25 March 2013
EMA/MB/195991/2013 Adopted
Management Board

Minutes of the 79th meeting of the Management Board

Held in London on 20-21 March 2013

Wednesday meeting, held on 20 March 2013

At the annual Management Board two day meeting in March the Wednesday session is traditionally dedicated to the discussion of scientific or strategic topics. The Chair of the European Medicines Agency's Management Board, Sir Kent Woods, welcomed all participants, particularly the chairs of all Scientific Committees who were invited along with senior staff at the European Medicines Agency (EMA) for the Wednesday session. The four newly nominated representatives from civil society also attended for the first time. The meeting addressed:

- A discussion on regulatory science
- Sustainability of the system

The Executive Director opened the meeting by reminding all of the societal and scientific changes that are re-shaping the regulatory landscape.

Session 1: A discussion on regulatory science

The Senior Medical Officer introduced the reflection by reminding the Board of the difference between capacity, the total amount that can be produced, and capability, the ability to do something. Regulatory science should be prepared to face scientific and technological progress that may require specific capability, such as pharmacogenomics, growing need for raw data analysis, analysis of risk-acceptance data by patients, adaptive licencing-lifespan approach, imaging biomarkers, nanotechnologies and all advanced therapies. When benchmarking the assumed regulatory capacity of the European medicines regulatory network towards other regions of the developed world, this seems adequate. It is harder to assess though if the required capability to support innovation in Europe is accessible to the necessary degree. Capability needs may be addressed by hiring staff, consulting with existing internal scientific bodies, collaborating with external centres for excellence, outsourcing or specialisation, which has been particularly advocated in the past. Each of these options entails advantages and risks. In conclusion the issue of the scientific sustainability of the whole system rests on the right balance between process and scientific content as well as between generalists and specialists, and on how to make sure that expertise and talent are always at the disposal of regulators.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Many members of the board welcomed these points for reflection and discussed the most salient topics among which whether the system has the right specialist and generalist balance. If seen from a regulatory perspective, the centralised procedure processes complex innovative products with the contribution of specialists, while the decentralised procedures handle large numbers of mostly generic applications, requiring a more generalist approach. Some worried however that the current system requires too much administrative work, which is particularly taxing on small national competent authorities, who have to dedicate specialised staff to also do generalists' tasks. Progress in simplification of the procedures might free up substantial resources in an agency. It was also believed by many that the necessary capability is present within the national authorities, although perhaps not adequately mapped and known to the system in general. Some members invited the board to consider the importance of other specialisations besides statistical capability, such as a greater emphasis on the biological area, and stressed the importance to nominate experts to the committees who fulfil identified scientific needs in order to fill gaps and avoid overlaps. Relevant statistical capability should be applied with a risk based approach, to be developed by the Committees themselves. Outsourcing was discussed, also in connection to 'crowdsourcing', however many Member States have no legal provisions for it. Specialisation needs to be developed, but concentration should not be encouraged, to avoid the risk of unchallenged 'crowd-thinking'. Finally, adaptive licensing, allowing patients earlier access to medicines and greater focus on new study design, is framed by existing legislation and will need to be further discussed.

Session 2: Sustainability of the system

At the meeting of 13 December 2012 the board had entrusted a subgroup with preparing a framework for discussion at the March meeting on how to ensure that operations within the whole system (European Medicines Agency, National Competent Authorities (NCAs) and European Commission) remain sustainable in the years to come, in the light of ever-increasing pressure on resources. Klaus Cichutek, Xavier de Cuyper, Jonathan Mogford, Marcus Müllner, Paola Testori Coggi and Guido Rasi participated in the subgroup which was led by Aginus Kalis.

