will become mandatory on 13 June 2016. Four further post-audit deliverables would be provided in future releases, and their delivery plan was noted and agreed as binding for the Agency. On 6 January 2016 a release went live delivering the complete set of post-audit deliverables, completing all agreed functionality in line with the specifications agreed by the PSUR Repository Advisory Group (PRAG), the pharmacovigilance governance structure, PRAC, CMDh and EU Telematics. As future steps a new release providing further system enhancements is planned for 14 May 2016. A 'switch-on' phase to transition the system to the mandatory use was started on 11 February 2016, allowing NCAs the use under simulated mandatory use conditions. In the maintenance phase the PRAG will become a new Maintenance Group of the eSubmissions Change Management Board. The successful delivery of the project was credited to close collaboration and communication between EMA and the PRAG.

B.14 Report by the Steering Group on the Management Board data gathering initiative

Pharmacovigilance time data collection

HMA TF on sustainability: sharing of collected pharmacovigilance time data prior to submission to EMA

[EMA/MB/173650/2016] The Management Board noted the 8th Interim Report by the Steering Group of the Management Board data gathering initiative. The data gathering is progressing in accordance with a high level plan which is compatible with the timelines of the European Commission for the independent evaluation. Work on methodology is now focussed on time data collection for 'Working Party Activities', previously referred to as 'Guidelines'. The Agency continues to provide information and support to national contact points in the NCAs, and has held numerous presentations at PDCO, COMP, QRD, GMP IWG and GCP IWG to support initiation of the exercise. The current phase is very active, with data collection started on the majority of remunerated human medicines authorisation procedures together with procedural and 'horizontal' activities of the PDCO and COMP. On the veterinary side collection on all remunerated authorisation activities is active and the exercise will be extended in April to Pharmacovigilance and MUMS/limited markets. Working Party activities data collection is targeted to be initiated in April, while it has been ongoing since March for Pharmacovigilance/GXP inspection activities. A 'stopping rule' was set for end October 2016 in order to allow for the time necessary to prepare the reports for delivery to the European Commission by end of December 2016.

Concerning human pharmacovigilance activities, the Steering Group had decided not to duplicate a data collection already foreseen in a legislative requirement of the Pharmacovigilance Fee Regulation. The collection will need to be carried out every year and will be included for 2015 in the annexes of the

2015 AAR and as a summary in the 2016 Annual Report. Starting in 2016 NCAs should be able to collect data prospectively on a data reporting template similar to the one used in the data gathering exercise. The Agency will facilitate the exercise by providing a methodological protocol and a quarterly reminder listing the procedures carried out by each NCA. A pharmacovigilance specific webinar with the contact points of the NCAs will be organised.

In the discussion that followed the quality of data obtainable from data collection on horizontal activities was questioned. This reservation could in principle be shared by the Agency, but understanding resources going into each area of activity is necessary. Concerning visibility of the raw data ahead of the final report, members were reminded that all information received is made available to all on the MMD system. Statistical analysis of the emerging data set will be reported as of Q3. An obligation to report time spent on pharmacovigilance by EMA staff also applies, and will be handled in parallel to data provided by NCAs. Appreciation was expressed for the clear explanation by the Agency and for the provision of a methodological protocol for the pharmacovigilance data collection.

The European Commission provided further information on its activities concerning EMA fees. On request by some NCAs the timelines for comments to the roadmap outlining the planned evaluation have been extended until the end of March. The European Commission will consider the comments, which will be published on the web, when drafting the Terms of Reference for the evaluation, and agreed to consult the board on the draft Terms of Reference. As the European Commission is aiming to start the evaluation by end of 2016, it is important that the data gathering exercise delivers by that time. The European Commission informed the board of the discussion on fees that took place in the Council Working Party of 10 March 2016. A proposal was discussed to amend regulation (EC) No. 726/2004 under the so-called 'Lisbonisation' by amending the legal instrument by which fees are set. Member States feared long delays due to the evaluation exercise, and expressed a preference to see the results of the evaluation before making a decision on the legal instrument. It should however be stressed that there is no link between the legal proposal, which was adopted in 2014, and the recent initiative to start the process for the evaluation of the fee system, which has the objective to assess effectiveness, efficiency and relevance of the EU legislation and is necessary before an impact assessment of a possible legal proposal may be started.

Members welcomed the clarifications provided. Concerning the question as to whether the Management Board would continue to have a role in the repartition of fees as a consequence of a possible new legislative instrument on fees, the Commission confirmed that while the board would not, the Member States would retain this prerogative.

