4 August 2010
EMA/MB/404038/2010

Minutes of the 67th meeting of the Management Board

Held in London on 10 June 2010

The Vice-Chair, Lisette Tiddens-Engwirda, opened the meeting by welcoming meeting participants and by asking Members to declare any specific interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interests were declared.

Election of the Management Board Chair

The Vice-Chair continued to chair the meeting during the election process of the Management Board Chair. In accordance with Management Board Rules of procedure there are 35 voting members in the Management Board, 28 members were present at the time of the election and 4 proxies were received: from the Czech Republic to Denmark, DG Enterprise to DG Sanco, Greece to Italy and Sweden to Slovenia. In total there were 32 votes cast. Observers from Liechtenstein and Norway were appointed as tellers.

The Management Board re-elected Pat O'Mahony as its Chair for a new three-year term, by unanimous vote.

32 votes cast	
Pat O'Mahony	32

1. **Draft agenda for 10 June 2010 meeting**

[EMA/MB/210895/2010] The agenda was adopted with amendments to agenda item 14.

2. **Declaration of conflict of interests**

This item was considered at the beginning of the meeting by the Vice-Chair.

3. **Minutes from the 66th meeting, held on 17-18 March 2010**

[EMA/MB/194352/2010] The Management Board noted the final minutes, adopted by written procedure on 26 April 2010.

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4. **Highlights**

Lessons learned during the volcanic eruption

Due to the disruption of travel following the volcanic eruption in Iceland, the Agency's Committee for Medicinal Products for Human Use worked extensively using teleconferencing tools. The experience was largely welcomed by the committee Chair and members. Currently, the Agency uses teleconferencing for meetings involving small numbers of participants. However, if combined with physical meetings of the scientific committees, the use of other meeting technologies would increase the efficiency of the use of scientific resources. CHMP and CVMP meetings are already broadcast internally and now the technical facilities are available to broadcast to national competent authorities. A detailed report on lessons learned will be provided for the October meeting. The Management Board telematics committee will prepare an overview of available options.

European Commission initiative on vigilance system for substances of human origin: cells, tissues, blood

Following the discussion at the March 2010 meeting about the allocation of responsibility within the EU on a vigilance system for substances of human origin, the Executive Director wrote a letter to the European Commission that was followed by a discussion between DG Sanco and EMA staff. When deciding where to allocate the responsibilities for the new task, the European Commission may consider whether to combine the capacities and experience of collaboration of the two agencies (EMA and ECDC).

The European Commission study estimates that 5-7 full time equivalents will be needed for this task. However, the European Commission representative stated that the Commission will be unable to allocate additional resources and the tasks will have to be accommodated within the existing human and financial resources at either Agency. The Management Board asked the European Commission to provide the aforementioned study before it can respond about the Agency's ability to take on the new responsibility. A group of the Board's topic coordinators (Austria, France, Denmark and the Chair) together with the Agency's staff will reflect on the proposal. A separate discussion with the ECDC will be organised.

Ombudsman and access to EMA documents

In the context of the two appeals, the European Ombudsman concluded that the Agency has to grant access to adverse drug reaction reports and clinical trial data.

Providing such access demands significant resources for the Agency. Legislation on access to documents requires making documents held by the Agency public, while the requirements to safeguard commercially confidential information and personal data restrict access. Adverse drug reaction reports contain a large number of fields which need to be reviewed to protect the identity of a person when granting access to the report. The number of data fields to be removed varies in different cases. As a consequence, resources needed to respond to a single request are currently disproportionate.

The Agency works to address the issues and will adopt the same approach to data released reactively and proactively. Common systems need to be developed for proactive release of information. However, an agreement on what information should be considered confidential is pending.

In the meantime, the Agency will present its proposals for the policy on access to documents, which will also address the release of clinical trials data following completion of procedures, at the July meeting of the Heads of Medicines Agencies.

Chairs of management boards of EU agencies

The second meeting of the chairs took place on 31 May 2010. Fourteen agencies participated and elected Pat O'Mahony as the chair of the group. The group met with a Commission representative to discuss the findings of the evaluation of the EU agencies carried out by the European Commission in 2009.

New appointments

The Executive Director announced the appointment of Jean-Claude Brival as head of the newly created Product Data Management Sector in Veterinary Medicines and Product Data Management Unit and Alexis Nolte as head of the Sector for Quality of Medicines.