The framework for the discussion was set with a few figures presented by the Executive Director on workload estimation for the CHMP and PRAC, on the distribution of rapporteurships, attendance to meetings by Member States and scenarios of different complexity for referral procedures, followed by a presentation by Jonathan Mogford. This highlighted the interdependency between all elements of the network, often mirrored by financial flows. Financial and workload pressures are mounting, while some work remains not remunerated. In this scenario consideration should be given to the funding of the network, as well as achieving efficiency gains both at NCA and EMA level, by ensuring that work is done at the most appropriate level and is well supported by integrated IT systems. Steps in this direction have been undertaken with the internal EMA re-organisation exercise and the Heads of Medicines Agencies (HMA) and EMA strategy development for IT with a new, shared governance. A proposal was presented to establish a Working Group to develop a strategy for an integrated, resilient, EU medicines agencies network based on a vision encompassing 2020. Key elements would be efficiency of the parts of the network, funding, resourcing and prioritisation and an IT strategy as enabler of the network. Agreed principles would be at the basis of the work.

The European Commission representative reminded the board that the European regulatory model is a mixed system where, differently from other regulatory areas, centralised authorisations coexist with national authorisations. The mixed regulatory system has the consequence that responsibility and communication is divided between EU bodies and NCAs depending on authorisation procedure of the products. This view was not shared by some Member States who see themselves as first responders vis-à-vis citizens on their own territory. Several members agreed that it is urgent to discuss how to

achieve the best balance in allocation of workload and resources in the network, if necessary by setting priorities and looking at activities that can be simplified or do not add value. The internal re-organisation effort at EMA can provide efficiency gains for the agency alone, while improvements in the integration and performance of IT systems can be benefited from also by Member States. Committees should be included in the reflection, taking into account their specificities. A better understanding is needed of the reasons that prevent some NCA from contributing more fully to centralised activities. There was in general interest in pursuing a further reflection which should be widened to include also HMA, along the same lines agreed for the ICT governance. The subgroup will therefore reconvene to present a proposal including terms of reference and membership structure to the HMA at their April meeting and subsequently to the Management Board at the meeting in June.

Thursday meeting, held on 21 March 2013

The Chair of the European Medicines Agency's Management Board, Sir Kent Woods, opened the meeting by welcoming the new members Gwenole Cozigou representing the European Commission, Doubravka Košťálová, representing the Czech Republic, as well as Nikolaos Dedes, Christophe Hugnet, Wolf-Dieter Ludwig and W.H.J.M. Wientjens in their capacity as civil society representatives.

1. Draft agenda for 21 March 2013

[EMA/MB/685719/2012] The agenda was adopted.

2. Declaration of conflicts of interests

The chair informed members of the Management Board that he has reviewed members' declared conflicts of interests, together with the secretariat, in accordance with the Board's policy on conflicts of interests. No conflicts relating to today's agenda were 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 to be prejudicial to their independence with respect to the items on the agenda, with a specific attention to point B.14, Annual report and review of the operation of the Minor Use/Minor Species (MUMS) scheme for Veterinary Medicines. No conflicts of interests were declared.

3. Minutes from the 78th meeting, held on 13 December 2012

[EMA/MB/810387/2012] The Management Board adopted the final minutes. A written procedure for adoption was launched on 23 January and concluded on 6 February 2013 with the adoption of a version incorporating comments revised by the Management Board chair. One comment was however not deemed to have been fully implemented by the proposing Member and was adopted at the meeting of 21 March 2013.

The chair on this occasion reminded the board that the objective of the minutes is to provide an accurate account of what topics are discussed by the Board and, for each item, the conclusions reached/action agreed. Minutes are not intended to be a verbatim account of the discussion. If there is any specific point on which delegates wish to have their view recorded in the minutes, that must be declared at the time the item is being discussed.

4. Decision determining the start date of the term of office of members of the Management Board appointed by Council Decision

[EMA/MB/82143/2013] The Management Board adopted the decision determining the start date of the term of office of the civil society representatives, with their 3 year mandate commencing on 21 March 2013. The civil society representatives briefly introduced themselves to the board.

