5 May 2014
EMA/MB/169928/2014 Adopted
Management Board

Minutes of the 83rd meeting of the Management Board

Held in London, 19–20 March 2014

Wednesday meeting, held on 19 March 2014

Sir Kent Woods, Chair of the Management Board of the European Medicines Agency (EMA), welcomed participants and opened the meeting by reminding all participants that the Wednesday afternoon session would be considered a formal part of the March meeting.

Session 1: Management Board data-gathering initiative

The Chair summarised the decision taken by the Board at the December 2013 meeting to develop a programme to gather the evidence needed by the European Commission in drafting the future legislative proposal on fees. A draft mandate and description of the data-gathering initiative have been circulated to the Board members for discussion and adoption at the current meeting. The draft mandate foresees the creation of a steering group, reporting to the Management Board plenary, working closely with contact persons in the Members States able to provide the required data.

The Director of the Paul-Ehrlich-Institut informed the Board on the outline of the initiative of the HMA Task Force on sustainability of the resources within the EMA/NCAs (national competent authorities) network, aiming at developing a vision of the European medicines regulatory network comprising the EMA, NCAs and the European Commission. He supported participation of members of this Task Force in the steering group of the Management Board data-gathering initiative. Civil-society representatives at the Board also proposed to be among the members, to provide a different perspective.

Members of the Board suggested various elements that should be considered within the data-gathering exercise. Clear definitions of scientific work and scientific-coordination work are needed; a vision of the relation between EMA and NCA tasks is necessary; the exercise should look at both remunerated and non-remunerated activities; support needed for committees to make good scientific decisions needs to be described; the methodology should be geared to capture time spent on activities, rather than their financial cost; membership of the steering group should reflect experience with centralised activities, but also the complexity of the system, as different NCAs need different levels of support; time recording alone cannot convey the totality of what is being done and which can be termed 'regulatory science'; systems to maintain collected data sets for the future should be explored.

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The representative of the European Commission underlined the need to achieve an end-result that is agreeable to all parties involved. The Commission will provide indications on which data it needs to prepare for the impact assessment of a future legislative proposal on fees. Veterinary as well as human data should be prepared in a single package, but if it makes the task easier, the initiative could be started around human data only, and then extended to veterinary data once the methodology is stable. As to the timing, a timeframe of approximately one year should be adequate, with a few months to be added for an independent assessment body to deliver a final validation to the European Commission as foreseen following the recent trialogues on fees for pharmacovigilance.

Session 2: Review & Reconnect update

The Head of the Procedure Management and Business Support Division and the Head of the Scientific Committee Support Department informed the Board about recent developments in the Review & Reconnect project concerning changes in the operating model for scientific and procedure management throughout the lifecycle of a medicine. Since 2003, product team leaders (PTLs) have supported expert teams drawing on a variety of regulatory, scientific and communication expertise. Over the years, their tasks have expanded as the task of providing product oversight became more and more complex. The PTL will now be split into two new roles: a procedure manager (PM) to oversee the management of specific procedures and act as a primary contact point, and an EMA product lead (EPL) to maintain oversight of a medicine through the different stages of its lifecycle. Roles will be distinguished without new jobs being created. This fact is mirrored also in the new organisation of the two central divisions handling evaluation procedures for human medicinal products. The Procedure Management Department has been set up to improve consistency in the handling of procedures via the role of the PM. The EPL will maintain product oversight and overall knowledge about a medicine in the context of therapeutic groups and of previous interactions with the Agency. Both regulatory and legal advice will be sought at an early stage and throughout the processes as appropriate. The processes have been redesigned and streamlined, and NCAs have been consulted on interfaces between the EMA and staff at the NCAs. These new processes should provide benefits for the NCAs as well, as it will allow them to focus their contribution on high-value work. As knowledge is transferred through the lifecycle, the capacity of scientific committees to deliver high-quality opinions is increased. The transition to the new operating model will be implemented in two waves, the first taking place in April 2014 and the second in August 2014, at the time of the move to the new building.

The Board, in particular Board members with direct personal experience in the scientific committees, supported this approach. The role of the PTL was always appreciated as it channels contacts to the applicants without implicating the experts who are involved in the decision-making. The PTL further provides assessment teams with all other relevant information on a product available at the Agency, which can in some cases date back several years. Through this new structure, the PTL function continues to exist through the EPL and PM, and can further improve efficiency of the process and quality of the scientific opinions. Satisfaction was also expressed on the upcoming provision to the NCAs of dashboards on the EMA procedure-tracking system. Access to further systems is envisaged. The Executive Director concluded by inviting NCAs to provide feedback from their experts should they have any specific concerns on the new handling of evaluation procedures.

