17 March 2017
EMA/MB/183915/2017 Adopted
Management Board

Minutes of the 95th meeting of the Management Board

Held in London on 16 March 2017

The Chair of the Management Board opened the meeting by welcoming the new alternate members Emilia Mavrokordatou for Cyprus, Esa Heinonen for Finland, Birgit Naase for Germany and Sara Rosenmüller for Sweden.

The Chair invited nominations for the Analysis and Assessment of the Executive Director's Annual Activity Report (AAR) 2016 to be delivered at the June meeting. Last year's volunteers Belén Crespo Sánchez- Eznarriaga (Spain) and Hugo Hurts (the Netherlands) were joined by Nancy De Briyne. The position of a Management Board representative at the EU Telematics Management Board is vacant and interested members should write to the Chair or the MB Secretariat. Members were reminded that in case of membership of MB subcommittees the restrictions that apply in case of competing interests are the same as those for the MB itself.

1. Draft agenda for 16 March 2017 meeting

[EMA/MB/183915/2017] The agenda was adopted with no amendments.

2. Declaration of competing interest related to current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning topics "*B.5 Revised implementing Rules to the Fee Regulation, B.10 Policy on external sources reporting potential regulatory improprieties, B.12.b Preparation for Audit".* The Secretariat informed the board that all concerned members had been informed before the meeting. Should the need for a vote on the above topics arise, the chair would take up the matter again.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

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3. Minutes from the 94th meeting, held on 14-15 December 2016 adopted via written procedure on 3 February 2017

[EMA/MB/862367/2016] The Management Board noted the final minutes, adopted by written procedure on 3 February 2017.

A. Points for automatic adoption / endorsement

A.1 Repeal of Long term and short term contract agent rules

[EMA/MB/76149/2017; EMA/MB/66252/2017] The Management Board adopted the repeal of the Long term and short term contract agent rules of 10 April 2012, maintaining the rules of 4 October 2007 which, together with Staff Regulations and the Conditions of Employment of Other Servants, provide sufficient clarity until new specific rules on the engagement of Contract Staff in EU agencies are provided by the European Commission.

A.2 Derogation from Commission rules (Middle management rules, Function of Adviser, Learning & Development strategy)

[EMA/MB/58698/2017; C(2016) 3288; C(2016) 3827; C(2016) 3828; C(2016) 3855 with Annex; C(2016) 3214; EMA/MB/84839/2017; EMA/MB/58145/2017] The Management Board adopted a decision empowering the Executive Director to request to derogate from certain European Commission rules until model rules on the same subjects are finalised during 2017. The rules concern Middle Management staff, Function of Adviser and Learning and Development strategy, including training on the own initiative of member of staff.

B. Points for discussion

B.1 Highlights of the Executive Director

Brexit preparedness

The implementation of the 2017 Work Programme is progressing broadly in line with expectations for 2017, however the Agency is ready to reallocate or reprioritise resources should the need arise as a consequence of an important staff loss, and will inform the board accordingly.

Organisational changes

As of January 2017 David Mackay has taken up an advisory role for strategic objectives within the Veterinary Division, and Fia Westerholm has been appointed as the ad interim Head of the Veterinary Medicines Division. From 15 February 2017 the International Affairs advisory function has become the International Affairs Division to better address similar structures worldwide.

International Activities

The Agency welcomes the agreement on an annex to the EU-US MRA on GMP which has been achieved with the joint effort of the European Commission, the NCAs and the Agency and will enter into force on 1 November 2017. At a meeting held in Malta in early March ,African regulators of 17 countries, WHO, World bank, the NEPAD African development agency and the East African Community, in collaboration with the Bill and Melinda Gates Foundation, joined for the first time to discuss the potential of Article 58 together with the CHMP. The Agency participated in a twinning project with the Republic of Moldova supported by Lithuania and Poland.