A. Points for automatic adoption / endorsement

A.1 Amendment I to Annex I of Cooperation agreement relating to linguistic checking

[EMA/37307/2013] The Management Board adopted the amendment extending linguistic review of the product information in all languages also to changes following recommendation by PRAC within procedures concerning Periodic Safety Urgent Reports (PSUR) and Post Authorisation Safety Studies (PASS).

B. Points for discussion

B.1 Highlights from the Executive Director

2011 Discharge

The Committee on Budgetary Control (CONT) of the European Parliament has recommended to grant the budgetary discharge to the EMA for 2011. A vote in the plenary session should take place shortly.

Visit by Commissioner Tonio Borg

On his first visit to the EMA Commissioner Borg addressed staff on several issues. Handling of conflicts of interest, scientific excellence of opinions, transparency and communication of decisions, managing of Clinical Trials data as well as safety of medicines, fees for pharmacovigilance and implementation of the new legislation were discussed in an open and supportive manner.

Visit by the Environment, Public Health and Food Safety Committee (ENVI) of the European Parliament

The biennial visit by ENVI took place in February. MEP Mathias Groote led the delegation, which included the contact person for the European Parliament to the Agency, MEP Dagmar Roth-Behrendt and four other MEPs.

A detailed discussion on a variety of topics took place over two and a half days, allowing for the Members to learn more about the latest developments and main future challenges concerning the Agency.

Visit by Prof Anne Glover, Chief Scientific Adviser to the President, European Commission

During the visit by Anne Glover, the discussion focused on how to ensure that EU institutions and agencies communicate as effectively as possible on the evidence base of their decisions.

Exercise to improve effectiveness and efficiency of the agency

During the last few months the EMA has been heavily involved in the exercise to review its internal processes, procedures and organisation, named ‘Review and Reconnect’. This was made necessary in order to achieve the highest level of efficiency and effectiveness despite strains on resources, increasing complexity of procedures, such as referrals, and growing demands due to the handling of

access to documents and conflicts of interest. In the course of time a rapid succession of different layers of legislation have caused as many as 60 processes to coexist. These have now been all identified and assigned different levels of priority. The focus so far has been on the core business areas. The evidence gathered has enabled the agency to analyse issues using proven methodologies allowing the identification of building blocks for the implementation phase. The next phase will be a detailed description of candidate proposals, with prioritisation and sign-off of those that can be implemented immediately. Some members would like to see some financial benefit of the exercise being transferred to NCAs. However, it is unlikely that efficiency gains can directly be transferred to the network, as is the case for integrated ICT projects. The exercise has taken into account input collected from NCAs, committees and assessors, and will help streamlining procedure interfaces with the network.

Support was expressed in general for the exercise, as it was recognised that there are too many different processes at EMA and the procedures and their interfaces are sometimes too complex. This is the objective of the exercise, as it aims at simplifying the structures and the procedures The European Commission representative commended the effort which should also lead to a greater consistency and clarity of scientific opinions.

The need for scientific support to rapporteurs by the EMA secretariat was discussed. Perception seemed to vary on whether administrative rather than scientific support was required. There is a need to clarify the concept of scientific support, which can be seen as any action necessary to help the rapporteur by assuring consistency with previous opinions or the work of other committees, specialised secretarial work, editorial support etc. Nature of support varies depending on quality of dossiers, size of authorities, needs of experts and committee activities. While some NCAs might not require such support, this is not true of smaller countries, who appreciate the cooperation offered by EMA staff members. In no case however does the EMA see itself as involved in contributing to shape the opinion or in the decision making part of the work by the rapporteurs. The European Commission representative reminded all that the founding regulation of EMA foresees its responsibility in providing scientific and technical support to the committees. Other members expressed the view that scientific work is outsourced to the network, but the ultimate legal responsibility on the quality of scientific output is retained by EMA. Therefore the agency must always be in a position to achieve best possible results. It was agreed that a paper will be drafted to define the concept of scientific support, to be discussed at the future meeting of the Management Board.