New building and new structure – what will be different

The Head of the Administration Division reminded the Board of the discussions that led in March 2011 to the decision of the Management Board to relocate the Agency to 30 Churchill Place. Five factors were decisive: a positive cost/benefit profile of the new building; an option on expansion over four additional floors for a few years to come; easy access to a wide range of transportation, including the

future availability of Crossrail to Heathrow; security of the environs of the Agency for the over 7,000 delegates who visit the Agency annually and who often leave meetings late in the evenings; and high capacity of hotels near the Agency. A particularly favourable offer for the 10th floor has been taken up by the EMA as additional tasks were recently allocated to the Agency, and further space was required. No further expansion is expected for the time being.

A presentation providing information on the current status of the new building and of the new facilities was provided by the Head of the Infrastructure Services Department, as was information on the stepwise move into the new building, which will start at the end of June and be completed by the end of July.

Thursday meeting, held on 20 March 2014

The Chair of the Management Board opened the meeting by welcoming new members Ioannis Kkolos (alternate), representing Cyprus, Katerina Fameli (member), representing Greece, Constant van Belkum (alternate), representing The Netherlands, and Marius Tanasa (alternate), representing Romania.

The Board was reminded that the term of office of the current Chair of the Management Board will expire in early June. Elections of a new chair will take place at the beginning of the June meeting. The Chair informed the Board that since he is eligible for re-election, he would be willing to stand for a second mandate. The Executive Director will write to members of the Board inviting nominations for the appointment of a chair.

The Chair further asked for volunteer topic coordinators for the analysis and assessment of the Executive Director's annual activity report 2013, which will be discussed at the June meeting.

1. Draft agenda for 20 March 2014 meeting

[EMA/MB/2712/2014] The agenda was adopted.

Resuming the topic of the Management Board data-gathering initiative from Session 1 of the previous day, the Chair expressed concern that the detailed discussion of the proposed amendments to the mandate would be too time consuming. He proposed to the Board that it adopt instead the composition of the steering group of the initiative to assemble evidence on workload and resources to inform the Commission's proposal for the revision of the fees regulations. The Management Board will work through a steering group chaired by the Management Board chair, with initial membership composed of one representative of the European Commission, four representatives of Member States (Germany, Ireland, Estonia and the United Kingdom), one civil-society representative and two EMA representatives. It will be the steering committee's first task to draft a mandate to be submitted to the Management Board. Veterinary fees will be included at a second stage, and will be part of the final output. The Management Board may add or substitute members if needed as the work progresses, and will review progress at each plenary meeting, with a final report to be completed in twelve months' time.

The Management Board agreed to this approach.

2. Declarations of conflicts of interests

The Chair informed members of the Management Board that he had reviewed their declared interests, together with the secretariat, in accordance with the Board's policy on conflicts of interests. No concern about conflicts relating to today's agenda was identified.

The Chair invited members to further declare any specific interests that could not be drawn from their declarations of interests that could be considered prejudicial to their independence with respect to the items on the agenda. No conflict of interests was declared.

3. Minutes from the 82nd meeting, held 11–12 December 2013

[EMA/MB/723234/2013] The Management Board noted the final minutes, adopted by written procedure on 12 February 2014.

A. Points for automatic adoption / endorsement

A.1 Revised Management Board rules of procedure

[EMA/MB/91953/2014; EMA/MB/115339/2004/en/Rev.5 Draft] The Management Board adopted the revised Management Board Rules of Procedure, including the publication of the agenda ahead of the meeting of the Management Board and clarifying the concept of 'oldest member'.

A.2 Revision of PRAC Rules of Procedure following the implementation of pharmacovigilance legislation in the European Economic Area

[EMA/MB/130072/2014; EMA/PRAC/567515/2012 Rev.1] The Management Board adopted the revised Rules of Procedure of the Pharmacovigilance Risk Assessment Committee (PRAC), bringing them in line with those of other EMA scientific committees to reflect the involvement of Members nominated by the EEA-EFTA countries in the PRAC following incorporation of Regulation (EU) 1235/2010 and Directive 2010/84/EU into the Agreement on the European Economic Area.

A.3 Implementing rules to the Financial Regulation applicable to the budget of the European Medicines Agency

[EMA/MB/100697/2014; EMA/61802/2014; EMA/MB/99010/2014] The Management Board adopted the Implementing rules to the Financial Regulation applicable to the budget of the European Medicines Agency. On 15 January 2014, the Management Board had adopted a new Financial Regulation for the Agency. The implementing rules are based on model implementing rules developed by an inter-agency and Commission working group. The European Commission has provided prior consent. The implementing rules shall apply as of 1 January 2014.

