14 June 2013
EMA/MB/367978/2013
Management Board

Minutes of the 80th meeting of the Management Board

Held in London on 13 June 2013

The chair of the European Medicines Agency's Management Board, Sir Kent Woods, opened the meeting by welcoming the new member Ivar Vollset, representing Norway. He congratulated the Board on its 80th meeting and acknowledged the upcoming retirement of Patrick Le Courtois, who has been working at the Agency since 1997 and was previously involved in his capacity as CPMP member.

1. Draft agenda for 13 June 2013 meeting

[EMA/MB/197800/2013] The agenda was adopted.

2. Declaration of conflicts of interests

The chair informed members of the Management Board that he had 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 specific attention to point B.15, Revision of the minor use, minor species (MUMS)/limited market policy for authorisation of veterinary medicines. No conflicts of interests were declared.

3. Minutes from the 79th meeting, held 20–21 March 2013

[EMA/MB/195991/2013] The Management Board adopted the final minutes. The minutes were circulated for adoption by written procedure on 2 May 2013 and amended following comments received during the consultation phase. The Board adopted a version proposed by the chair after careful consideration of all comments received. Detailed contributions from the topic coordinators for the budget will be made available at the December meeting.

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A. Points for automatic adoption / endorsement

A.1 Management Board meeting dates 2014

[EMA/MB/290754/2013] The Management Board adopted the following proposed meeting dates for 2014:

- Wednesday, 19 March & Thursday, 20 March;
- Thursday, 12 June;
- Thursday, 2 October;
- Thursday, 18 December.

The Board also noted the following proposed meeting dates for 2015:

- Wednesday, 18 March & Thursday, 19 March;
- Thursday, 11 June;
- Thursday, 1 October;
- Thursday, 17 December.

B. Points for discussion

B.1 Highlights from the Executive Director

Pending court cases concerning access to documents

Several complex and high-profile court cases regarding release of information are pending before the General Court. A ruling is not expected before the beginning of 2015. The Agency will respect the outcome of the court ruling but is in the meantime appealing against an order to suspend decisions until final judgement. The Agency has received wide support from Member States and the European Ombudsman.

Policy on proactive publication of clinical-trial data

The policy was drafted after the successful workshop held on 27 November 2012 and on the basis of advice received from five advisory groups that were active from January to April 2013. The draft policy will be published on 30 June for public consultation until 30 September. A consolidation phase will follow, after which the Management Board will discuss and endorse it before the end of the year. Implementation of the policy will require a number of practical tools to be developed, and it is not expected that it will enter into force before 2015.

Article 57 data submission

Following the legal requirements for pharmaceutical companies to submit structured data on all authorised medicines to the European Medicines Agency, more than 420,000 EVCODEs, representing over 300,000 unique marketing-authorisation numbers have been submitted so far. Access to complete and reliable data is important as it supports work on various business processes, such as correct EudraVigilance data analyses and correct information on products involved in referral procedures. A quality-control check on a sample of submitted data showed error rates that need to be addressed. The Agency is, therefore, looking at ways to build quality assurance into the process, but

needs in the meantime to introduce some cost-efficient quality-control measures. Work over the next months includes a one-off de-duplication of substance names (of which there is a backlog of approx. 120,000) by internal resources, an ex-post control to clarify the compliance rate, and work in the field of quality control, on the basis of the preliminary findings, in collaboration with the pharmaceutical industry. Outcomes of this work were presented at a recent workshop with European industry associations. Their approach was cooperative, as they acknowledged the need to improve data quality and agreed to work with the Agency to build quality assurance and control into the overall process.

'Black symbol'

The black symbol, an inverted black triangle, will start appearing on the package leaflet and in the summary of product characteristics of medicinal products under additional monitoring, starting in autumn 2013. The Pharmacovigilance Risk Assessment Committee (PRAC) will compile the list of medicines under additional monitoring, and will review it monthly.

Medication errors workshop report

A very successful workshop was held and has identified multiple opportunities to collaborate for public health.