B.2. Annual report 2012

[EMA/MB/151012/2013; EMA/95980/2013] The Management Board discussed and adopted the Annual Report 2012. This year's annual report appears with a changed format and content, focusing on outcomes and hot issues, and introducing Committee Members through a few short 'essays'. The layout has been changed as well to engage wider audiences. The content is focused on the implementation of the pharmacovigilance legislation, on the launch of the PRAC and the Scientific Coordination Board, on new frameworks on handling of Conflicts of Interests and transparency. The output of scientific opinions for initial applications is stable, while orphan designation applications are increasing. Furthermore there has been a significant increase in reported ADRs, particularly for veterinary medicines. Members welcomed the new approach. Small editorial changes might be present in the final version.

The Board nominated topic coordinators for the analysis and assessment of the Executive Director's annual activity report 2012, which will be discussed at the June meeting,: Belén Crespo Sánchez-Eznarriaga and Christina Åkerman.

B.3 Preliminary draft work programme 2014

[EMA/50749/2013] The Board adopted the Preliminary draft work programme 2014 (PDWP). This has incorporated suggestions by the Topic coordinators and has a new structure, which includes resources grouped by activity areas. Budget and programme documents are now linked more explicitly. The focus is on core activities, similar to 2013, with continuing efforts on the implementation of pharmacovigilance legislation, preparation of upcoming new veterinary legislation, development of communication and transparency activities. Efficiency of operations and successful cooperation with the network of national authorities will remain a high priority. Overall assessment activities are stable, with a marginal increase in pre-authorisation procedures (5-8%), and a major increase in PSUR assessments (17%). The new pharmacovigilance legislation also affects work on SMEs classification, which may see a sharp increase of 79%. Inspection activities will stay stable, but requests for certificates should grow by 6%. Increasing complexity of procedures will also be a decisive workload driver. While the outcome of the 'Review and reconnect' exercise is not yet captured in the PDWP, it is expected that the review of the data architecture will result in major investments to open access to NCAs, as well as in integration with network systems. Reflection on raw data analysis will focus on the identification of capacity in the network to deploy statistical resources, when needed on a risk basis, in order to support opinions and in the context of publication of Clinical Trials data. Cooperation with HTA bodies will continue, while Scientific Advice in the framework of post authorisation safety and efficacy studies (PASS and PAES) will become increasingly important. On the veterinary side workload will remain stable, with a predicted increase in Variations and greater focus on scientific advice and MUMS. Stakeholders will continue to be at the centre of EMA communication, with the launch of a new corporate website, a revised Intranet and a new Extranet allowing for greater inclusion of delegates and the network, while progress on the European medicines web portal is on-going. Access to documents remains a major driver. Initiatives are on-going to reduce workload by improving processes. Finally, the physical move to a new building, which will take place starting from August 2014, will provide the opportunity for a profound culture change.

Grzegorz Cessak, as topic coordinator, expressed appreciation for the new presentation of the PDWP and presented an analysis of the document, recommending it to the board.

Some board members were interested in how adaptive licensing can be implemented in the absence of legal changes. This can be achieved by using existing regulatory tools, such as conditional approvals and approvals in exceptional circumstances. More detailed information on prioritisation of implementation of pharmacovigilance legislation was considered to be desirable. Efforts to make more data available to the network were supported, as well as on-going initiatives to achieve greater transparency. Concerning the need for raw data analysis/reanalysis, various opinions and options were expressed. Some members considered that this activity should be left to third parties or to crowdsourcing, and that more emphasis should be put on clinical trial design. Others advocated a deeper reflection on the subject, as it might bring about a substantial shift in the approach to regulatory work. Finally some supported identifying capacity and capability, accompanied by the development of criteria to perform analysis. The representative of the European Commission emphasised that greater transparency on clinical trials data will be brought about also by new legislation, and that regulators need to take responsibility and be able to analyse the data whenever a doubt arises. Concerning the upcoming veterinary legislation timelines need to be reviewed, as for technical reasons it will not be ready by 2014. The Draft work programme which will be presented by the EMA at the December meeting will contain further details on identification of capability and approach to raw data analysis, prioritisation of pharmacovigilance implementation and likely timelines for the new veterinary legislation.