5. Outcome of the evaluation of the Agency

The Management Board noted the outcomes of the evaluation of the Agency which was conducted in 2009 at the request of the European Commission. The conclusions of the evaluation are positive and highlight the effectiveness and the efficiency of the Agency, as part of the network, as well as recognising its contribution to EU policies. The whole report can be found on the website of the Commission: http://ec.europa.eu/health/files/pharmacos/news/emea_final_report_vfrev2.pdf

The European Commission and the Agency will organise a conference on 30 June 2010 to discuss the outcomes of the evaluation with stakeholders. The proposals coming from the discussions will be classified into those requiring legislative changes and those that can be implemented without changing the legislation.

6. Analysis and assessment of the Executive Director's annual activity report 2009

[EMA/MB/297535/2010; EMA/MB/168222/2010] The Management Board adopted the analysis and assessment of the annual activity report 2009. The Board gave a positive assessment of the Agency's performance on a broad range of issues in 2009.

The Executive Director's report covers the achievements in key policy areas as well as describes the management system to provide reasonable assurance on the effective and efficient use of resources to achieve the policy objectives. The report contains the Executive Director's declaration of assurance.

The Board thanked the topic coordinators – Jytte Lyngvig, Pat O'Mahony and Kristin Raudsepp – for preparing a comprehensive draft analysis and assessment of the report.

7. Review of fees payable to the EMA (Fee Regulation)

[EMA/MB/276960/2010; EMA/319831/2010] The Management Board noted the Agency's report to the European Commission providing the Agency's views on the experience with the Fee Regulation.

The current fee system consists of around 130 different fees. The system is complex and therefore requires simplification, while assuring sustainability and providing needed flexibility. During its discussion, the Board reflected on the issue that a significant amount of work done by the national competent authorities is not compensated in the current fee system. The Board stressed that it is essential for the national competent authorities to recover the costs fully. It is important to have a linkage between the volume of work and the resources made available to carry out the required work. Otherwise, the national competent authorities may have significant difficulties contributing to activities which are important for public health. The Board made a general scrutiny reservation about the report.

The report will be reviewed by the European Commission in preparation of the Commission's report to the Council on the implementation of the Fee Regulation by November 2010. Following this, the Council will give its advice on whether the Fee Regulation needs to be reviewed. The topic will also be addressed in the EC/EMA conference on the outcomes of the evaluation of the Agency.

8. Preparation for a written procedure on adoption of the Agency's final accounts for the year ending 31 December 2009

[EMA/MB/289198/2010] Pending the receipt of the opinion of the Court of Auditors on provisional accounts, a written procedure will be launched shortly to adopt the Management Board opinion on the Agency's annual accounts for the year ended 31 December 2009. Following the adoption, the Board's opinion and the final accounts will be sent to the relevant EU institutions.

9. Update on future accommodation of the Agency

The lease of the Agency's premises expiries in 2014. The Agency started work to identify and review options for future accommodation taking into account financial and functional requirements, including accessibility of the Agency by experts. The decision on the option may need to be taken this year to allow adequate time to involve relevant EU institutions and to prepare the Agency for changes, if necessary. The Board constituted a group of topic coordinators to work together with the Agency's staff: Chair, Vice-chair, Kent Woods, Giuseppe Nisticò, Guido Rasi. A further update will be provided in October.

10. Procedure for the appointment of the Executive Director

[EMA/MB/372194/2010, EMA/MB/400828/2010] The Management Board noted the decision of the European Commission to re-open the vacancy announcement following advice of the European Commission legal service with regard to a wider publication of the vacancy. The re-opening of the vacancy will be announced by 26 June with a four-week deadline for applications. The Board was advised of the list of scientific, international and national publications in which the announcement is to be placed. The procedure for the appointment of the Executive Director will be discussed in October.

The European Commission will contact the candidates and those applicants who were late to send their applications to explain the procedure. The Board also asked the European Commission to assure timely communication with the Board at the highest level.

In case an Executive Director cannot be appointed by the end of 2010 or is unable to start office from 1 January 2011, the Board asked the Executive Director to inform the Board about the arrangements to appoint an interim director for discussion at the October meeting.

10bis Appointment of Accounting Officer ad interim

[EMA/MB/354158/2010] The Management Board endorsed the appointment of an ad interim accounting officer until the return to office of the accounting officer.

11. Management Board meeting dates 2011

[EMA/MB/298674/2010] The Management Board adopted its meeting dates for 2011 and noted tentative meeting dates for 2012. The dates for 2011 are as follows: 16-17 March, 9 June, 6 October and 15 December.

12. **Key principles of a revised policy and procedure for the handling of conflicts of interest**

[EMA/MB/311343/2010; EMA/255244/2010; EMA/MB/353273/2010] The Management Board discussed and agreed in principle on a way forward for introducing changes to the way the Agency handles potential conflicts of interests of experts involved in the evaluation of medicines. The Board also considered the analysis of the impact of proposed changes on the current membership of the committees and scientific advisory groups.

