European Medicines Agency

EMEA/MB/366757/2009/EN/Rev.1*
1 October 2009

Minutes of the sixty-third meeting of the Management Board
London, 11 June 2009

1. Draft agenda for 11 June 2009 meeting

[EMEA/MB/45799/2009] The agenda was adopted.

2. Declaration of conflicts of interest

Members were asked 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.

3. Minutes from the 62nd meeting, held on 4-5 March 2009

[EMEA/MB/45799/2009] The Management Board noted the adoption of the minutes by written procedure.

4. EMEA highlights from the Executive Director

New appointments
The Executive Director announced the appointment of Edit Weidlich as head of the Agency's internal audit and Fergus Sweeney as head of the Agency's inspections sector.

Update on EMEA work in relation to novel influenza
The Management Board heard an update on the Agency's work in the field of novel swine influenza (so called A/H1N1). The Agency has done significant work on antiviral medicines to date. Specifically, the scientific committee reviewed scientific information and recommended extending the shelf life of Tamiflu from 5 to 7 years; it also provided an opinion on the use of antiviral medicine Tamiflu in children under one year and in pregnant and breastfeeding women. A similar extension was approved for Relenza by the Member States.

Currently, the Agency is in dialogue with manufacturers of vaccines and with European and international regulators to discuss scientific and regulatory issues in order to facilitate the availability of vaccines for use in an influenza pandemic situation. In preparation for the bird flu pandemic, the Agency has developed a novel approach using a mock-up virus for assessment of pandemic vaccines. The Agency works with vaccine manufacturers to identify the required data to allow for the modification of the marketing authorisation which would replace the current mock-up virus with one of the A/H1N1-derived pandemic-like strains as recommended by the WHO.

In addition to the centralised regulatory approval, there may be for some A/H1N1 vaccines the option to obtain approval via national authorisation routes. The Management Board stressed that it is essential to come to an agreement at the EU and intentional levels on the requirements for pandemic vaccines.

* Revision refers to amendements made in item 16.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu www.emea.europa.eu

The members welcomed the significant work done in the area to date. The Board expressed a concern that once vaccines are developed the regulators will be under significant pressure from various parties to authorise the products. The benefit/risk evaluation of vaccines needs to be conducted taking into account the infectivity and virulence potential of the virus.

The Executive Director thanked the members of the Committee for Medicinal Products for Human Use and vaccine working party for their work in the field.

Paediatric investigation plans
The Management Board was informed that the court of first instance dismissed a company's application in relation to suspension of the Agency's decision and the adoption of interim measures.

5. The Annual Activity Report 2008 and the Analysis and assessment of the Annual Activity Report 2008

[EMEA/MB/186559/2009; EMEA/MB/319028/2009] The Management Board adopted the analysis and assessment of the Executive Director's annual activity report 2008. The analysis and assessment will be sent to the budgetary authority and the Court of Auditors.

The Management Board welcomed the results of the Agency's operations in 2008 and the strong contribution of the EMEA to EU-wide efforts in support of making high-quality, safe and effective medicines available for use in human and animal populations. The Board noted the progress made in the previous year, major developments in the management and control systems and conclusions of audits. The Board expressed concern about the European Commission's intention to cancel the arrangements which allowed treating positive balance of the Agency's outturn account as 'earmarked revenue' for the Agency for subsequent years. This becomes an emerging risk for the financing of the Agency in the light of the likely negative financial impact of the revised variations regulation, uncertainty of the impact of a new payment system to Member States and the current economic climate.

The Board thanked the topic coordinators (Mindaugas Būta, Jytte Lyngvig Marcus Müllner, Pat O'Mahony and Kristin Raudsepp) for detailed review of the report and the proposed analysis and assessment.