B.4.a Preliminary draft budget and establishment plan 2014

[EMA/MB/128440/2013; EMA/MB/113216/2013] The Management Board discussed and adopted the preliminary draft budget (PDB) and establishment plan 2014. The PDB is a provisional document, as it is based on forecasts, specifically on fees and revenues. Further uncertainty is added by the fact that the future budgetary perspective including the budget proposal for 2014 in the EU is not yet agreed. The overall growth in the EMA budget is foreseen to amount to 3.3% compared to 2013, including a 1% increase in the contribution by the EU and a 2.5% inflationary growth in fee revenues. On the expenditure side, payment for scientific services provided by NCAs should increase by the same inflation factor. ICT costs have been reduced in 2013 and will remain stable for 2014. Increased administrative expenses will take into account the costs for the relocation of the agency in 2014. The multi-annual staff policy plan 2014-2016 (see B.4.b) has been submitted to the European Commission and is currently under discussion, as part of the uncertain overall situation of financial planning in the EU. This is an indicative document, providing the upper ceiling of possible staffing evolutions.

The topic coordinators Klaus Cichutek, Kristin Raudsepp and Grzegorz Cessak considered that the PDB 2014 is suitable for supporting all EMA activities in 2014. As part of their analysis they highlighted that the EMA budget increase is a positive development for NCAs as it could be used for coordination of activities and ICT services. Topics identified for further consideration were whether the contribution for orphan medicines is adequate with regard to estimated demand, the possibility of staff exchange between EMA and NCAs, a more detailed description of ICT expenditure/projects, as well as further details on the distribution and activities of staff involved in the coordination of human/vet procedures, with special emphasis on their support to evaluation activities. It was proposed to adopt the PDB, under the provision that these issues will be discussed and taken into account in the draft budget 2014 to be presented in December.

The European Commission representative was satisfied with the information provided by EMA and the MB topic coordinators on the use of staff and resources, considering it to be probably the most transparent on this matter in the network, and provided further information on budgetary developments in the EU. The financial perspective document 2013-2020 has not been adopted yet. The European Commission hopes for answers by the European Parliament by June. The overall budget of DG SANCO has been cut by 16%, and it has not yet been decided how to distribute the reduction within all its areas of competence, among which are three agencies. Furthermore, the President of the European Commission expects all institutions and agencies to decrease their staff by 2% per year from 2013-2017. Further issues are the repartition of the grades and the impossibility to accept an establishment plan extending beyond 2013, given the current uncertainties. For this reason the European Commission has to abstain from adopting the PDB and establishment plan 2014. The German board member presented his Member State's objection to the adoption of the PDB on instruction by his Finance Ministry and Interior Ministry.

B.4.b The multi-annual staff policy plan 2014-2016

[EMA/MB/128444/2013; EMA/817331/2012] The Board noted the multi-annual staff policy plan 2014-2016 which was presented for information. The plan will be updated according to upcoming budgetary developments and presented again to the board.

B.4.c Revision of the budget structure and remarks

[EMA/MB/29440/2013] The board noted the revised budget structure and remarks, which was amended to provide a more transparent and rational presentation and was presented for information.

B.5 ICT overall budget 2012-2014

[EMA/69347/2013] The board noted the ICT overall budget which was presented for information. This provides more details on the part of the budget dedicated to ICT. Members proposed that such information, possibly structured according to costs for internal and external telematics, telecommunications, website, etc. be presented in the future as an addendum to the budget itself.

B.6 Revised Implementing Rules to the Fee Regulation

[EMA/MB/112878/2013] The Management Board adopted the revised implementing rules which increase the fee levels for inflation by 2.6% and clarify some definitions and fee type. The changes had been approved by the European Commission. The revised implementing rules will enter into force on 1 April 2013.