B. Points for discussion

B.1 Highlights from the Executive Director

Staffing for the 2015 work programme

The Executive Director sent a message to the Board about a recent development concerning reduction of staffing levels in decentralised agencies of the EU. This has repercussions on the EMA establishment plan and preliminary draft budget (PDB) for 2015, which will have to be discussed under Point B.6.

Outcome of the discharge procedure 2012

The European Parliament's Committee on Budgetary Control adopted the draft report for the discharge procedure for the financial year 2012 on 17 March 2014, proposing the granting of the discharge. The final adoption in plenary in Strasbourg is planned for April 2014.

Scientific Coordination Board

A meeting with the Scientific Coordination Board took place. Members took a tour of the new premises in Churchill Place, where meeting-room facilities and delegates' break-out areas were appreciated by the Chairs. The Committee for Medicinal Products for Veterinary Use (CVMP) will hold the kick-off meeting in the new building in July. The Chairs were consulted on the development of a 'one-stop shop' concept to foster early dialogue on product development. There was broad support, with requests for extension into later phases of development to allow knowledge transfer to be maintained. The Chairs also supported an initiative on professional development and continued education of experts/assessors across the network. The veterinary colleagues requested an extension of the 'multinational assessment team' pilot to co-rapporteurs at the CVMP, and this was agreed for initial marketing authorisations, at both the CVMP and the Committee for Advanced Therapies (CAT). Furthermore, the possibility to compensate NCAs for part-time chairs of the Committee for Medicinal Products for Human Use (CHMP), the CVMP and the PRAC could be explored.

Availability of detailed pipeline of submissions for centrally authorised products

As part of the business-pipeline-monitoring service, the Agency is proposing to accelerate the provision of information on upcoming centralised marketing authorisations, with an end-of-April report target to CxMP members and the Heads of Medicines Agencies (HMA), as well as increased transparency of content. It is hoped that this will facilitate forward planning of assessment resources across the network.

Access to SIAMED data

In the past, access to the procedure-tracking systems of the Agency could not be provided to NCAs, due to technical issues. A business-intelligence tool can now offer user-friendly access to information in the form of real-time or historic 'dashboards' (procedural timelines, assigned workload for NCAs, status of procedures, etc.). In the next few weeks, a pilot with interested NCAs will be organised, with a view to offering access to all NCAs very soon.

Payments to rapporteurs concerning applications with fee reductions

The scale of fees is based on a percentage share of the fee charged to the applicant from the pharmaceutical industry. However, for applications with fee reductions, actual euro amounts paid to NCAs differ, depending on the legal grounds for the reduction. Subject to the availability of funds, and in all cases where the workload for rapporteurs and co-rapporteurs is not reduced, the Agency would like to harmonise payments to NCAs and keep them financially neutral when a fee reduction is granted to the applicants. Reductions will be charged only to the EMA's part. For 2014, subject to all conditions being fulfilled, this would apply to the following cases:

- Fee Regulation 297/95 Article 9 (1st paragraph) (human and veterinary) - Reductions granted on case-by-case requests for exceptional circumstances and imperative public-health reasons.
- Minor uses, minor species (MUMS) (veterinary).
- Pandemic (human) scientific advice and post-authorisation (except annual fee).

Following the review of the budget, and if the budgetary trends are positive, a separate document on extending these payments will be presented to the Board in June.

Training

The current outlook on the 2015 budget might be further adjusted to allow further funds for training activities. The Agency has kicked off an initiative to set up and run professional development and continued education, capitalising on previous work done in the OTSG. The first step is the prospective collection of planned courses at the Agency and within the EU network, creating a two-year overall training calendar. This calendar will be made available through the use of an intuitive interface accessing a repository of available trainings. Christa Wirthumer-Hoche and Zaide Frias were appointed as co-chairs of the joint HMA/EMA OTSG initiative at the Athens HMA meeting.

EU telematics

As can be seen from the Agency's budget, around EUR 14 million of the IT budget relates to development and maintenance of telematics projects. The Agency aims to ensure that the development budget for telematics projects is agreed jointly with NCAs.

Adaptive licensing

When the topic of adaptive licensing was discussed at the Management Board in the past, the feedback received was very positive. Since then, there have been extensive discussions with the Commission, EMA committees, patient groups and informally with EU health-technology-assessment (HTA) representatives. It was concluded that an appropriate next step to explore the potential benefits and challenges of adaptive licensing pathways would be to invite industry to present 'live assets' for informal discussion; this should happen in a non-committal safe-harbour environment. An invitation for industry to engage in these discussions has now been published on the Agency's website.

