3 July 2014
EMA/MB/325638/2014
Management Board

Minutes of the 84th meeting of the Management Board

Held in London, 12 June 2014

The Vice-Chair, Walter Schwerdtfeger, opened the meeting and welcomed Hugo Hurts, the new member for The Netherlands.

1. Draft agenda for 20 March 2014 meeting

[EMA/MB/22128/2014] The agenda was adopted.

2. Declarations of conflicts of interests

The Vice-Chair informed members of the Management Board that the outgoing Chair 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 Vice-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. Election of the Chair of the Management Board

The Management Board received one nomination from Kent Woods (United Kingdom). Members noted the procedure for the election of the Chair. The Vice-Chair announced votes by proxy:

- Belén Crespo Sánchez-Eznarriaga (Spain) for agenda item 3 only and Jacqueline Genoux-Hames (Luxembourg) to Xavier De Cuyper (Belgium)
- Ioannis Kkolos (Cyprus) to Katerina Fameli (Greece)
- Christoph Hugnet (representative of veterinarians' organisations) to Dominique Maraninchi (France)

The Board appointed Rannveig Gunnarsdóttir and Audun Hågå, observers from Iceland and Norway, to act as tellers. The vote took place by secret ballot.

The results of the vote were as follows:

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[redacted]

The Vice-Chair announced the election of Kent Woods as Chair of the Board for a three-year term. Following the election, Prof. Woods stressed that the Management Board must continue to act as the guardian of the medicines regulatory system on which it is the best informed expert. As the whole system faces the strains from financial pressure, the board must provide guidance and stewardship to ensure that the upcoming evolution of the business environment and of the agency, including the restructuring of its organisation, is carried out successfully, and that it can continue to fulfil its role in the protection of public and animal health.

Following the election Kent Woods chaired the meeting.

4. Minutes from the 83rd meeting, held 19-20 March 2014

[EMA/MB/169928/2014] The Management Board noted the final minutes, adopted by written procedure on 5 May 2014.

A representative of the European Parliament requested the inclusion in the minutes of his request for a guideline on the topic of off-label use. The representative of the European Commission confirmed that an initiative on off-label use is planned (see B.3).

A. Points for automatic adoption / endorsement

A.1 Management Board meeting dates 2015

[EMA/MB/226104/2014] The Management Board adopted the following meeting dates for 2015:

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

The Board also noted the following proposed meeting dates for 2016:

- Wednesday, 16 March and Thursday, 17 March;
- Thursday, 9 June;
- Thursday, 6 October;
- Thursday, 15 December.

B. Points for discussion

B.1 Highlights from the Executive Director

Multinational teams

The European Medicines agency took part in a recent meeting organised by the Finnish agency and including nine Member States participating in the current pilot. Experience so far has been very positive and has yielded four multinational teams. The concept will now be further expanded to other Committees and to full rapporteurships.

Payments to Member States

A number of measures benefiting experts and their employers have been explored and proposals will be further discussed under point B.5.

Memorandum of Understanding with ECHA

The memorandum signed on 14 May 2014 with the European Chemicals Agency in Helsinki will address cooperation in the areas of exchange of information regarding evaluation and risk management of chemicals, toxicological assessments, environmental risk assessments, and attendance of conferences and meetings of interest, such as the upcoming nanotechnology workshop.

New Clinical Trial Regulation

The Regulation was published in the Official Journal on 27 May 2014. Implementation work for the development of the EU Portal and Database by the agency with the Member States and the European Commission is well underway.

New pharmacovigilance fee regulation

The publication in the Official Journal is expected at the end of the month and the agency is pleased to be able to start paying for work done by the Member States at the PRAC. The Cooperation agreement needs to be amended and will be further discussed under point B.4.

Results from 1st quarter

Key indicators are on target and major programmes and objectives are on target, while the budget situation is in line with expectations. A very positive trend is apparent for Scientific Advice. Furthermore, the training project is progressing well. A full report will be provided in October.