B.7 EU Telematics governance model

[EMA/MB/117699/2013; EMA/795730/2013] The board adopted the new EU telematics governance model which had already been adopted by the HMA in the meeting in Dublin of 30 January 2013. The chair underlined how with this step the implementation is progressing ahead of the original schedule. Some members expressed the view that the new governance constitutes a good model, but is rather complex. Attention must be paid in the implementation to assure that all concerns are collected and addressed to EMA and that all NCAs feel adequately represented. One of the first tasks of the new governance will be to review the old telematics implementation groups (TIGs) and decide on whether to disband them or turn them into Project Teams. The Management Board will be represented in the EU Telematics Management Board, which replaces the MBTC, by three members. Luca Pani, Wim Wientjens and Andrzej Ryś for the European Commission were nominated.

B.8 Progress on costing evaluation activities

[EMA/MB/90210/2013] The board discussed how to take forward the need to establish a cost based remuneration system. Following previous discussions at the December 2012 meeting the EMA had been asked to prepare a model based on applying different purchasing power coefficients to the payments to National Competent Authorities. The simulation performed by applying EUROSTAT coefficients to past remunerations showed a marked potential to increase compensation to the highest paid NCAs, while reducing it for the lesser paid. A number of members found it unacceptable on the grounds that it would further provide disincentives for smaller agencies, as well as on the basis of discriminatory treatment of equal work. From the perspective of the European Commission such a system would in any case not qualify as being cost based as requested by the Court of Auditors and the European Parliament. The Commission recently worked on a cost based approach in preparing the proposal on the pharmacovigilance fees. A concern was expressed that the cost assessment for this proposal is done only in respect of the EMA's costs without having sought input from the NCAs. The representative of the Commission pointed out that this was due to the urgency and the difficulties involved in putting forward a legal proposal on new pharmacovigilance procedures for which only limited data was available, therefore requiring estimations. The Chair reminded all that the discussion on the costing evaluation has been carried out for a number of years and that it has proven impossible to reach a decision. The proposal on applying coefficients to the payments to the NCAs is not viable, as is the option to hire a consultant, who, it was considered, would not be able to access different data from those which were considered inadequate a few years ago. Internal discussions have not produced a solution as NCAs have an intrinsic conflict of interest on the matter, and a small group is not suited as it has to be an inclusive multiparty process.

The remaining option is to carry out the revision of the remuneration system in the context of the overall revision of the entire fee system, once the legal proposal on pharmacovigilance fees has been adopted. The representative of the European Commission stated that the Commission is working hard to adopt the pharmacovigilance fee proposal by June 2013 with a view to hopefully complete the legislative procedure by April 2014. After adoption of the legal proposal it will start looking at the overall revision of the fee system.

B.9.a Report from the European Commission

The European Commission reported on the following developments of EU legislation and policies in the public-health area:

- A Commission implementing regulation on the black symbol has been adopted.
- After the conclusion of the public consultation on situations where a PAES may be required, first expert discussions on the delegated act will now take place.
- A series of implementing measures relating to the falsified medicines directive have been adopted, are in the stages of impact assessment or of consultation.
- Concerning importation of active substances good progress has been achieved in obtaining feedback by all relevant third countries. Of these some will issue written confirmations, and apply for listings subsequently. The listing will be done by the Commission with coordination by EMA of cooperation of MS inspections of third-country sites.
- The integrated roadmap for the Antimicrobial Resistance action plan has been published and a progress report is foreseen for end of 2013. EMA is being asked for advice on which substances have an impact on public health and animal health.
- The cross border directive will be transposed by October 2013. The Commission is actively working with Member States in the Cross-border Healthcare committee to prepare the implementing act on HTA network. Work is ongoing on implementing measures to develop criteria for the establishment of European references networks.
- Early dialogue with HTA is being piloted, and EMA will be observing upcoming EUnetHTA activities.
- Within the Process on corporate responsibility in the field of pharmaceuticals three platforms have been active. *Ethics and transparency* has issued their Guiding Principles, *Access to medicines in Europe* will present outcomes from six sub-groups in April, and *Access to Medicines in Africa* will finalise its output in autumn. Input to future Strategic Political Initiative will be provided.
- Following the positive vote by the European Parliament on 6 February the Commission has prepared and adopted an amended proposal for the Transparency Directive which is now available to all parties involved.