EU activities

Mrs. Biljana Borzan, the EMA's new liaison MEP of the ENVI Committee, visited the Agency on 7-8 February to meet senior management and discuss Brexit preparedness activities, access to medicines, shortages, the new Clinical Trial Regulation and transparency. She is likely to return to the Agency in April, as part of the 2-yearly visit of an ENVI delegation to the Agency.

Update on the discharge 2015 procedure

The Agency has received a positive opinion from the European Court of Auditors with regard to the 2015 annual accounts and implementation of the 2015 budget. A positive outcome at the European Parliament is expected in April. A draft report proposing to grant discharge to the Executive Director contains positive comments with regards to budget implementation, continuing efforts around management and prevention of conflicts of interest and increased transparency, implementation of recommendations from audits and the establishment of a dedicated task force on preparedness for Brexit.

Pilot on Parallel Distribution

As announced at the December 2015 meeting of the Management Board, the Agency last year conducted a one year pilot initiative on fee reductions for notification of parallel distribution in the Maltese language. The objective was improving availability of centrally authorised products and the Agency is now conducting an ex-post evaluation. The Maltese authorities have requested a one year extension of the initiative to allow further uptake. If successful the initiative might be of interest also to other Member States.

Update on Court cases and Data Protection

Two important cases have been won by the Agency in the areas of procurements and referrals. Concerning access to documents, however, two appeals against interim orders were ruled against, but while awaiting the first judgment on the main case the Agency's daily activities on access to documents must continue as there is a legal obligation to respond to all requests and there is no judgment on the merits yet. A new legislation on the protection of personal data (also called GDPR) shall be applicable by May 2018 and will be discussed with the board once an impact assessment will have clarified its implementation.

Clinical Trial Regulation Workshop

EMA hosted a workshop organised by the EU Clinical Trial Regulation Coordination Group on 14 February. About 80 delegates from Clinical Trials units, ethics committees and IT directors from Member States attended together with DG SANTE, EMA teams and representatives of the board and of heads of Agencies in an effort to look together at how challenges can be overcome at every level.

Information on biosimilars

The Agency, in collaboration with the scientific experts form Member States and from the European Commission, is preparing an information guide, to be launched in May, to provide reliable information on biosimilars for healthcare professionals.

Antimicrobial Resistance (AMR)

On 15 March ECDC presented at the Patients and Consumers Working Party & Healthcare Professionals Working Party on the European Antibiotic Awareness Day as a first step toward a dedicated EMA/ECDC joint session on AMR which will take place on 19 September.

Lumpy Skin Disease (LSD)

A stakeholder meeting on availability of authorised vaccines against LSD was held at the EMA on 31 January. The Agency has not been involved in assessing products used without an authorisation by Member States under Article 8 of the Veterinary Directive 2001/82/EC in response to emerging animal infectious disease and has no legal mandate to become involved. The EMA is open to exploring also with the European Commission how it can foster cooperation by acting as a catalyst to find solutions and promote closer cooperation, e.g. with EFSA.

Appreciation for EMA's willingness for greater involvement in LSD vaccines was expressed. A request was made for discussion at the board of how HTA and the initiatives on parallel scientific advice and on adaptive pathways may be interlinked. The topic could be discussed at the June or the October meeting of the board if the workload at these meetings allows it.

B.2 Report from the European Commission

The representative of DG SANTE concentrated his report on selected points.

Antimicrobial Resistance (AMR)

Building on improved cooperation with EFSA and the global political momentum, the European Commission is working on a new Action Plan to be ready before summer.

Vaccination hesitancy

There is scope for a joint initiative in Europe where vaccination hesitancy is very high. The Commission will hold a seminar on 30-31/05 to discuss the challenges that need to be addressed.

Lumpy Skin Disease (LSD)

Access to vaccination through the Commission vaccine bank has allowed the effective control of the LSD outbreak in Europe. Legislation allows the use immunological veterinary medicinal products without a marketing authorisation in certain cases of emerging infectious disease, however any advancement of understanding of the vaccines is welcome, and the Commission will continue to liaise with EFSA and EMA to assure good coordination and progress of knowledge.