International initiatives

The recent visit to Japan has highlighted how an integrated and coherent vision facilitates leadership in medical innovation. A strong political will to advance Japan as a global lead in drug development has led to a staff increase of 30% from 2009 to 2013, and to strengthen Japan's role as first authorising authority, particularly in the field of cell therapy. There is a risk that diverse research strategies and approaches to innovation, as well as national versus European fragmentation, could leave Europe further behind on innovation and access to medicines.

EMA/EC-FDA bilateral

The periodic meeting will take place at the EMA from 31 March to 1 April. Among the topics to be discussed is a request from the U.S. Food and Drug Administration (FDA) for increased inspection capacity. A strategic reflection is needed on how best to support bilateral and multilateral activities (ICH, IPRF, ICMRA, IGDRP).

B.2 Report from the European Commission

The representative of the European Commission provided an update on legislative and policy developments, including the following:

- Preparation of Delegated Act on Post-authorisation efficacy studies (planned publication Q2 2014).
- Progress with Joint Action SCOPE – Strengthening Collaboration for Operating Pharmacovigilance in Europe.

- Procedural aspects of fees for pharmacovigilance (planned applicability Q3 2014 for procedure-based fees and 1 July 2015 for annual fee).
- Report on the functioning of the Advanced Therapies Regulation expected to be adopted and published in March 2014.
- Implementing measures for the falsified medicines legislation (delegated act on the detailed rule for a unique identifier for medicinal products to be adopted end of 2014; delegated act on principles and guidelines of GMP for active substances in the EU planned for Q2 2014; establishment of a common EU logo for online pharmacies adoption before summer; guidelines on GDP for API and risk assessment for GMP excipients ongoing.
- Status of implementation of importation of active substances.
- Progress of Clinical Trials Regulation to be adopted in April and enter into force two years after publication.
- Draft legislative proposal for revision of veterinary medicines legislation planned for adoption during 2014.
- Initiatives on antimicrobial resistance in the human and veterinary sector.
- Status of legislation on revision of medical devices (MD) and in vitro diagnostic medical devices (IVD), first reading to be completed in April.
- Creation of a Health Technology Assessment Network started with a meeting in October 2013. All Member States and the EMA are involved. Cooperation between the EMA and EUnetHTA is ongoing at the scientific level.
- Progress with the e-Health network with first guidelines on sharing of patient summary data adopted November 2103 and Guidelines on ePrescription in preparation. Two Commission Decisions on European References Networks (ERN) have been adopted.
- Mutual recognition of prescriptions – transposition measures are currently under assessment.

The Board recommended timely implementation of practical arrangements for the administrative processing of the pharmacovigilance fees that are expected to become applicable as of August or September 2014 (July 2015 for the annual fee). Some members addressed the issue of advanced-therapy products under hospital exemption. It is important to strike the right balance between providing experimental innovative treatment to patients with severe diseases where processing in industrial facilities is not obtainable, and preventing commercial interests to avoid regulatory scrutiny. The representative of the European Commission pointed out that two types of legislation exist: ATMP, and tissues and cells. It might be interesting to further examine the interactions between these areas, but the way forward will be a matter for decision under the next Commission. Concerning safety features, the role of NCAs in supervision of the repository was considered unclear. The European Commission will provide further information. Finally, the Board was informed that the Italian Presidency will try to organise a common meeting between HMA and HTA bodies in Rome.

B.3 Annual report 2013

[EMA/MB/145678/2014; EMA/88206/2014] The Management Board discussed and adopted the Annual report 2013. As in last year's report, three essays, provided jointly by an expert from an NCA and a member of the EMA staff, highlight thought-leadership on current topics. The content of the report focuses on high-impact projects and initiatives, such as the implementation of new legislation, the reorganisation of the Agency, the instigation of a global debate on access to clinical-trial data,

collaboration with HTA bodies, reflection on the right balance in handling conflicts of interests, and attention to antimicrobial resistance and medication errors. Overall, the level of activities at the Agency was stable in 2013, despite a decrease by 17% of initial marketing authorisations, with 81 new recommendations and 45 safety reviews finalised for human products, and 12 positive opinions issued for veterinary medicines. Scientific advice and protocol assistance increased by 12%. Pharmacovigilance-related activities were high, reaching over 1 million adverse drug reactions reported to EudraVigilance (an increase of 26%), 2,449 signals reviewed (increase of 11%), 436 PRAC recommendations on periodic safety-update reports (PSURs), and 487 risk-management plans assessed.