Veterinary issues

The Agency continues to have a strong focus on epizootic diseases for livestock. In May, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted the first positive opinion for a vaccine against foot-and-mouth disease using an innovative multi-strain approach. The Agency further continues to support the maintenance of a portfolio of epizootic vaccines by providing fee support for products that are not sold due to eradication of a disease but might be needed in future. An example is the support to the authorisation of bluetongue vaccines.

A joint expert working group of the CVMP and the Committee for Medicinal Products for Human Use (CHMP) has received a wide mandate and started work on providing advice to the European Commission on antimicrobial resistance.

Concern was expressed by one Board member that quality assurance for Article 57 procedures might not ensure that data will retain high quality once one-off data-cleaning has been performed. It would be more desirable to build a European database from data provided by the Member States. The Agency reassured the Board that the industry is committed to improving data quality, and that the Article 57 database will be helpful in many ways, such as facilitating PSUR submission and for liaison with marketing-authorisation holders. All data will be made available to Member States once satisfactory quality can be assured. Input from the national competent authorities — on quality of data as well as on completeness of information on logged national marketing-authorisation holders — would of course be helpful. Problems of a more general nature, such as resource-effective maintenance and consistency between European and national databases, could be best addressed by the EU Telematics Management Board (EU TMB), which was recently created to provide a joined-up telematics strategy.

B.2.a Internal reorganisation of the Agency

The Executive Director updated the Board on progress with the internal exercise 'Review and Reconnect', whose purpose is to continuously improve the quality of work in the processes concerning human medicines. After a phase of gathering issues and opportunities, and of analysis of the findings, 23 proposals for change have been identified. By looking closer at the role of the product team, it emerged that competences are currently scattered across the organisational structure. A set of guiding

principles was defined to set up a new organisational structure. A new terminology was created, substituting the old structure of 'units', 'sectors' and 'sections' with 'divisions', 'departments', 'services' and 'offices'. The implementation of the new structure has been planned in transitional steps, which will take place over the next 12 months, leading up to the physical step of moving into the Agency's new premises at 30 Churchill Place in July 2014. A Programme Design Board, which will include managers, leads and sponsors, will be an important part of the programme governance for the transformation/implementation. The implementation will run alongside the day-to-day business of the Agency, to avoid disruption of operations. Current sections will be left intact, where possible, while some new entities may be created, including in parts of the Agency not involved in human medicines. The first appointments have been made and others are soon to follow, to provide the Agency with division and department heads with a mandate to complete the transformation of the organisational structure. The new appointees were presented: Enrica Alteri will lead the Human Medicines Evaluation Division, and Alexis Nolte the Procedure Management and Business Support Division, while Fergus Sweeney will be responsible for the Inspections and Human Medicines Pharmacovigilance Division. Noël Wathion will be appointed Chief Policy Adviser and Agnes Saint Raymond will lead the Programme Design Board.

Members congratulated the Agency on the impressive task undertaken, and expressed their expectancy that it might lead to further improvements of the way the Agency works, as well as of its cooperation with the national competent authorities.

B.2.b Role of the scientific secretariat

The Board heard an outline of the topics to be included in a paper intended to detail the concept of scientific support foreseen by the founding regulation of the Agency, with successive expansions in the tasks allocated to the Agency by further legislation. The reflection on the provision of better support to the work of the scientific committees and of the European network of medicines regulatory authorities has been a major driver of the Review and Reconnect exercise, and has helped to shape the contours of the new divisions to better match the regulatory lifecycle of medicinal products.

Concerning the paper on scientific support, it would be desirable to postpone it to Q4 2014, to be able to describe a steady-state situation. As for its scope, it should extend beyond statements of principles by examining also the role and contribution of the Member States and the need for availability of the best-possible expertise to operate efficiently in the network.