Considerations on the impact of Brexit

On 1 March the European Commission has issued a White Paper on the future of Europe, which opens a new chapter for the future of the European project on the occasion of the celebration of its 60th anniversary. The 5 scenarios proposed in it by the Commission are not mutually exclusive and intend to focus the attention on the choices to be made for the future. During the consultation process, which extends until June 2019, there will be time to reflect on the future steps, which might also affect the direction of health policy. Brexit must therefore be considered in this context. As there is now certainty that Article 50 will be triggered before the end of March, a specific period of the length of two years begins, and it is prudent to start considering the cut-off dates that will affect the Agency and its committees. There is a concrete opportunity and need for the remaining 27 Member States to focus on increasing assessment capacity on the basis of the very good analysis performed by the Operations and Relocation Preparedness Task Force regarding current involvement of UK in EMA activities. As for the relocation of the Agency, this will need to take place at the latest when the UK leaves the European Union and becomes a third country, therefore the 1st April 2019 needs to be considered as the latest target date. The decision on the new location will be taken by the Heads of State and Government who need to be very aware of the importance to guarantee business continuity at the Agency, which is a well-established organisation with a world class reputation, and the impact of the timing of its relocation. The Commission is very satisfied with the data and information material provided by EMA

that contribute to the relocation criteria which will be prepared in line with the common approach on decentralised agencies focussed on logistics, accessibility, facilities for families and labour market. The decision arrangements should allow for an orderly relocation without business disruption.

HTA

A consultation on EU cooperation on HTA beyond 2020, launched in October 2016 and closed in January 2017, aims at addressing policy options on EU cooperation on HTA, specifically concerning type of participation, scope, funding mechanism and governance. Numerous replies were received from citizens and from administrations, organisations and associations and the results and full analysis will be published Q2 2017. The preliminary results show all respondents very positive on HTA cooperation, specifically for pharmaceuticals. As next steps a number of studies to support the impact assessment process with facts and figures will be performed and bilateral meetings will be held with Member States. The impact assessment is planned for Q4 2017 and will lead to a EU initiative, which might be for a legislative or non-legislative proposal.

Mutual Recognition Agreement EU/US on pharmaceutical GMPs

The Agreement, which was concluded on 1 March, is to be considered a real accomplishment by all parties involved. Now the focus should be on the implementation of the Confidentiality commitment to be signed by EC/EMA and the FDA, and on the completion of the assessments of the Member States in order to meet the deadline for recognition of inspections from 1 November 2017 onwards. It is therefore important that Member States ensure sufficient resources for the submission of the necessary information to the US and meet key dates in the agreement.

Clinical Trials Regulation

With the adoptions of the Act on GCP inspections procedures in March 2017, of the Act on GMP for investigational medicinal products (IMP) in March/April followed by 2 months scrutiny of the EP and Council, and of the Guidelines for GMP for IMP in April, the European Commission will have completed the legislative work.

Concerning Brexit, the representative of the UK offered full cooperation until arrangements for leaving the EU are put in place, referring also to the expression of interest by the Secretary of State on future close cooperation with EMA. The representative of the European Commission invited all to focus on the preparation that is needed in order to ensure continuity and effectiveness of EMA operations. In particular, Member States will need to build up their capacity to compensate for the contribution by the UK once it is no longer part of the EU. The EMA confirmed that the list of EMA criteria for the relocation will be shared with the board once they have been transmitted to the European Commission.