B.9.b The Commission Roadmap on the follow-up to the Common Approach (outcome of the Inter-Institutional WG on Decentralised Agencies)

The representative of the European Commission updated the board on the follow-up to the Common Approach concerning EU decentralised agencies. 32 agencies with a total of 7000 staff members are covered by an interinstitutional agreement aiming at increasing European Parliament and Council governance. The Commission is responsible for its implementation and has adopted a roadmap including 90 initiatives to be taken by all. Five areas have been identified and will need to be implemented in close cooperation with all agencies. EMA is largely conforming to most requirements.

B.10 Report from the Heads of Medicines Agencies

Due to time constraints the oral report was not provided. Members noted the written report.

B.11.a Update on the implementation of Pharmacovigilance Legislation

[EMA/MB/147218/2013; EMA/115971/2013] The board noted an update focusing on experience with the operation of the PRAC. Since its inauguration in July 2012 the PRAC has held six meetings. Main issues to date are a steadily increasing workload combined with problems in rapporteurship appointments, need for fine-tuning of some business processes which were identified and where action is being undertaken, limited interaction between PRAC and CHMP and PRAC and CMDh, as well as further consideration to be given to the follow-up of PRAC outcomes for nationally authorised products.

B.11.b Public hearing

[EMA/MB/172763/2013; EMA/542982/2012] The discussion of this point was deferred to the June meeting. Members may send written comments to the Management Board secretariat. On the basis of comments received also by the PRAC a teleconference might be scheduled.

B.12 EMA Code of Conduct

[EMA/MB/102832/2013; EMA/385894/2013] The discussion of this point was deferred to the June meeting.

B.13 Renewal of the mandate for the Joint Expert Group on 3Rs

[EMA/95290/2013; EMA/CHMP/CVMP/JEG-3Rs/442724/2012; EMA/521929/2012] The board adopted the revised Terms of reference, objectives and rules of procedure for the joint CVMP/CHMP ad hoc expert group on the application of the 3Rs extending its mandate for a further two years. The board also noted the report of the work of the group to date and the current and future work plan for the next two years.

B.14 Annual report and review of the operation of the Minor Use / Minor Species (MUMS) scheme for Veterinary Medicines

[EMA/MB/114227/2013; EMA/62481/2013; EMA/129599/2013] The board noted the annual report and discussed the review of the MUMS/limited market policy. The report showed success in the identification of MUMS and in the classification, which allows for reduction of data requirements. The board was invited to consider the possibility to suspend financial incentives while reflecting on improved criteria to identify products deserving public support. Members agreed on the need to continue to support the classification criteria, while elaborating more stringent criteria for financial incentives. Use in food producing animals might be considered as deserving support. Given that the MUMS scheme is a joint initiative with HMA, it was decided to continue discussions at the April meeting of HMA with a view to possibly present a new proposal to the board at the June meeting.

B.15 Annual report on the performance of the Agency's scientific procedures

[EMA/MB/102832/2013; EMA/385894/2013] The discussion of this point was deferred to the June meeting.

A.O.B.

None

Documents for information

- [EMA/MB/128889/2013] EU telematics operations report.
- [EMA/MB/116611/2013] EU telematics projects report.
- [EMA/MB/113901/2013] Minutes of the MBTC from 6 December 2012 meeting.
- [EMA/MB/67488/2013] Outcome of written procedures during the period from 22 November 2012 to 27 February 2013.
- [EMA/MB/89378/2013] Summary of transfers of appropriations in the budget 2012.
- [EMA/MB/185063/2013; EMA/127361/2013] First Annual Report on EudraVigilance for the European Parliament, the Council and the Commission.