Anti-fraud strategy

According to the Road map on EU decentralised agencies produced by the inter-institutional working group all agencies will have to adopt and implement an anti-fraud strategy by 31 December 2014. The agency is working on a document based on the OLAF guidelines and will submit it to the board.

EPL concept

The board has been updated regularly since December 2012 on the Review & Reconnect progress. At the March 2014 the concept of the EMA Product Leader and Procedure Manager was presented in detail and discussed. Support was received from the Management Board members who were exposed to the working of the committees and by the CHMP chair. In the current implementation phase the agency is very open to suggestions, beyond the already planned consultations. Specific questions or requests for further discussion are welcome. A document on initial experience will be circulated to the board.

Re-examination of original study data

A request for further information was received from the board's vice-chair. After a discussion at the meeting in March 2013 the raw data project is currently on hold. However, pressure from academia, researchers and the public, and also by some regulators to address the issue is increasing. In order to build a proposal the CHMP needs to explore scenarios requiring enhanced analytical capabilities. Capacity and capability in the network will need to be assessed as well. The European Medicines Agency will produce a final Reflection Paper to be discussed at the Management Board by the end of the year.

Some members stressed the need for an agreed approach to which limited cases call for a re-analysis. This is needed to proceed to assess what capacity is needed in the network and where it can be found. A good starting point is provided by the Biostatistics Working Party.

B.2 Assessment of the Executive Director's Annual Activity Report (AAR) 2013

[EMA/MB/286545/2014; EMA/145663/2014; EMA/262020/2014] The board noted the 'Annual activity report 2013' and adopted the document 'Analysis and assessment of the Executive Director's annual activity report 2013', which had been drafted by the topic coordinators Christa Wirthumer-Hoche and Christina Åkerman.

The topic coordinators particularly noted the considerable work programme delivered in 2013 and the strong contribution by the agency to the European medicines regulatory system, the progress in developing the policy on publication and access to clinical trial data, the new organisational structure to better support the scientific work of the Committees, the well planned transfer to the new premises in July, the balanced approach to the revision of the policy on the handling of conflicts of interest, the initiative by the Executive Director to review and improve IT procurement and project management and finally the absence of open critical or very important recommendations from the IAS. More work will be needed to deliver a number of specific measures from the new legislation on pharmacovigilance which were delayed due to the absence of fee income from pharmacovigilance activities. Furthermore, the topic coordinators looked forward to further discussions on the role of the EPL in the framework of reporting on progress of the Review and Reconnect programme.

B.3 Report from the European Commission

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

- Publication of the report on the performance of pharmacovigilance tasks by EMA on 2 May 2014, first report on performance by Member States due by 21 July 2015
- Publication of the regulation on pharmacovigilance fees on 27 June 2014
- Report on the Regulation on advanced therapy medicinal products might lead to a decision by the next Commission on the review of the regulation
- Implementing measures for the Falsified Medicines Directive (Detailed rules for a unique identifier to be adopted by end 2014 at the earliest; principles and guideline of GMP for active substance adopted in May 2014; establishment of a common Eu logo for online pharmacies adoption in June; guideline on GDP for API and risk assessment for GMP for excipients in consultation.) Progress with importation of active substances: lessons learned to be discussed at a future HMA
- Regulation on Clinical Trials Regulation published on 27 May 2014

- Update on timelines for Veterinary Medicines legislation with draft legislative proposal planned for adoption within 2014
- Update on initiatives on antimicrobial resistance
- Status of the revision of the medical devices legislation
- Progress with the Health Technology Assessment Network and possible involvement after 2020 of the European Medicines Agency in long term provisions as well as in the next joint action. This topic should be further discussed in an upcoming meeting of the board.
- Outcome of the eHealth Network meeting, with the agency invited to report on interoperability of pharma databases
- Developments with the ICH reform, VICH and the creation of the International Pharmaceutical Regulators Forum. Progress with the establishment of the International Coalition of Medicines Regulatory Authorities and with the EU-US Trade negotiations
- Update on discussions at the Pharmaceutical Committee concerning adaptive licencing and timely access of patients to medicines.