B.3 EMA preparedness on Brexit

An update report on the work done by the Operations and Relocation Preparedness Task Force (ORP) was provided to the board. Starting on 24 June 2016 the Task Force has worked on four work streams: relocation preparedness, Operational and financial preparedness, HR related matters and communication actions. Initiatives undertaken by the Task Force include the development of prerequisites for a new location including generic specifications for the building, conduct of an impact assessment on the consequences of Brexit on the operations of EMA including identifications for remedial solutions also in collaboration with the European Institutions and the Scientific Committees of the Agency, development of a dedicated Brexit BCP (Business Continuity Plan) in case of staff loss and of a physical relocation BCP, development of a dedicated recruitment and selection strategy and of a 'Relocation transition' package for staff, conduct of two staff surveys and continuous provision of up-

to-date information to staff, development of arrangements for requests for information and for visits to EMA to increase understanding of the operations and functioning of the Agency. Once Article 50 has been triggered, the EMA proposes to hold a dedicated meeting including Management Board members and Heads of Agencies (both human and veterinary) who are not members of the board to discuss the impact of the UK leaving the EU as regards workload and resources. The provisional date of 27 April 2017 has been identified.

The board expressed its wish for an early decision on the relocation of the Agency and welcomed the opportunity that will be provided to discuss more in depth also matters concerning workload and resources. A representative of patients' organisations recommended considering matters relating to competitiveness and innovation when preparing a BCP that may affect the EMA Work Plan. A reprioritisation impacting on Work Plan deliverables will be in any case discussed and agreed by the board. Members expressed their commitment to increase their contribution to scientific work, and called for an orchestrated approach, that will allow single NCAs to invest in areas where resources need to be usefully allocated.

B.4 EMA Annual Report 2016

[EMA/MB/133379/2017; EMA/77204/2017] The Management Board adopted the Annual Report 2016. The report focusses on key achievements that have a positive impact on public health. As in the previous years it contains interviews with representatives from the Agency's partners and stakeholders on topics of high current interest. Statistics and trends on core activities are provided. Key projects and initiatives with public health impact include proactive publication of clinical trials data, the PRIME initiative and the response to public health challenges, such as the actions on Zika virus or collaboration on AMR. Opinion pieces provide the views of partners and key stakeholder on vaccine hesitancy, creating an agile organisation and reinforcing surveillance of antimicrobial consumption. Statistics on performance by the Agency show 81 medicines for human use including 27 new active substances and 2 advanced therapy medicinal products approved in 2016. The accelerated assessment procedure was used 7 times. Trends show an increase by 20% for requests of scientific advice compared to 2015. For veterinary medicines, 5 of the 11 recommended for marketing authorisation were new active substances. There was a 21% increase in the reporting of ADRs to EudraVigilance. There was also a significant increase of 18.5% in GMP inspection requests, linked to growing number of centrally authorised products.

B.5 Revised implementing rules to the Fee Regulation as of 1 April 2017

[EMA/MB/97414/2017; EMA/MB/97423/2017] The Management Board adopted the revised implementing rules to the Fee Regulation as of 1 April 2017. In accordance with legal provisions on adjustment to inflation all fees increase by 1.2%, rounded off to the nearest EUR 100, and to the nearest EUR 10 for administrative charges. All proposed changes had been given a favourable opinion by the European Commission. The amendment of the levels of fees and remuneration to the national competent authorities is pending the adoption of the corresponding Commission regulation adjusting the fee levels of Council Regulation (EC) No 297/95.

B.6 Appointment of new Accounting Officer of the European Medicines Agency

[EMA/MB/27835/2017; EMA/MB/27838/2017] The Management Board appointed Paola Samassa as the new Accounting Officer of the Agency, succeeding Michael Lenihan who has been appointed as Head of Department for Strategic Planning and Governance.

B.7 Revision of rules for reimbursement of expenses for delegates attending meetings

[EMA/MB/144135/2017; EMA/MB/144136/2017] The board adopted revised rules for reimbursement of expenses for delegates attending meetings. The rules were reviewed to take into account the Commission's own revision of daily allowances and hotel ceilings for staff travel, which are also used for delegates at EMA, the roll-out of public hearings in the course of 2017, and the increase of training sessions and meetings outside the Agency's premises. The revision introduces new ceilings for daily allowance and hotel expenses, daily allowances taking into consideration length of travel, passenger rights and shorter timelines for submission of travel expenses.