The Board stressed that it is of utmost importance to guarantee the involvement of best scientific expertise to ensure assessments of the highest quality. Therefore, the right balance between restricting the involvement of experts with conflicting interests in the Agency's activities and ensuring the availability of the best scientific expertise to support the Agency's scientific opinions should be ensured.

Transparency is the key aspects of the new proposals. Amongst other measures to increase transparency, all declarations of interests submitted by the experts will be systematically published on the website. The proposals will be implemented in a stepwise approach. The Board recognised that practices adopted at the EMA will impact on the arrangements put in place at the national level.

Written comments were invited within 2 weeks after the meeting. The final adoption of an updated policy is expected in October 2010. The Board thanked the topic coordinators –Jean Marimbert and Lisette Tiddens – for their contribution to this work.

13. **Referrals to CVMP of veterinary medicinal products: a report from the Agency**

[EMA/MB/282448/2010] The Management Board heard the report on arbitration and referral activities of the CVMP. Activities related to referrals increased since the 2004 review of legislation. While the number of referrals for arbitrations arising from consideration of applications by CMDv eased, the referrals taking up increasingly resources of the Committee and the Agency secretariat relate particularly to harmonisation and 'Community interest' referrals which set precedents and practice that will be followed in subsequent, similar cases. The Board was informed that the CVMP established a Task Force on referrals which will review strategic options for the harmonisation of products, develop a methodology for prioritisation of issues for referral and will develop proposals in relation to future legislation concerning veterinary medicinal products on issues related to referrals.

14. **Nominations to CVMP and CHMP under consultation**

[EMA/MB/298741/2010] The Management Board discussed two ongoing consultation procedures: one for the CVMP and one for the CHMP. During the discussion, the Management Board considered both nominations in their wider context of the workings of the Committees and reflected favourably on both of the nominees' background and professional experience, with the exception of the European Parliament representative, Prof. Giuseppe Nisticò, who asked that his specific remarks be included in the minutes: "The previous Polish CHMP member's curriculum, who was considered in the CHMP as the reference member for assessment of drug treatment in respiratory diseases, is much more specific and appropriate in terms of regulatory and clinical competence, as opposed to that of the newly proposed member. The activity of the newly proposed member in his capacity of a surgeon is only very marginally linked with the objectives of the CHMP. The newly proposed member never worked as a member of the CHMP and has no specific experience as an employee at the National Medicines Agency. Therefore for all the aforementioned reasons, Prof. Nisticò does not endorse the nomination of the new nominee from Poland as CHMP member".

In response to this observation, the Polish representative to the Board emphasised that: "The decision to nominate a candidate to the CHMP is a sovereign decision of a Member State and Poland based its decision on the candidate's scientific background and professional experience."

15. **Contractual arrangements: monitoring of key performance indicators**

[EMA/MB/302460/2010] The Management Board had adopted revised contractual arrangements which contain a number of key performance indicators. The Management Board endorsed the subset of key performance indicators which will be monitored and reported upon.

The first report is expected at the beginning of 2011. The number of indictors will be expanded in future, once experience with the agreed indicators is gained and systems for reporting on other indicators are established.

16. **Draft reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA**

[EMA/MB/338709/2010; EMA/712397/2009] The Management Board noted the draft reflection paper, which elaborates on four areas of action from the strategy paper 'Acceptance of clinical trials conducted in third countries for evaluation in Marketing Authorisation Applications'.

The actions encompass EMA processes having an impact on clinical trials carried out at different stages of the lifecycle of medicinal products and the relationship with regulators in all parts of the world, with a view to achieving a robust framework for the oversight and conduct of clinical trials.

The reflection paper has been released for public consultation until 30 September 2010. A workshop will be organised on 6-7 September 2010 as part of the consultation process, to which a wide range of EU and third-country regulators and stakeholders will be invited. The Board noted the proposed agenda of the workshop. A high-level update on the outcomes of the workshop will be provided to the Management Board in October.

17. **EudraVigilance status report 2009**

Human medicinal products

[EMA/MB/345587/2010] The Management Board discussed the new format of the EudraVigilance report. In addition to information that used to be provided previously, the report now elaborates on how EudraVigilance contributes to the conduct of pharmacovigilance in the EU. The report contains information for 2009 on what action has been taken by the rapporteur and the regulatory outcome, where relevant.

The report will now be presented to the HMA in July and published on the Agency's website. The Board discussed the possibility of publishing, in future, information on Member States' compliance with the legal timeframe of 15 days for transmission of individual case safety reports (ICSRs) to the Agency.