A representative of the European Parliament asked that a report on the annual activity of CAT and its costs should be prepared and sent to the European Parliament and European Commission. This would allow to evaluate the possibility to modify the present legislation and include some experts of the CAT Committee into the CHMP. In addition, this would reduce the cases of possible conflicts among experts and balance the final opinion, putting as priority objective the health needs of the patients.

Concern was expressed on the high price of some new molecules, which place them above the budget of some Member State. The Commission has no competence in this matter, but encouraged Member States to look at the upcoming joint procurement agreement, which originates from the experience with pandemic vaccines, but might be used for other medicines. Also some Member States have modified their legislation to allow for off-label use motivated by costs in addition to public health reasons. The Commission is preparing a report on off-label use, taking account of the legal situation in some countries.

B.4 Addendum to Cooperation Agreement between EMA and NCAs

[EMA/MB/258645/2014; EMA/MB/292242/2014; EMA/MB/337289/2014] The Management Board adopted two addenda to the Cooperation Agreement between the European Medicines Agency and the National Competent Authorities. Annex 1, addendum 3 is necessary for remuneration under the pharmacovigilance fees legislation to be applied once the fees are implemented. The addendum includes KPIs from the Pharmacovigilance Fee Regulation. Annex 1, addendum 4 relates to changes necessary to align with the revised Financial Regulation, the Lisbon Treaty and procedures on data sharing with the FDA. The pilot on monitoring of a subset of Quantitative Key Performance Indicators (KPIs) will continue until the expiry of the Cooperation Agreement on 31 December 2015. The addenda will be signed individually by the NCAs.

B.5.a Revision of rules for reimbursement for delegates and experts attending meetings

[EMA/MB/270653/2014; EMA/MB/270654] The board adopted revised Rules for reimbursement for expenses for delegates and experts attending meetings. The revision introduces a flat-rate reimbursement of 0.5 daily allowance for travel to and/or from the place of meeting outside a meeting day.

B.5.b Compensation of employers of the Committee Chairperson

[EMA/MB/349441/2014] The Management Board endorsed the principle of recognising compensation to employers of the Committee Chairpersons. The Agency put forward the proposal in light of the increasingly complex pharmaceutical legislation, which has expanded responsibility and workload for the chairs, who cannot perform their duties fully at a national level. The Executive Director has a legal responsibility for the good functioning of the committees, and for the interaction between them. He therefore asked the European Commission to explore further with a view to finding a solution and to update the Management Board at the next meeting in October.

The proposal was supported by the board, which is well aware of the effort and time-commitment required from chairs. The representative of the European Commission assured the board of their good will in finding a solution, which should, however, be fair, have a sound legal basis and be in line with practices in the EU. He could not commit to a solution being found by October since several Commission Services need to be involved and any solution would not be limited to the European Medicines Agency. The board will in any case be updated in October.

B.5.c Harmonisation of payments to NCAs for applications with fee reductions

[EMA/MB/150667/2014] The board adopted a harmonisation of payments to NCAs to keep them financially neutral when a fee reduction is granted to applicants. In the light of the recent budget review for 2014 this applies to Fee Regulation 297/95 Article 9 (1st paragraph, human and veterinary), minor uses, minor species, pandemic (human) scientific advice and post-authorisation (except annual fee).

B.6. EMA Internal Audit Charter

[EMA/MB/264031/2014; EMA/145450/2014] The Management Board adopted the Audit Charter which has been revised to reflect the new Financial Regulation and new reporting duties by the Audit Function to the board.