B.8 Framework of collaboration between the EMA and academia

[EMA/MB/125458/2017; EMA/124964/2017; EMA/58661/2017; EMA/125511/2017] The Management Board adopted the framework of collaboration between the European Medicines Agency and academia in relation to medicines intended for human and veterinary use. The framework had been presented at the December meeting of the board, when it had been agreed to extend the timeframe for provision of comments by a month before a new submission to the board. The comments received had been largely accepted and incorporated in the document and the scope of action and role of NCAs better clarified. A fourth objective on developing regulatory science was introduced following a proposal in collaboration with NCAs. The framework was requested by the European Commission's Internal Audit Service and is aligned with the existing EMA frameworks for patients, healthcare professionals and industry. Member States may nominate contact points, but are not bound to set up dedicated offices for academia at national level.

It was pointed out that the EU Innovation Network has the task of screening innovation in Member States and providing support to academia ahead of Scientific Advice, and will take initiatives to make its activities better known to the network and to HMA.

B.9 Report by the Steering Group on the Management Board data gathering initiative

[EMA/MB/134040/2017; EMA/174166/2017] The board noted the 12th Interim report of the Steering Group on the Management Board data gathering initiative. A draft Executive summary had been circulated to the board ahead of the full draft report, to be endorsed by written procedure after the meeting of the board. The objective of the initiative, started at the board three years before, and now nearing completion, had been to collect information on time spent at EMA and NCAs on procedures. The exercise has been largely successful in gathering data on fee generating and also in some non-fee generating human and veterinary procedures, as well as on some horizontal activities at the Working Groups and committees. Due to small sample size some data needed to be extrapolated and some other will continue to be collected until June. The compliance rate for the provision of data was high

and representative of the contribution of NCAs in the network. Emerging patterns across procedures were considered to be consistent and coherent with the roles of NCAs and of the EMA Secretariat. Some high variability of datasets was noted. Collection of data from Working Parties presented some challenges due to inconsistent reporting compliance rate and difficulty in separating procedure specific from non-procedure related work. The final draft report will be circulated to the Management Board for endorsement by written procedure by 28 March, so that it may be finalised by the Steering Group and transmitted to the Management Board and to the Commission on 4 April.

The Chair thanked the Steering Group for the great effort that had gone into this Management Board mandated initiative over the last three years, which had required a great number of virtual meetings. The board had been kept informed at all times by means of access to all documentation and through reporting at every meeting. Concerning a request to extend the deadline for comments by a week in order to provide the members with more time for comments, members did not see the possibility to do so. The data work should now be considered as completed and be trusted. It is now time to deliver it to the contractor who is conducting the external evaluation of the fee system, and who will soon start testing a survey with a set of NCAs. Members considered that the report mainly contains information of a factual nature, which are not likely to change in a consultation. The report should be transparent as to its limited scope. The collected data might give rise to further reflections in the future, also on how some procedures could be run more efficiently. There was appreciation for the Commission's willingness to make an exception in allowing NCAs to interact with the contractor, and the wish was expressed for further involvement in the discussion once the contractor finalises the report, possibly in a meeting of the board. The last teleconference of the Steering Group to finalise the report will be open to all members of the board.

B.10 Policy on external sources reporting potential regulatory improprieties

[EMA/MB/68192/2017; EMA/283205/2013] The board endorsed Policy 0072 on EMA's handling of information from external sources disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products. The policy sets down in a structured way the principles that have been in use at the Agency since 2013. External source reports undergo a triage that starts with the provision of a dedicated form and dedicated mailbox. EMA checks whether allegations concern an area under its remit and whether they fall under other policies of the Agency. Applicable principles concern among others protection of the identity of the external source, protection of the information, collaboration with institutional, national and international partners, notification to the external source of the outcome of its examination, transfer to other authorities if not competent. The text of the policy has been agreed with DG SANTE and OLAF.