B.4 Amending budget 01-2014

[EMA/MB/45191/2014] The Board adopted the amending budget. This was necessary due to a reduction in revenues, as the fee revenue for 2014 was estimated taking account of the full impact of the changes in the variations guideline as of 4 August 2013, as well as a 2.5% inflationary increase in fee levels. Following clarifications and interpretation of the variations guideline by the European Commission, these had to be revised with a decrease of EUR 5.8 million. A further decrease of EUR 2.2 million is due to the fact that inflation in the 2014 budget forecast was estimated at 2.5%, but has now been assessed by Eurostat to amount to only 1.5%. On the expenditure side, allocation to NCAs for evaluation work will consequently be reduced by an estimated amount of EUR 3.4 million. Furthermore, the correction coefficient for salaries adopted by the European Commission in January 2014 is set at 39.2, instead of at 48 as expected by the Agency. An adjustment of minus EUR 4.6 million was proposed as a consequence, with a total revenue and expenditure reduction in the 2014 budget of EUR 8 million.

B.5 Preliminary draft work programme 2015

[EMA/MB/121028/2014; EMA/80156/2014] The Management Board discussed and endorsed the preliminary draft work programme, providing comments that were noted and will be proposed in the next version of the document. This will be due for adoption in December 2014, in line with the normal cycle. The document will be discussed with the topic coordinators ahead of the December meeting.

The draft work programme 2015 is influenced by the global business environment trends. The high cost of R&D raises expectations by industry for predictability of regulatory decisions, and support to SMEs in a complex regulatory environment, if Europe intends to remain attractive for innovation. Globalisation is moving clinical trials and manufacturing to other world regions, straining inspection resources. The Agency intends to respond to these challenges by supporting early stages of medicines development through a 'one-stop shop' approach, facilitating provision of scientific advice, which has proven to have a positive effect on the outcome of marketing-authorisation applications and the availability of medicines to patients. The Agency intends to continue to focus on international collaboration among regulators, particularly in the field of inspections, and on openness and patient engagement, with its efforts concerning access to clinical-trial data. The Agency must further continue to manage increasing tasks stemming from new legislation, effectively managing complexity and constant growth in workload. Focus remains on delivering high-quality assessment activities and contributing towards building a strong network. This is dependent on NCAs being strong, healthy and adequately funded. The Agency intends to further develop its collaboration with the NCAs by developing IT systems that deliver benefit to the network through joint allocation of telematics funds, support to training initiatives, increased exchange of experts, and support to the multinational-assessment-teams initiative, facilitating participation of smaller NCAs in the centralised activities. Overall, the outlook for number of applications in 2015 is stable, with some increase expected for scientific-advice procedures and orphan-medicine designations. However, the complexity, including

interdependencies and interfaces between procedures, is rising. In post-authorisation, variations are likely to continue to increase moderately, while PSURs should increase significantly, due to the new pharmacovigilance provisions concerning nationally authorised products. Veterinary activities are expected to remain stable, with some increase in scientific advice and variations. Steady growth is forecast for inspections, particularly for good-manufacturing-practice (GMP) inspections. Workload dependent on transparency and access-to-document requests, as well as demands on legal services, are also expected to increase. Finally, in January 2015, there will be the 20th anniversary of the inauguration of the EMA.

Grzegorz Cessak, as topic coordinator, provided the Board with an analysis of the priorities and key objectives in the draft work programme. He highlighted the focus on efficient use of resources, which sees cooperation with international and European partners as the basis for efficiency, and recommended the endorsement of the document to the Board.

In the discussion that followed, the representative of the patients' organisations suggested putting greater emphasis in the work programme on initiatives to provide faster access to medicines for patients, e.g. through adaptive licensing, as well as mentioning work on shortages and the needs of special groups, such as the elderly. Concerning the need for strengthening scientific advice, it was mentioned that this is also carried out at the NCAs, and engagement by all is needed to achieve progress. Furthermore, the inclusion of simplification initiatives on some processes and interactions would be desirable. While the ambitions, priorities and objectives of the work programmes were fully supported by all, some members pointed out the connection between the Agency's work programme and the work programmes of individual NCAs. These are affected by the objectives set out by the Agency, and the work programme should reflect this fact in an even more explicit reference to the contribution of the network, providing adequate visibility on its efforts.

The Agency noted all comments and will provide an updated version of the document at the next occasion at which it will be discussed by the Board.