B.7 IAS consultancy report on IT Project Management

[EMA/272472/2014; Ares(2014)951143 – 27/03/2014] The board noted the IAS consultancy report on IT project management in the European Medicines Agency and the actions taken by the agency. The report had been sent to board members on 3 April by the Chair, who had decided to monitor closely the resulting corrective actions. The audit was requested by the agency to the IAS in August 2013 to provide assurance on effectiveness of projects and on their control. Following the audit recommendations several changes were implemented, among which the establishment of a new structure for programme and project management, the reassignment of accountability for programmes to business and the transfer of budget accountability. The full draft action plan will be circulated to the board.

B.8.a 2013 annual reports of Audit Activities at the Agency Annual Internal Audit Report (IAS-EC) 2013 and B.8.b Annual Report of the Internal Audit of EMA 2013

[EMA/MB/272800/2014; Ares(2014)1119073-09/04/2014; EMA/MB/272889/2014; EMA/76509/2014] The Management Board noted the Annual Internal Audit Report for 2013 by IAS and the Annual Report of the Internal Audit of EMA 2013. The Head of audit reminded the board that as required by the new

Financial Regulation a report will be provided to the Executive Director and to the Management Board each year. An audit plan will be submitted for the approval of the board at the December meeting. The two reports presented show a good performance by management. Recommendations are addressed speedily, no critical recommendations are still open, and only a few other actions remain to be closed. The Head of audit looked forward to closer cooperation with the board.

B.9 Telematics Strategy

[EMA/MB/325379/2014; EMA/289808/2014] The Management Board endorsed the EU Telematics Strategy 2014-2016. The strategy contains the new governance structure and builds on the vision of a European IT collaboration that will deliver a broad range of cost-effective, efficient and inter-operable services to the European Medicines Regulatory Network and to its stakeholders. The document contains specific objectives but must be seen as a living document to be updated by the EU Telematics Management Board if the need arises. The strategy will be presented for final endorsement to the HMA at their meeting in July.

B.10 Proposal for the establishment of an AD hoc expert group on VEterinary Novel Therapies (ADVENT)

[EMA/299310/2014; EMA/CVMP/139369/2014] The Management Board endorsed the Mandate, objectives and rules of procedure for the CVMP Ad Hoc Group on Novel Veterinary Therapies (ADVENT). The proposal comes after the agency opened in 2013 the Innovation Task Force to veterinary products. CVMP further confirmed that there is a need for guidance at class level for technologies that are new to veterinary medicine. The ad hoc experts group will be composed of a small core group of experienced regulators, supplemented by specialist groups for specific technologies. These will be disbanded once the relevant guidance has been produced. The ad hoc group will operate for an initial period of two years, after which its work will be reviewed by the CVMP and the resulting report will be considered by Management Board when deciding if the mandate should be renewed.

B.11 Report by the Steering Group on the Management Board data gathering initiative

[EMA/MB/333172/2014; EMA/MB/333935/2014; EMA/MB/49037/2014] The board noted progress with the data gathering initiative and discussed the mandate of the Steering Group. A first interim report was presented to the board, proving information on the approach developed by the Steering Group. An evidence base is currently being built, mapping out EMA-related tasks specified in all the relevant legislation, activities being carried out by the NCAs and EMA to support EMA-related processes, fees and income streams collected by EMA that fund these activities. An updated mandate was presented to propose chairmanship held by a trio composed of representatives of the European Commission, the Agency and the Member States. The board agreed on principle, and will adopt the mandate by written procedure once the Member State representative has been nominated.

The representative of the European Commission informed the board that it is not yet known at what point in time the independent assessment of the data will take place, but that the board will be informed as soon as possible. Furthermore as an impact assessment normally provides for several options, the Steering Group should not engage in statements of principles, but focus on the good work done so far on data gathering.