B.11 Report from CVMP Chair

David Murphy, Chair of the CVMP, presented to the board an overview of the committee's achievements and current and future issues. The CVMP is not only responsible for assessment of veterinary medicines and establishment of maximum residue limits, but with its working parties contributes to the development of veterinary medicines and medicines regulation. It is supported by 10 Working Parties and Working Groups, two of which are in common with the Human sector. The output trends for 2016 show a drop in Scientific Advice procedures, which is expected to be reversed in 2017, and some decrease in marketing authorisation applications. Of the 18 products which were assessed in 2016, five were classified as MUMS (minor use minor species) of which two were notable

for their use in food producing animals: the first DNA vaccine in the EU recommended for use in salmon, and the first product in the centralised procedure for the treatment of bees. Consumer safety evaluation on MRLs continues to decrease, as not many new products are developed for food producing animals. Since 1995 174 veterinary medicinal products have been authorised, and in 2016 a total of 18,413 adverse reports were received for them. CVMP is active also in production of guidance documents, with 8 guidelines finalised in 2016, 3 reflection papers, various Q&A documents and problem statements released for public consultation by the Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT). Other areas of significant activity of the committee concern antimicrobial resistance, for which a strategy 2016-2020 was adopted in 2016; availability of veterinary medicines under the MUMS limited markets policy and the Joint EMA/HMA action plan on vaccines availability; consumer safety and environmental risk assessment. The publication in 2017 of a joint EFSA/EMA opinion on EU measures to reduce antimicrobial use in animals was the result of considerable effort and an example of good collaboration. Among the current issues is the need to continue to produce high quality scientific input with limited resources. Significant support is found in the EU Network Training Centre, while there is still limited experience with Multinational Assessment Teams (MNATs). As new veterinary legislation is on the horizon, it appears that there could be a significant impact on the CVMP. The committee will further need to examine workload distribution in the context of Brexit.

B.12.a Clinical Trial EU Portal and Database

[EMA/MB/123839/2017; EMA/52673/2017;] The Management Board noted the status update on the development of the Clinical Trial EU Portal and Database. The workshop organised on 14 February by the EU Clinical Trial Regulation Coordination Group brought together 80 participants from all the Member States, the European Commission, the chair of CTFG, five Heads of Agency including three representatives of the Management Board and its chair. Among the conclusions of the workshop were the recognition of the need for all involved parties to work closely to deliver the implementation in the agreed timeframe, developing working procedures for cooperation at the national level and between Member States, identifying pragmatic solutions for the transition period during the first 3 years of operation and establishing the process for post audit review and reporting to the board. Concerning the development, the new IT supplier has completed the take-over and provided detailed planning of two more releases before the audit, and one post-audit. It needs to be noted that the next two releases will be noticeably larger and will bring a steep increase in functionality. The first release delivered by the new supplier has shown a clear reduction in number of high severity bugs, but given the complexity and size of the project, continuous monitoring of actual effort compared to estimates is needed to confirm whether the project remains on track or needs intervention. Current signs show that the development is moving forward at the limit of sustainable progress. The timetable for the audit to confirm that the EU Portal and EU Database have achieved full functionality and the systems meet the functional specifications will involve the board in early October 2017. In mid-November 2017 a workshop with Member States and board representatives will take place to discuss the final report of the audit, including also an addendum on the implementation of any corrective action, before presentation to the board at the December 2017 meeting for decision.

B.12.b Preparation for audit

[EMA/MB/171044/2017; EMA/170854/2017;] As part of the preparation for the audit the board endorsed risk mitigation measures to support maintenance of the audit dates for the EU portal and database and the subsequent timeline of decision making and entry into application of the Clinical Trial Regulation.