B.6.a Preliminary draft budget and establishment plan 2015

[EMA/MB/120006/2014; EMA/MB/651/2014] The Management Board discussed and endorsed the preliminary draft budget (PDB) and establishment plan 2015, with the understanding that the current version will be substituted by an amended document, reducing the overall number of temporary posts to remain at the 2014 level of 599, while increasing the number of contract agents by 20, as well as modifying a position grading in the establishment plan. This was necessary due to a very recent communication by the European Commission. An amended version of the document will be circulated to the Board after the meeting.

Compared to the budget 2014, the PDB 2015 increases by 2.2%. It presents a reduction of 15.8% in the EU contribution and of 18.7% in assigned revenue, while revenue from fees increases by approximately EUR 16 million, or 7.3%. IT expenditure has been reduced as the IT requirements for the new premises are planned to be completed in 2014, but includes provisions for systems related to the new clinical-trials legislation. The share of IT expenditure for network rather than corporate systems has been steadily increasing, and amounts in 2015 to 54% of total expenditure, of which 62.5% for development within telematics projects. Similarly, allocations for network-related activities (scientific evaluation, meetings, workshops and training, national experts as well as telematics) total over EUR 140 million.

The topic coordinators Klaus Cichutek, Grzegorz Cessak and Kristin Raudsepp presented their analysis of the PDB 2015 and proposed its endorsement. They considered that while the overall budget increases by 2% compared to 2014, if the relocation effect is excluded, the so-called 'workable budget'

is reduced by 4% compared to 2014. The main increases in revenue stem from the new fee income due the pharmacovigilance fee regulation and from inflationary adjustments. Of these, the main expenditure is payments to NCAs. The increase in number of national experts was welcomed. An increase in the EMA staff allocation can be supported subject to an increase in the workload. Activity-based budgeting should continue, and provide more transparency to the Management Board, as well as contribute to an integrated view of the whole network. The German Board member presented his Member State's objection to the endorsement of the PDB on instruction by his Ministry of Finance.

B.6.b Multi-annual staff policy plan 2015-2017

[EMA/MB/120236/2014; EMA/120424/2014] The multi-annual staff policy plan is an overview document that is provided to the European Commission for planning purposes. The plan will be updated according to the endorsed preliminary draft budget and establishment plan 2015.

B.7 Revised implementing rules to the Fee Regulation as of 1 April 2014

[EMA/MB/785541/2013; EMA/MB/153694/2014; EMA/145687/2014] The Management Board adopted the revised implementing rules to the Fee Regulation as of 1 April 2014. In accordance with legal provisions on adjustment to inflation, all fees are increased by an inflation rate of 1.5%, rounded up to the nearest EUR 100, or EUR 10 for administrative changes. Furthermore, amendments to Annex III (new fee for notification of bulk changes in notifications of parallel distribution) and Annex VII (exemptions from payment of fees for applications for MUMS, certain activities by SMEs, bluetongue vaccines) are included, along with some clarifications.

B.8.a Update on the implementation of pharmacovigilance legislation proposed principles for improving the RMP process

The Board noted an update on implementation of the pharmacovigilance legislation. The issue of a possible revision of the risk-management plan (RMP) process after the experience of 12 months in operation has been discussed on various occasions. Several options have been developed by the CHMP and the PRAC. Since the preferred options were not aligned, the Agency's secretariat has been looking for a solution and discussed options with the (vice-)chairs of both Committees. A solution is now being considered that will take into consideration the workload in pharmacovigilance departments at the NCAs, and for all parties involved. In April/May, a new proposal will be presented to the PRAC and CHMP, and then discussed at the May HMA meeting and June Management Board meeting.

B.8.b PSUR single-assessment procedure for NAPs

[EMA/MB/141196/2014; EMA/146102/2014] The Management Board endorsed a proposal on handling of single assessment of PSURs (PSUSAs) for nationally authorised products (NAPs). The Agency has now proposed to accept submissions as originally foreseen. Cooperation by the NCAs with transitional support was requested until certain systems are fully functional (1Q 2015). Pilots on PSUSAs with cantrally authorised products (CAPs) and NAPs will start immediately.