B.12 Update on the implementation of Pharmacovigilance Legislation New proposal for improving the RMP process

[EMA/MB/329595/2014; EMA/37444/2014] The board noted the document on Improving the revised RMP assessment process. Review of the experience with the revised RMP assessment process implemented in July 2012 had identified issues concerning implementation of the 'third eye principle' and the current gap week between PRAC and CHMP/CMDh meetings. An agreement was reached after discussion with CHMP and PRAC (Vice)chairs, and was subsequently endorsed by PRAC and CHMP in May.

B.13 EMA policy on the publication of and access to clinical data

[EMA/MB/333011/2014; EMA/240810/2014] The Management Board discussed the European Medicines Agency policy on publication of clinical data, endorsed the direction and approach taken, as well as the proposal by the Executive Director to include a more user-friendly solution for academic and non-commercial research purposes, allowing to download, save and print the same clinical data already available for general information purposes on screen. The journey of the policy started following a public workshop in 2012 and went through two rounds of public consultation. During the first round an exceptional number of contributions were received. Following this, a targeted stakeholder consultation took place in May 2014 after the Management Board had agreed on a set of key principles at the March meeting. In the current absence of specific legal provisions in Regulation (EC) 726/2004 for publication of such data, the policy provides provisions for additional transparency developed according to Art. 80 of the Founding Regulation. Positions of stakeholders have been very polarised, and compromise positions were needed.

The representative of the European Commission (SANCO) pointed out the importance that documents, particularly those intended for adoption or endorsement by the board, are submitted well in advance of the meetings as many of these documents require internal consultation within the Commission. As regards the proposed policy on publication of clinical data, he informed the board that the letter by the General Director circulated to the board is the result of discussions with other Directorates General and generally supports the policy while providing a number of comments and suggestions, such as a clear statement that the policy does not prejudice access to documents under Regulation (EC) 1049/2001. The publication of a document summarising results of the consultation together with a Q&A document will be very helpful. Furthermore, another Commission representative (ENTERPRISE) underlined the importance of practical arrangements that should be defined and be put in place before entry into force of the new policy.

The board supported the proposal for a further step towards user-friendliness. In particular the representatives of Patients' and Healthcare professionals' organisations welcomed this development. Suggestions were put forward, such as on ensuring timely provision of information on upcoming publication of studies based on the data obtained and on identification and handling of commercially confidential information. Given the strong desire by the board to proceed swiftly, it was agreed for the Agency to submit by 20 June an updated text taking into account comments made for a two-week written adoption procedure. Should the written procedure not be finalised by then, the draft policy would be discussed again at the October meeting.

Post meeting note: the written procedure was started on 20 June and was suspended on 7 July after numerous comments were received from members of the board. A full record of all comments received was circulated to the board on 22 July in preparation for further discussion at the next meeting of the Management Board.

B.14 Annual report on the performance of the Agency's scientific procedures

Deferred to the next meeting.

B.15 Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA "eligibility"

a) Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA eligibility

b) Criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency activities

c) Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency (EMA) activities

[EMA/MB/247583/2014; EMA/566453/2012; EMA/24913/2005 Rev. 2; EMA/1661137/2011 Rev.1] The board adopted the document on Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA eligibility, and consequently the revisions of the Criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency activities and of the Criteria to be fulfilled by healthcare professionals' organisations involved in the European Medicines Agency activities. The document on evaluation was needed to define how financial information provided by each organisation is used to conclude whether that organisation is eligible to take part in agency activities. For the new evaluation process a set of updated information will need to be provided by the organisations. During the evaluation process the agency will look at four different parameters, among which is diversity of funding and the organisation's transparency regarding their sources of funding. The new process will apply immediately for organisations that are new to the agency, and within 18 months for already eligible organisations.

B.16.a Opinion on the Agency's annual accounts for the financial year 2013

[EMA/MB/291478/2014; EMA/MB/292607/2014; EMA/277014/2014; EMA/292683/2014; EMA/14575/2014] The Management Board noted the Final Accounts for the financial year 2013, the Court of Auditors' preliminary observations and the Agency's reply as well as the Report on budgetary and financial management of the agency and adopted the Opinion on the Final Accounts for the Financial Year 2013. The board noted with satisfaction that no observation had been put forward by the Court of Auditors concerning accounts, procurement and recruitment procedures. The final accounts will be sent together with the opinion of the Management Board to the Union institutions.