The chair invited volunteers to act as topic coordinators for the audit report. Rui Santos Ivo will join Karl Broich and the other board representatives by June when their activity will begin. Following a suggestion, the opportunity to meet with representatives of the consortium which is developing the system will be provided to board members, to provide assurance on how the project will be delivered in line with the schedule. Concerning the possibility for Member States to start testing system functionalities end-to-end, this will be provided with the delivery of iteration 0.8 in Q4 2017. Once specifications have been finalised, Version 1 of the application programming interface will be built by December. . The representative of the European Commission manifested his appreciation for the excellent collaboration with EMA and underlined the need to ensure compliance with the agreed timelines.

B.13 Pharmacovigilance Programme: Update on the EudraVigilance Auditable Requirements Project

[EMA/MB/60610/2017] The board noted an update on the EudraVigilance Auditable Requirements Project. The independent audit has taken place in February 2017 and an Independent Audit report with a recommendation by the PRAC will be provided to the EMA Management Board, who will need to confirm and announce when full functionality of the EudraVigilance database has been achieved and the system meets the functional specifications which it endorsed in December 2013. No major issues were reported and a final audit report will be delivered to EMA by 31 March 2017. An addendum to the final audit report examining implementation of the findings will be provided by 19 April 2017. At its March and April meetings PRAC will be updated in preparation for its recommendation in May 2017. The independent audit report with the PRAC recommendation will then be circulated to the EMA Management Board on 5 May to confirm and announce by written procedure that the EudraVigilance database has achieved full functionality and the system meets the functional specifications. EMA will organise a dedicated teleconference to address any questions by the board that may arise during the written procedure. The written procedure is scheduled to end on 19 May 2017.

B.14 Update on PSUR Repository

The board heard an oral update on the PSUR Repository maintenance phase. The system, which is foreseen in legislation and referred to in the Network Strategy to 2020, is the first to go through the new deployment flow at the Agency. After beginning of its mandatory use in June 2016 it is now in the maintenance phase where usability releases ca. every 2 months ensure that continuous development takes place. The system is considered to be intuitive and fit for purpose, as shown by a steep decrease in technical queries by NCAs and Industry since its mandatory use, and by the high volume of use since its go-live. All in all the system has delivered all benefits that were envisaged, and its user friendly interface is appreciated.

B.15 7th Annual Report Veterinary MUMS/limited market

[EMA/MB/29936/2017; EMA/868034/2016] The Management Board endorsed the 7th report on the operation of the policy on veterinary medicines for minor use minor species (MUMS)/limited market. The policy has been successful in facilitating access to market for MUMS through classification and incentives, of which financial incentives are restricted to food producing animals only since the update in 2013 and the revision in 2014. The report highlighted continued interest in the scheme by stakeholders, leading in 2016 to 25 requests for classification for a wide range of both minor species and major species limited use indications and 3 centralised authorisations. The full financial impact of

the revised policy on the Agency will be visible in the next few years once a growing number of classified products moves to the authorisation stage.

B.16 Composition of the Paediatric Committee – Joint membership

[EMA/MB/124057/2017; Ref. Ares(2017)446809 - 27/01/2017; EMA/139965/2017] The Management Board noted an exchange of letters between the Agency and the European Commission concerning the composition of the Paediatric Committee, in the specific case the five 'joint members' of PDCO and CHMP foreseen by Article 4(1) of the Paediatric Regulation (EC) No 1901/2006. As a consequence of difficulties in appointing these joint members, some of the seats have remained vacant, posing a challenge to the full composition of the PDCO. Following interpretative guidance provided by the European Commission, which was brought for information to the PDCO and for discussion and agreement to the CHMP, each Member State that is not represented through the members as appointed by the CHMP can nominate one member and one alternate until a joint member is appointed. Coordination between the two committees will be ensured through a joint pilot on collaboration between PDCO and CHMP and through the Scientific Coordination Board. The CHMP will notify the Management Board in writing that it is currently not in a position to nominate five joint members. The above approach will be subject to a regular review by the board.