B.3.a Executive Director's annual activity report (AAR) 2012

[EMA/MB/311042/2013; EMA/203755/2013] The Management Board noted the 'Annual activity report 2012'. This provides an account of the results of the Agency's activities and describes the management systems in place. The report comprises a summary of the 'Annual report 2012' and a description of the management system, including: annual assessment of the effectiveness of internal control standards; annual corporate risk assessment; operation of ex-ante and ex-post control systems; and internal and external audits. A special section was included, describing prevention and managing of conflicts of interests and procedures related to 'revolving door' cases. Based on the assurance provided by the management, control and supervision system, the Executive Director has signed the declaration of assurance without reservations.

B.3.b Analysis and assessment of the AAR 2012

[EMA/MB/302752/2013] The Board adopted the document 'Analysis and assessment of the Executive Director's annual activity report 2012', which had been drafted by the topic coordinators Belén Crespo

Sánchez-Eznarriaga and Christina Åkerman. The final document takes into account comments made at the meeting. Topic coordinators had particularly noted the efforts by the Agency, together with the network, to implement pharmaceutical legislation, the initiative to develop a plan to mitigate and manage shortages of important medicines, and the launch of the new Scientific Coordination Board, and welcomed the progress in the approach to transparency, which was also appreciated by the European Parliament.

B.4.a Report from the European Commission

The European Commission reported on EU legislative and policy developments in the public-health area:

- New pharmacovigilance legislation is in force as of 5 June 2013; the public consultation on situations where a PAES may be required is concluded and first discussions in different fora have taken place.
- The report on experience with the Paediatric Regulation is about to be finalised, while a report on the functioning of the Advanced Therapies Regulation is planned for the end of 2013.
- Several implementing measures concerning the Falsified Medicines Directive have been published or are in the consultation phase, while work on importation of active substances is progressing well, with main producing countries listed, in the process of being audited for listing, or having begun to issue written confirmations. Monthly newsletters keep national competent authorities informed.
- The discussion on the Clinical Trials Regulation is progressing well, and a first reading agreement is expected by the end of 2013; a vote by ENVI, the lead committee of the European Parliament, took place on 29 May.
- The legislative proposal for the revision of the veterinary medicines legislation is expected to be adopted by the end of 2013. Availability of veterinary products is the main driver, and the proposal might try to achieve this goal through simplification of procedures.
- An integrated roadmap for the five-year antimicrobial resistance action plan will be published by the end of 2013, along with a progress report. A conference on antimicrobial resistance will be held in December 2013.
- The proposed EU directive on the application of patients' rights in cross-border healthcare will have important consequences in the pharmaceutical field, with the creation of a network of health-technology-assessment (HTA) bodies, mutual recognition of prescriptions and the adoption of several papers on eHealth. The Agency has been invited to attend HTA network meetings, and will cooperate with EUnetHTA in upcoming pilots to test convergence of recommendations.
- The Commission proposal on the Water Framework Directive does not contain pharmaceutical substances in the priority list, but it is expected that some will be included in the watch list.
- A report on personalised medicines prepared by the Directorates-General for Health and Consumers and for Research and Innovation, in consultation with the Pharmaceutical Committee and the Agency, is planned for the second half 2013.
- The proposal on the Transparency Directive, after having received a positive opinion by the European Parliament and being revised by the Commission earlier this year, must undergo further discussion at the Council. The proposal's objective is to update common rules for pricing and reimbursement — not to determine their level.

- The process on corporate responsibility in the field of pharmaceuticals should be finalised by 2013. Its results will be used in the future Commission policy initiative on the pharmaceutical industry in 2014.
- As regards developments in the area of international relations, the Commission representative agreed to send information after the meeting about the outcome of the discussions on the reform of ICH, following the meeting in La Hulpe, Belgium, 1-6 June 2013, and of the new International Pharmaceutical Regulators Forum that has been set up.

Some concerns were expressed on the availability of active pharmaceutical ingredients after 2 July. The Commission representative assured the Board that most main manufacturing countries would by that time be listed or issue written confirmation. A greater problem might be the delayed transposition of the legislation in some Member States, which may create double legal standards. As for the HTA initiative, while the European Parliament representative advocated centralisation of pricing, other members were interested in learning more about possible future developments. The topic will be taken up again in a dedicated slot in a future Management Board meeting.