B.16.b Mandate for the Executive Director to sign the lease and all associated documents for 30 Churchill Place

[EMA/MB/340709/2014; EMA/343507/2014] The Management Board adopted a mandate for the Executive Director to sign the lease and all associated documents for the Agency's new headquarters at 30 Churchill Place.

A.O.B.

Documents for information

- Update on Telematics from the EU Telematics Management Board (EU TMB)
- Report from the Heads of Medicines Agencies
- Outcome of written procedures during the period from 22 February 2014 to 12 May 2014
- [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.
- Letter from the European Commission Ares(2014)1905076 - 11/06/2014

Written procedures from 22 February 2014 to 12 May 2014

- Consultation no. 02/2014 on the appointment of Panayiotis Triantafyllis as CHMP member, proposed by Cyprus, ended on 7 March 2014. The mandate of the nominee commenced on 8 March 2014.
- Consultation no. 03/2014 on the appointment of George Savva as CHMP alternate, proposed by Cyprus, ended on 7 March 2014. The mandate of the nominee commenced on 8 March 2014.
- Consultation no. 04/2014 on the appointment of Filip Josephson as CHMP alternate, proposed by Sweden, ended on 2 April 2014. The mandate of the nominee commenced on 3 April 2014.
- Written procedure for adoption of 83rd Management Board meeting minutes ended on 5 May 2014. The minutes were adopted.

List of participants at the 84th meeting of the Management Board, held in London, 12 June 2014

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria		Zlatina Gueorguieva
Czech Republic	Doubravka Kostalova	
Croatia		Viola Macolić Šarinić
Denmark	Else Smith	Matilde Kyst Behrens
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	Kristen Raudsepp	
Ireland	Pat O'Mahony	
Greece	Katerina Fameli	
Spain	Belén Crespo Sánchez-Eznarriaga	
France	Dominique Maraninchi	Jean-Pierre Orand Miguel Bley
Italy	Luca Pani	Pietro Erba
Cyprus		*Apology received*
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg		*Apology received*
Hungary	Beatrix Horváth	
Malta	John Joseph Borg	
Netherlands	Hugo Hurts	Constant van Belkum Birte van Elk
Austria	Christa Wirthumer-Hoche	
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Hélder Mota-Filipe	Maria Morais
Romania	Marius Savu	
Slovakia	Jan Mazág	
Slovenia	Matej Breznik	Katarina Štraus
Finland		Pekka Kurki
Sweden		Bengt Wittgren
United Kingdom		Ian Hudson Saira Madden
European Parliament	Giuseppe Nisticò Björn Lemmer	
European Commission	Gwenole Cozigou (DG ENTR)	Andrzej Rys (DG SANCO) Lenita Lindstrom Chloe Spathari
Representatives of patients' organisations	W.H.J.M. Wim Wientjens Nikos Dedes	
Representative of doctors' organisations	Wolf-Dieter Ludwig	

	Members	Alternates (and other participants)
Representative of veterinarians' organisations	*Apology received*	
Observers	Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) Audan Hågå (Norway)	

European Medicines Agency	Guido Rasi Andreas Pott Noël Wathion Hans-Georg Eichler Agnès Saint Raymond Stefano Marino David Mackay Zaïde Frias Enrica Alteri Alexis Nolte Fergus Sweeney Nerimantas Steikūnas Emer Cooke Hilde Boone Edit Weidlich Michael Lenihan Anthony Humphreys Sylvie Benefice Isabelle Moulon Martin Harvey Allchurch Dina Tsiambaou Frances Nuttall Ulrike Nagl Silvia Fabiani Sophia Albuquerque	