Tabled documents

- Updated draft Agenda version 3.0
- B.11.b [EMA/MB/172763/2013; EMA/542982/2012] Public hearing
- C.4 [EMA/MB/185063/2013; EMA/127361/2013] First Annual Report on EudraVigilance for the European Parliament, the Council and the Commission.

List of written procedures during the period from 22 November 2012 to 27 February 2013

- No. 01/2013 on the appointment of Ines Lindner as CVMP alternate; ended with endorsement on 30 January 2013.
- No. 02/2013 on the appointment of Joseph Emmerich as CHMP alternate; ended with endorsement on 5 February 2013.
- No.03/2013 on the appointment of Kersti Oselin as CHMP alternate, ended with endorsement on18 February 2013.
- Written procedure for the 78th Management Board meeting minutes; ended with adoption on 6 February 2013.

List of participants at the 79th meeting of the Management Board, held in London, 20 - 21 March 2013

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	Evelin Blagoev	
Czech Republic	Doubravka Košťálová	
Denmark	Apology received	Nina Moss Matilde Kyst Behrens
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	Kristin Raudsepp	
Ireland	*Apology received*	Rita Purcell
Greece	Apology received	Aikaterini Moraiti
Spain	Belén Crespo Sánchez-Eznarriaga	
France	*Apology received*	Jean-Pierre Orand Jean-Baptiste Brunet Miguel Bley
Italy	*Apology received*	Paolo Siviero Daniela Salvia
Cyprus	Arthur Isseyegh	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	Claude A Hemmer	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
Netherlands	Aginus Kalis	Birte Van Elk
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Helder Mota-Filipe	Eurico Castro Alves Maria Morais
Romania	Marius Savu	
Slovakia	*Apology received*	Barbora Kučerová Valeria Pernišová
Slovenia	Matej Breznik	
Finland	*Apology received*	Pekka Kurki
Sweden	Christina Åkerman	Bengt Wittgren
United Kingdom		Jonathan Mogford Saira Madden
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission	Paola Testori Coggi Gwenole Cozigou	Salvatore D'Acunto Sabine Juelicher Olga Solomon Lenita Lindstrom

	Members	Alternates (and other participants)
Representatives of patients' organisations	Nikolaos Dedes	
Representatives of patients' organisations	W.H.J.M. Wientjens	
Representative of doctors' organisations	Wolf-Dieter Ludwig	
Representative of veterinarians' organisations	Christophe Hugnet	
Observers: **Croatia** **Iceland** **Liechtenstein** **Norway**	 Luka Vončina *Apology received* Brigitte Batliner Gro Ramsten Wesenberg	 Viola Macolić Šarinić Einar Magnússon Ivar Vollset
Scientific Coordination Board **CHMP** **CVMP** **PRAC** **PDCO** **COMP** **HMPC** **CAT** **CMDh** **SAWP-V** **SAWP-H**	 *Apology received* Anja Holm June Raine Daniel Brasseur Bruno Sepodes Werner Knoss Christian Schneider Peter Bachmann Rory Breathnach *Apology received*	
European Medicines Agency	Guido Rasi Patrick Le Courtois David Mackay Andreas Pott Luc Verhelst Noël Wathion Peter Arlett Emer Cooke Martin Harvey Allchurch Tomasz Jablonski Michael Lenihan Frances Nuttall Agnes Saint Raymond Spiros Vamvakas Ulrike Nagl Monika Benstetter Dara Forde Karen Quigley Alexis Nolte	

	Members	Alternates (and other participants)
	Maria Alves Sophia Albuquerque Silvia Fabiani Zuzana O'Callaghan Nerimantas Steikūnas	