B.4.b Legal proposal on pharmacovigilance fees

A representative of the European Commission presented the principles and approach followed in the legal proposal for fees for pharmacovigilance. The proposal is going to be adopted shortly as a self-standing regulation of the European Parliament and of the Council. After the public consultation in 2012, the Commission had to reorient its approach, which took some time. The legal proposal is based on estimated overall costs of the pharmacovigilance activities at EU level, and it was preceded by an impact assessment that took its data from, among other sources, estimation of costs by the Agency and estimated costs of rapporteur activities provided in the 2009 costing exercise. The proposal contains fees for three identified pharmacovigilance procedures and an annual flat fee. The procedure-based fees will vary for the marketing-authorisation holders, depending on the proportion of their products in the total number of products involved in the procedure, and part of the fee will be used for the remuneration of rapporteurs. An annual flat fee will be charged once a year to the marketing-authorisation holders to cover the Agency's costs, and will be based on the number of authorised products. Centrally authorised products will be exempt because they are already covered by a different annual fee. Reductions and waivers of fees are foreseen, notably for small and medium-sized enterprises, in accordance with an EU-wide policy. The regulation will apply alongside national fees and the current Fee Regulation. An overall review of all Agency fees will be undertaken once the legal proposal on pharmacovigilance fees is adopted in summer.

Some Board members would have welcomed further details on expected amounts of remuneration to rapporteurs and on the economic reasoning underlying the proposal and the impact assessment, in particular with reference to costs carried by the national competent authorities, an example of which was provided to the Board concerning a particularly complicated procedure. Furthermore, the proposal comes with some delay on the implementation of the pharmacovigilance legislation and there is some scope for overlap with other fee systems that should be clarified. Assurance was provided that the Lithuanian presidency has set a priority for the pharmacovigilance fees legislation, and discussions will begin as early as July.

B.5 Meeting of the chairs of the management boards of EU decentralised agencies

The vice-chair of the Board reported on the meeting organised by the European Commission to discuss the 'common approach' of the European Parliament and Commission, and the Commission roadmap on

the follow-up to the common approach. The common approach sets out principles that should be taken into account concerning future decisions on EU decentralised agencies. The main elements concern the structure and governance of the agencies, operations, programming of activities and resources, and requirements concerning accountability, controls and transparency. An inventory of initiatives to be taken will be compiled, to be taken into account when modifying agencies' basic acts. Concerning the European Medicines Agency though, the chair and vice-chair of the Board noted that most expectations are met, but that a few differences may have to be addressed in the future.

B.6 Report from the Heads of Medicines Agencies (HMA)

The chair of the HMA management group provided a comprehensive written summary of activities of the Heads of Medicines Agencies. The Board considered that such a document could be circulated for information rather than discussion in the future.

B.7 Proposed 'Working Group on Sustainability'

The Board noted a short presentation provided by the European Commission and the HMA setting out the role of the European Medicines Agency and the role of the national competent authorities. The chair reminded the group that, in order to progress with its work, a proposal to the Management Board for the terms of reference and membership structure was needed.

B.8 Annual report on the performance of scientific procedures

[EMA/97787/2013] The Board noted the 'Annual report on the performance of the Agency's scientific procedures' for 2012. The current report has been expanded, compared to the previous years, to include a number of performance indicators related to the post-authorisation phase, and is combined with the report provided to the CVMP.

B.9 Transfer of appropriations to allow for implementation of simplified ICT budget structure

[EMA/MB/273259/2013] The Management Board adopted the transfer. This was needed in order to implement the new simplified budget structure concerning ICT elements, consolidating 18 budget lines into four.

B.10 Report from the EU Telematics Management Board (EU TMB)

[EMA/MB/285651/2013; EMA/MB/276321/2013] The Board noted the first report by the EU TMB. The transition from the MBTC to the new EU TMB governance structure, adopted at the March Management Board meeting, is almost complete. Appointments to the IT Directors Group have been received and their meeting will take place on 2 July, followed on 3 July by the TMB meeting, during which the EU TMB chair will be elected. The Board will receive a further report at the October meeting.