List of written procedures finalised during the period from 17 November 2016 to 16 February 2017

- Consultation no 14 /2016 on the appointment Christophe Focke as CHMP alternate, proposed by the Belgium, ended on 16 December 2016. The mandate of the nominee commenced on 17 December 2016.
- Consultation no 15 /2016 on the appointment Eleftheria Nikolaidi as CHMP member, proposed by Greece, ended on 21 December 2016. The mandate of the nominee commenced on 1 January 2017.
- Consultation no 16 /2016 on the appointment Maria Dimokleia Ziotopoulou as CHMP alternate, proposed by the Greece, ended on 21 December 2016. The mandate of the nominee will commence on 1 January 2017.
- Consultation no 01 /2017 on the appointment Eva Maliková as CHMP alternate, proposed by the Slovakia, ended on 10 January 2017. The mandate of the nominee commenced on 11 January 2017.
- Consultation no 02 /2017 on the appointment Renate Makovska as CVMP alternate, proposed by the Latvia, ended on 11 January 2017. The mandate of the nominee commenced on 12 January 2017.
- Consultation no 03 /2017 on the appointment Brigitte Hauser as CVMP member, proposed by the Austria, ended on 17 January 2017. The mandate of the nominee commenced on 1 March 2017.
- Consultation no 04 /2017 on the appointment Petra Falb as CVMP alternate, proposed by the Austria, ended on 17 January 2017. The mandate of the nominee commenced on 1 March 2017.
- Consultation no 05 /2017 on the appointment Mary O'Grady as CVMP alternate, proposed by the Ireland, ended on 24 January 2017. The mandate of the nominee commenced on 25 January 2017.

- Consultation no 06 /2017 on the appointment Alexandre Moreau as CHMP member, proposed by the France, ended on 25 January 2017. The mandate of the nominee commenced on 26 January 2017.
- Consultation no 07 /2017 on the appointment Jacqueline Poot as CVMP alternate, proposed by the Netherlands, ended on 15 February 2017. The mandate of the nominee commenced on 16 February 2017.
- Written procedure for adoption of the 94th Management Board meeting minutes, ended on 3 February 2017. The minutes were adopted.

Documents for information

- [EMA/MB/98968/2017; EMA/98876/2017] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/122153/2017; EMA/9942/2017] 2016 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2016
- [EMA/MB/27995/2017] Outcome of written procedures finalised during the period from 17 November 2016 to 16 February 2017
- [EMA/MB/49397/2017; EMA/49388/2017] Third six-monthly report on ex ante and ex post evaluation of projects for the period 1 July to 31 December 2016
- [EMA/MB/124297/2017] Summary of transfers of appropriations in budget 2016
- [EMA/MB/27750/2017] Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2016

Tabled documents

- Draft agenda for the 95th meeting of the Management Board
- Written updates from the Commission 16 March 2017
- EMA annual report 2016

List of participants at the 95th meeting of the Management Board, held in London, 16 March 2017

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	*Apology received from Assena Stoimenova*
Czech Republic	Zdenek Blahuta *(member)*
Croatia	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)* [1] Mette Aaboe Hansen *(alternate)* Tina Engraff *(observer)*
Germany	Karl Broich *(member)* Birgit Naase*(alternate)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	Despina Makridaki *(member)*
Spain	Belén Crespo Sánchez- Eznarriaga *(member)* Laura Franqueza Garcia (alternate)
France	Dominique Martin *(member)* Jean-Pierre Orand (alternate) Miguel Bley *(observer)*
Italy	Gabriela Conti *(alternate)*
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Csilla Pozsgay *(member)*[1] Beatrix Horvath (alternate)
Malta	John-Joseph 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	Nicolae Fotin *(member)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Andreja Čufar *(member)*[1]
Finland	Esa Heinonen *(alternate)*
Sweden	Catarina Forsman *(member)* Sara Rosenmüller *(alternate)*

[1] Competing interest declared resulting in no participation in decision with respect to agenda points B.5, B.10 and B.12.b.

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

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