The European Commission reminded the board that the data gathering exercise must rely on trust and transparency to provide reliable data. For this reason any prior submission of data to an authority other than the EMA would cause a very bad signal as it could lead to questioning the credibility of the data. Sharing of information and experience among NCAs is otherwise warmly encouraged.

B.15 6th Annual Report Veterinary MUMS/limited market

[EMA/MB/129634/2016; EMA/57157/2016] The Management Board endorsed the 2015 annual report on the policy on veterinary medicines for minor use minor species (MUMS)/limited market. The report highlights continued interest in the policy by stakeholders, of which 46% were SMEs, resulting in 28 requests for classification, for 7 of which financial incentives were granted. Requests for classification covered products indicated for a wide range of minor species and of minor indications in major species. The number of products indicated for food producing species, and thereby receiving financial incentives, increased, confirming the success of this strategic priority for the scheme. Since 2009, 152

requests for classification have been received, of which 11 resulted in new MUMS centralised marketing authorisations, and other products that have been authorised nationally. The guidelines on data requirements for MUMS/limited market products were updated in 2015 to ensure that opportunities for data reduction are fully taken into account, and these revised guidelines are currently released for consultation. In conclusion the policy is widely appreciated by stakeholders and continues to deliver its objective to stimulate the development of new veterinary medicines for minor species and for rare diseases in major species that would otherwise not be developed under current market conditions.

List of written procedures finalised during the period from 3 November 2015 to 19 February 2016

- Consultation no. 12/2015 on the appointment of Nithyanandan Nagercoil as CHMP alternate, proposed by United Kingdom, ended on 17 December 2015. The mandate of the nominee commenced on 18 December 2015.
- Consultation no. 01/2016 on the appointment of Ines Baotic as CHMP member, proposed by Croatia, ended on 12 January 2016. The mandate of the nominee commenced on 13 January 2016.
- Consultation no. 02/2016 on the appointment of Katarina Vucic as CHMP alternate, proposed by Croatia, ended on 12 January 2016. The mandate of the nominee commenced on 13 January 2016.
- Written procedure for adoption of the 90th Management Board meeting minutes, ended on 9 January 2016. The minutes were adopted.

Documents for information

- [EMA/MB/105085/2016; EMA/46655/2016] Report on EU Telematics
- [EMA/MB/89899/2016] Summary of transfer of appropriations in the budget 2016
- [EMA/MB/134134/2016; EMA/34490/2016] 2015 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission (Reporting period: 1 January-31 December 2015)
- [EMA/MB/67089/2016; EMA/MB/67088/2016] Second six-monthly report on ex ante and ex post evaluation of projects for the period 1 July to 31 December 2015

Tabled documents

- Agenda for the 91st meeting of the Management Board (version 4)
- Documents relating to Agenda point B.5 – EMA involvement in EU funded projects (IMI, FP & H2020)

List of participants at the 91st meeting of the Management Board, held in London, 17 March 2016

Chair: Christa Wirthumer-Hoche

	Members	Alternates	Other participants
Belgium	Xavier De Cuyper		
Bulgaria	Assena Stoimenova		
Czech Republic	Zdeněk Blahuta		
Croatia		Siniša Tomić	
Denmark	Mette Aaboe Hansen		Matilde Kyst Behrens
Germany	Karl Broich		Anna Afentaki Andre Berger
Estonia	*Apology received from Kristin Raudsepp*		
Ireland	Rita Purcell		
Greece	*Apology received from Despoina Makridaki*		
Spain	Belén Crespo Sánchez-Eznarriaga		
France	Dominique Martin		Miguel Bley
Italy		Gabriella Conti	
Cyprus	Loizos Panayi		
Latvia	Svens Henkuzens	Janis Zvejnieks	
Lithuania	Gintautas Barcys		
Luxembourg	Laurent Mertz		
Hungary	*Apology received from Csilla Pozsgay*		
Malta		Gavril Flores	
Netherlands	Hugo Hurts		Birte van Elk
Austria	Christa Wirthumer-Hoche		
Poland	Grzegorz Cessak		Magdalena Pajewska
Portugal	Rui Santos Ivo		Maria Joao Morais
Romania	Nicolae Fotin		
Slovakia	Ján Mazag		
Slovenia	Andreja Čufar		
Finland		Pekka Kurki	
Sweden	Catarina Forsman		
United Kingdom	Ian Hudson	Jonathan Mogford	
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European Commission	Xavier Prats-Monné (DG SANTE) Carlo Pettinelli (DG		Lenita Lindstrom (DG SANTE) Chloe Spathari (DG

	Members	Alternates	Other participants
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Representatives of patients' organisations	*Apology received from* W.H.J.M. Wim Wientjens Nikos Dedes		
Representative of doctors' organisations	Wolf-Dieter Ludwig		
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