B.9 Report by the CHMP Chair

Tomas Salmonson, chair of the Committee for Medicinal Products for Human Use (CHMP), presented his views on the current situation of the CHMP to the Board. In general, the Committee works well and can count on many committed members, who are willing to take up even unpaid work. Since the creation of the PRAC, work inthe CHMP has decreased, and even more attention can be given to quality of opinions. The Scientific Advice Working Party (SAWP) is particularly active, and processes

approximately 200 procedures in a year. Thought should also be given to developing post-approval scientific advice and expanding the range of competence. The SAWP's structure seems to contribute to its success, as the workplan is agreed first, and afterwards the group is populated with experts. Interactions with other committees are good, also because of some overlaps in composition. Some processes could be improved, such as the RMP process currently under discussion at the PRAC and CHMP. The new organisation at the Agency was highly needed, as it was developed 20 years ago, when the organisation was new. The Chair of the CHMP supported the separation of procedural and scientific support, which should benefit committee functionality. Interaction with other organisations is an area where support from the EMA is very useful. The Agency has worked a lot on transparency and has an intensive dialogue with HTA bodies, helping to explain positions in ways that can be used in relative-effectiveness discussions. New approaches to post-authorisation efficacy studies (PAES) and adaptive licensing mean that the Committee must work with other stakeholders, in particular with patients, who do not have voting rights, but can provide direct advice on products. The current model is sustainable, thanks also to the Agency's administrative support to the multinational-teams initiative. This allows for a better allocation of scientific resources, which benefits not only small NCAs, as even larger NCAs might sometimes need additional experts to complete a team. This is not only perceived as an optimisation of resources, but also as a way of working according to a European spirit. There is, however, a general sense that some NCAs are under pressure, and financial contribution from the EMA for currently unremunerated work would be welcome. In conclusion, the Committee is proud of its work and feels very much part of the rather complex EU regulatory system.

Members of the Board were appreciative of the work done in the CHMP. A representative of the European Parliament thanked the Chair for the guidelines on Alzheimer's disease, and suggested that a guideline on antidepressant medicines for elderly patients is also needed, which the Chair noted. The Chair of the CHMP further assured members that, with support from the EMA, cooperation with the FDA is good, as divergent decisions can be explained. There may, however, be some problems for the external world in understanding the interaction and different roles of the PRAC and the CHMP. Concerning quality of opinions, there seems to have been significant improvement; however, early access to regulatory/legal advice would improve interaction with the European Commission. The Executive Director welcomed support from the Chair of the CHMP on separation of regulatory and scientific activities, and assured him that implementation of the reorganisation is proceeding on target. Further support to the CHMP members will be available through detailed early pipelines and through access to procedural tracking-system data, allowing for better planning and managing of procedures at the NCA level. Concerning financial support, the Agency is looking into the matter and is working on identifying budgets saved through efficiency gains, along with finding the appropriate provisions.

B.10 Draft revised EMA policy on the handling of declarations of interests of scientific committees' members and experts

EMA/MB/144336/2014; EMA/145339/2014; EMA/513078/2010] The Management Board endorsed the revised EMA policy on the handling of declarations of interests of scientific committees' members and experts. The revised policy takes into account the outcome of the 6 September 2013 EMA public workshop 'Best expertise vs conflicts of interests: Striking the right balance'. The nature of declared interests has been organised in three categories, determining different consequences in the extension of conflict over time and in the involvement in EMA activities. Key definitions and concepts were revised. Among these, a much debated distinction on the recipients of grants or funds from organisations and institutions was achieved. A first impact assessment has been conducted on four scientific committees and two scientific advisory groups, leading to different restrictions than the ones previously applied, but not changing on balance the ability of the groups to perform. The main changes

to the current policy will be explained in the revised policy and a guidance document (currently being drafted), which will be published shortly.

The Board supported the new revised policy, which was perceived to bring a more balanced approach, particularly with regard to experts in academia. The representative of the European Commission stressed the importance for clear communication of the new policy and suggested aligning the wording of the document with the memorandum of understanding with the NCAs regarding the responsibility of NCAs for national experts. Further, the representative of the Commission suggested providing information in EMA's annual report on mitigating measures applied where situations of conflicts of interests have arisen. The Agency explained that, while NCAs remain responsible for staff at a national level, it will now be required from the (co-)rapporteur to declare that all experts in the team comply with the minimum requirements of the EMA policy.

B.11 Draft EMA policy on the publication of and access to clinical-trial data

The Board noted the progress made on the draft policy on proactive publication of clinical-trial data. After endorsement by the Management Board at its December 2013 meeting of a set of key principles, two workstreams have worked to draw up a managed publication process for clinical summary reports, a set of limited exceptions to the concept of commercially confidential information in CSRs and a consultation process with the marketing-authorisation holder in case of disagreement. A targeted consultation with key stakeholders will next take place in May on the further developed principles.

The final policy will be presented to the Management Board for endorsement at its June 2014 meeting.