Veterinary medicinal products

[EMA/MB/13787/2009] The Management Board noted the update report on the implementation of EudraVigilance for veterinary products.

18. **Memorandum of understanding between the EMA and the NCAs on the monitoring of the scientific level and independence of evaluations**

[EMA/MB/311466/2010] The Management Board discussed the memorandum of understanding (MoU) which clarifies the responsibilities between the EMA and national competent authorities for monitoring of the scientific level and independence of evaluations. The Board recognised that the arrangements on handing of conflicts of interest differ in different Member States and this needs to be reflected in the memorandum. The updated document will be presented at the HMA meeting in July and submitted to the Management Board for adoption by written procedure. Pending completion of these steps, the Board expressed a scrutiny reservation.

Further reflection may be needed at the HMA level as to whether it would be useful to agree on a minimum set of standards with regards to handling of conflicts of interest which could be used in the national arrangements. Members suggested that a questionnaire be prepared to gather and share information on what practices are put in place in NCAs with regards to the handing of conflicts of interest.

19. **Report from the European Commission**

The members noted the update report from the European Commission on a range of topics, including the following:

- The political agreement on cross-border healthcare directive.
- Progress on legislative proposals on pharmacovigilance, falsified medicines and information to patients.
- The ongoing work with a view to reviewing the Clinical Trials Directive. A new legislative proposal may be adopted by Autumn 2011.

20. **Report from the Heads of Medicines Agencies**

The members noted the update report from the Heads of Medicines Agencies (HMA) on a number of topics, including:

- The progress on the HMA strategy paper. The HMA aims to complete the paper by the end of this year.
- A strategic discussion on the benefits of e-readiness and the different systems being used by medicines agencies to work in an electronic-only environment.
- Improving linkage between HMA and medical devices competent authorities. HMA supported the constitution of a permanent group of medical devices competent authorities.

Documents for information

- [EMEA/221701/2010] Update report on the Agency's implementation of the EU telematics strategy.
- [EMA/MB/281850/2010] Outcome of written procedures during the period from 26 February 2010 to 2 June 2010.
- [EMEA/MB/298753/2010] Summary of transfers of appropriations in the budget 2010.

Tabled documents

- Agenda point 10_Advertisement of the vacancy notice for the recruitment of the Executive Director for the EMA.
- Discharge from the European Parliament on the EMA final accounts for the financial year 2008.
- Overview of the allowable conflicts of interests for the various EMA activities.
- Presentation on key principles of a revised policy and procedures on the handling of conflicts of interests of scientific committees' members and experts: Impact analysis and proposed way forward.

List of participants at the 67th meeting of the Management Board, held in London, 10 June 2010

Chair: Pat O'Mahony

	Members	Alternates and other participants
Belgium	Xavier De Cuyper	
Bulgaria	Jasmina Mircheva	
Czech Republic		Jiří Deml
Denmark	Jytte Lyngvig	
Germany	Walter Schwerdtfeger	
Estonia	Kristin Raudsepp	
Ireland		Rita Purcell
Greece	*Apologies*	
Spain	Cristina Avendaño-Solà	
France	Jean Marimbert	Miguel Bley Patrick Dehaumont
Italy	Guido Rasi	Silvia Fabiani
Cyprus	*Apologies*	
Latvia	Inguna Adoviča	
Lithuania	Gyntautas Barcys	
Luxembourg	Claude A Hemmer	
Hungary		Beatrix Horváth
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Wojciech Matusewicz	Grzegorz Cessak
Portugal	Jorge Torgal	Nuno Simoes Hélder Mota Philipe
Romania	Daniel Boda	
Slovenia	Martina Cvelbar	
Slovakia	Jan Mazág	
Finland	Sinikka Rjaniemi	
Sweden		Christer Backman
United Kingdom	Kent Woods	
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission	Isabel de la Mata	Nathalie Chaze Tiziana Palmisano
Representatives of patients' organisations	Mary G. Baker Mike O'Donovan	
Representative of doctors' organisations	Lisette Tiddens-Engwirda	
Representative of veterinarians' organisations	Henk Vaarkamp	
Observers	Einar Magnússon (Iceland) Brigitte Batliner (Liechtenstein) Gro Ramsten Wesenberg (Norway)	

European Medicines Agency	**Thomas Lönngren**	**Riccardo Ettore**
	Patrick Le Courtois	**Martin Harvey Allchurch**
	David Mackay	**Frances Nuttal**
	Andreas Pott	**Mario Benetti**
	Hans-Georg Wagner	**Yoshikazu Hayashi**
	Noël Wathion	**Arielle North**
	Hans-Georg Eichler	**Nerimantas Steikūnas**