B.11 Code of conduct

[EMA/MB/281556/2013; EMA/385894/2012] The Board endorsed the Agency's revised code of conduct. The revised code is a consolidated document that comprises documents and policies to facilitate consultation by members of the Agency's Management Board and scientific committees, its experts and its staff on direct and indirect interests, and provides guidance on how to avoid and manage potential conflicts of interests. The chair acknowledged that this document reflects the progress made by the Agency, particularly in the area of strengthening rules on conflicts of interests.

B.12 Public hearings

[EMA/MB/351383/2013; EMA/542982/2012] The Board discussed and noted a paper setting out the Agency's current thinking on the organisation and conduct of public hearings. Public hearings were first discussed at the March 2012 meeting. The present document incorporates comments from that meeting made by the Agency/Member States Project Team on Communication and Transparency, comments made by Board members after a brief introduction at the March 2013 meeting, and comments made during a discussion at the May meeting of the PRAC.

Public hearings are foreseen by the new pharmacovigilance legislation, and should not only increase transparency and understanding of the evaluation of the safety of medicines for citizens, but add value to the evaluation process beyond already existing forms of stakeholder consultation. Public hearings should be held once all available data have been assessed and should inform the debate in the PRAC, providing input into the regulatory decision-making. Initially, they should be held on a case-by-case basis, according to key principles concerning openness and transparency. They should be open to all, within different modalities of participation.

Members welcomed the Agency's commitment to implement a process for public hearings that ensures they add value to the evaluation of medicines by enriching regulatory decision-making. In their discussion, the members provided further suggestions or raised questions, in particular concerning the possible future widening of linguistic options beyond English, use of technology, and the role of national competent authorities.

Rules of procedure for the conduct of public hearings are being defined and will be adopted by the PRAC before being released for public consultation. The final version will be submitted to the Management Board for endorsement.

B.13 Rules of procedure of the Paediatric Committee – Revision 1

[EMA/MB/190916/2013; EMA/348440/2008 rev.1] The Management Board adopted a favourable opinion on the revised rules of procedure, which needed to be modified to update the terminology they used and to include further details to bring them into line with the rules of other committees. The document will enter into force after receiving favourable opinion from the European Commission.

B.14 Report from the chair of the CVMP

[EMA/291244/2013] Anja Holm, newly re-elected chair of the Committee for Medicinal Products for Veterinary Use (CVMP), presented the Committee's work and resources, with a focus on the access to scientific expertise. The breakdown into paid and unpaid work in the Committee shows that for both, workload is increasing and is unevenly distributed, with high concentrations in a small number of national competent authorities. There might be several reasons for this at a national level, and the Board is invited to reflect on ways to encourage less-active agencies to take a more active part in the work of the Committee. Removing hurdles to encourage European teams seems a good way forward. Optimal scientific expertise is made up of scientific knowledge, committee competence and access to supporting resources. In order to improve overall expertise in the Committee, various options could be considered, ranging from stating necessary expertise prior to new appointments, selecting candidates, tracking participation and performance of Committee members.

Members were grateful for the thought-provoking report, which was considered as having the same relevance for all committees. The discussion focused on the hurdles to the constitution of multinational teams, which are often due to financial and administrative provisions. The representative of the European Commission agreed that a solution compatible with financial rules is urgent.

The Agency will increase its efforts to improve predictability and planning of workload, and will look at ways to facilitate fee-splitting among multinational teams.