A representative of the European Commission stated that they consider this topic to be complex and multi-faceted; therefore, some other parameters should be evaluated before proceeding to any final decisions, such as interaction with the TRIPS Agreement and the European patent system. In addition, it was proposed to include among the parties to be consulted SMEs specialising in innovative projects and other agencies, notably the European Chemicals Agency, to ensure that there will be no precedents set that could affect them.

B.12 Fourth annual report on the veterinary MUMS/limited market scheme

[EMA/MB/102900/2014; EMA/14945/2014] The Management Board endorsed the fourth annual report on the operation of the veterinary MUMS/limited-market scheme. The report provides information on the operation of the scheme, which represents joint activity between the Agency and the regulatory network intended to increase the availability of veterinary medicines. Under the policy, there has been an increase in demand for classification of products as MUMS/limited market by the CVMP, which allows applicants to access a range of incentives for authorisation of MUMS products. To ensure that public funds are directed to products of most benefit to animal and human health, since September 2013, financial incentives have been restricted to food-producing animals only, and the effect of this measure is being monitored. A review of the policy is ongoing and will be presented to the Management Board at a later meeting.

4. A.O.B.

Documents for information

- [EMA/MB/130082/2014] Update on Telematics from the EU Telematics Management Board (EU TMB).
- [EMA/MB/9624/2014] Outcome of written procedures finalised during the period from 22 November 2013 to 21 February 2014.
- [EMA/MB/85740/2014] Summary of transfer of appropriations in the budget 2013.
- [EMA/MB/143919/2014; EMA/145085/2014] EudraVigilance report 2013 for human medicinal products.
- [EMA/MB/121745/2014] Overview of Staff Regulation implementing rules signed by the MB Chair during the period from 16 November 2012 to 26 February 2014.

Written procedures from 22 November 2013 to 21 February 2014

- Consultation no. 21/2013 on the appointment of Helen Vella as CHMP alternate, proposed by Malta, ended on 4 December 2013. The mandate of the nominee commenced on 5 December 2013.
- Consultation no. 01/2014 on the appointment of Dimitrios Kouvelas as CHMP member, proposed by Greece, ended on 14 February 2014. The mandate of the nominee commenced on 15 February 2014.
- Written procedure for adoption of the new EMA Financial Regulation ended on 15 January 2014. The new EMA Financial Regulation was adopted.
- Written procedure for adoption of 82nd Management Board meeting minutes ended on 7 February 2014. The minutes were adopted.

List of participants at the 83rd meeting of the Management Board, held in London, 19-20 March 2014

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	*Apology received*	
Czech Republic	Doubravka Kostalova	
Croatia		Viola Macolić Šarinić
Denmark		Nina Moss
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	Kristen Raudsepp	
Ireland		Rita Purcell
Greece	Katerina Fameli	
Spain	Belén Crespo Sánchez-Eznarriaga	Laura Franqueza García
France	Dominique Maraninchi	Miguel Bley Jean-Claude Ghislain
Italy	Luca Pani	Pietro Erba
Cyprus		Ioannis Kkolos
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	*Apology received*	
Hungary	Beatrix Horváth	
Malta		Gavril Flores
Netherlands		Constant van Belkum Birte van Elk
Austria	Christa Wirthumer-Hoche	
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Hélder Mota-Filipe	Maria Morais
Romania		Marius Tanasa
Slovakia	Jan Mazág	
Slovenia	Matej Breznik	Katarina Štraus
Finland		Pekka Kurki
Sweden		Bengt Wittgren
United Kingdom		Ian Hudson Jonathan Mogford
European Parliament	Giuseppe Nisticò Björn Lemmer	
European Commission	Gwenole Cozigou (DG ENTR)	Andrzej Rys (DG SANCO) Sabine Juelicher (partly) Olga Solomon (partly) Miroslav Griva Chloe Spathari
Representatives of patients' organisations	W.H.J.M. Wim Wientjens Nikos Dedes	

	Members	Alternates (and other participants)
Representative of doctors' organisations	Wolf-Dieter Ludwig	
Representative of veterinarians' organisations	Christophe Hugnet	
Observers	Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) *Apology received* (Norway)	

European Medicines Agency	Guido Rasi Andreas Pott Noël Wathion Hans-Georg Eichler Agnès Saint Raymond Stefano Marino David Mackay Luc Verhelst Zaïde Frias Enrica Alteri Alexis Nolte Fergus Sweeney Nerimantas Steikūnas Michael Lenihan Tony Humphreys Sylvie Benefice Isabelle Moulon Martin Harvey Allchurch Monika Benstetter Dina Tsiambaou Silvia Fabiani Sophia Albuquerque	