B.15 Revision of the MUMS/limited market policy for authorisation of veterinary medicines

[EMA/324256/2013; EMA/327514/2013] The Management Board adopted a proposal for an amendment to the minor uses, minor species (MUMS)/limited market policy and endorsed a public statement. At the March meeting, the Agency had proposed suspending financial incentives to MUMS while reflecting on improved criteria to identify products deserving public support. The Board had supported the need to continue applying the classification criteria, which allow for reduction of data requirements. The use in food-producing animals had been considered as deserving financial support. In a discussion at their meeting in April, the Heads of Medicines Agencies agreed with this approach, deciding to pursue a two-tier classification, allowing all MUMS to access limited data requirements, while restricting the allocation of financial incentives to food-producing species. A wider reconsideration of the policy will take place at the time of the revision of the fee regulation implementing measures in March 2014. In the meantime, though, the Board agreed to revise the MUMS policy by written procedure and inform stakeholders by means of a public statement.

A.O.B.

Documents for information

- [EMA/321981/2013] Annual report of audit activities at the Agency for 2012.
- [EMA/276872/2013] Audit Advisory Committee annual report for 2012.
- [EMA/321159/2013;(Ares (2013)1285593)] Annual Internal Audit Report (IAS-EC) 2012.
- [EMA/255692/2013] Annual report of internal audit and advisory activities at the European Medicines Agency in 2012.
- [EMA/326221/2013] Veterinary EudraVigilance status report.
- [EMA/MB/283236/2013] Preparation for written procedure on opinion on the Agency's annual accounts for the financial year 2012.
- [EMA/MB/367978/2013] Preparation for written procedure for amendment to the Management Board implementing rules on the Agency's fees in relation to fee exemptions for certain pharmacovigilance-related type-IA variations.

Tabled documents

- Updated draft Agenda version 3.0.

Written procedures during the period 28 February 2013 – 24 May 2013

- No 4/2013 on the appointment of Toomas Tiirats as CVMP member; ended with endorsement on 7 March 2013.
- No 5/2013 on the appointment of Anna Wachnik-Święcicka as CVMP alternate; ended with endorsement on 10 April 2013.

- No 6/2013 on the appointment of Radka Montoniova as CHMP alternate; ended with endorsement on 10 April 2013.
- No 7/2013 on the appointment of Melinda Sobor as CHMP alternate; ended with endorsement on 14 May 2013.
- Written procedure for adoption of the 79th Management Board meeting minutes; ended on 6 February 2013. The adoption of the minutes was suspended.

List of participants at the 80th meeting of the Management Board, held in London, 13 June 2013

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	Evelin Blagoev	
Czech Republic	Doubravka Kostalova	
Denmark	Nina Moss	Matilde Kyst Behrens
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	Kristin Raudsepp	
Ireland		Rita Purcell
Greece		Aikaterini Moraiti
Spain		Laura Franqueza García
France	Dominique Maraninchi	Jean-Pierre Orand Miguel Bley Jean-Claude Ghislain
Italy	Luca Pani	Daniela Salvia
Cyprus	Arthur Isseyegh	
Latvia		Dace Ķikute
Lithuania	Gintautas Barcys	
Luxembourg	*Apology received*	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Helder Mota-Filipe	Maria Morais
Romania	Marius Savu	
Slovakia	Jan Mazág	
Slovenia	*Apology received*	
Finland		Pekka Kurki
Sweden		Christer Backman
United Kingdom		Jonathan Mogford Saira Madden
European Parliament	Giuseppe Nisticó	
European Commission	Andrzej Ryś Salvatore D'Acunto	Lenita Lindström Miroslav Griva
Representatives of patients' organisations	Nikos Dedes W.H.J.M. Wim Wientjens	
Representative of doctors' organisations	Wolf-Dieter Ludwig	
Representative of veterinarians' organisations	*Apology received*	

	Members	Alternates (and other participants)
Observers	Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) Ivar Vollset (Norway) Anja Holm (CVMP Chair)	 Viola Macolić Šarinić (Croatia)

European Medicines Agency	Guido Rasi Patrick Le Courtois David Mackay Andreas Pott Luc Verhelst Noël Wathion Fergus Sweeney Enrica Alteri Tony Humphreys Isabelle Moulon Emer Cooke Martin Harvey Allchurch Sophia Albuquerque Silvia Fabiani Nerimantas Steikūnas	