6. Budget 2010 update

The Management Board noted the developments in the budgetary procedure for 2010. For 2010, the EMEA requested a European Commission contribution of € 45 million for the conduct of public health-related activities. The European Commission indicated that it will propose to reduce this request by € 9 million. As discussed above, in addition there is a proposal at the Commission to cancel the earmarked revenue from the 2008 surplus. The retention of surplus (reserve) is important to provide stability to the Agency in case of reduction in the fee revenue, particularly in the light of risk factors mentioned above. The EMEA will approach the Commission's Directorate-General for Budget expressing these concerns.

7. EMEA corporate-identity project

[EMEA/MB/279887/2009] Following the consultation process, the Management Board considered and endorsed the proposals for the new corporate identity of the EMEA, including the new logo and acronym of the Agency. The proposals aim to create visual identity for the Agency, to further promote its recognition and reputation. The new corporate identity will be rolled out in December 2009, together with the new public website of the Agency.

8. Governance of EU agencies

- **European Commission communication**
- **European Commission guidelines on appointment of directors of the EU agencies**

European Commission communication on EU agencies
The Board was briefed about the ongoing inter-institutional debate on the creation and role of EU agencies. The Commission's Vice-President Margot Wallström leads the inter-institutional working group in which the EU agencies are represented. The group intends to work in three stages: draft the statements in consultation with the agencies under some 35 topics; consider the experience under those topics; make proposals for the future.

The Board discussed that it is important to understand that EU agencies differ in their roles, the sectors they operate in and the stakeholders they are accountable for. This process should be seen as a possibility to recognise EU agencies in the governance landscape of the EU. On the other side, care should be taken to avoid micromanagement of agencies and avoid creating a single model for all agencies that would take away flexibility when implementing tasks under their responsibility.

The Management Board wished to be engaged in the process and the discussions, and be involved more closely during the third stage. The Executive Director undertook to update the Management Board on the progress of the inter-institutional discussions. The Management Board will also be informed of the 35 statements once all the findings have been consolidated.

European Commission guidelines on appointment of directors of the EU agencies
The Management Board discussed the guidelines for appointment of executive directors of EU agencies. The selection and appointment process usually takes approximately 12 months. The Management Board is involved in 4 stages of the process: the provision of the opinion on the vacancy notice, nomination of an observer to a pre-selection committee at the European Commission, nomination of a director from a shortlist proposed by the European Commission, and appointment of the director after the nominee's presentation at a committee of the European Parliament (in the case of the EMEA – the concerned committee is the Committee on Environment, Public Health and Food Safety).

The European Commission guidelines state that directors of EU agencies are appointed at the AD14 grade. The Management Board discussed that the grade should reflect the size and complexity of an agency. The Board considered that the recruitment grade for a future director of the Agency should be increased. The Board will approach the European Commission with a request to review the recruitment grade for the EMEA's director. The decision is at the discretion of the European Commission.

The Board also considered that the nomination of a candidate can take place before June 2010 in a two-day meeting. The appointment process can be done by a written procedure. The Commission will aim to publish a vacancy announcement before the summer break 2009. The notice will be sent to all Board members for comments. The members suggested sending the public vacancy notice through the Heads of Medicines Agencies to the national authorities for publishing on national websites. The Chair invited the members to submit their expression of interests to participate as observers in the pre-selection committee.

9. Draft EMEA transparency policy

[EMEA/MB/305975/2009] The Board adopted the draft EMEA transparency policy for release for public consultation. The members discussed that it is important to reach an agreement among the stakeholders of what constitutes commercially confidential information. Members recognised that the Member States have different legislation and interpretation with regards to transparency and information. It is therefore important to find ways of ensuring a consistent approach throughout the

European Medicines Network, as having different practices would have a negative impact on the network, and robust policies need to be implemented alongside the transparency policy. The members stressed that the policy should be implemented in a stepwise approach, taking into account available resources. Stakeholders' expectations should be managed appropriately.

The comments received at the meeting will be incorporated and the policy will be published for public consultation. The Management Board thanked the Board topic coordinators (Aginus Kalis, Jean Marimbert, Marcus Müllner, Gro Wesenberg) for their contribution. A consequence analysis, including resource needs, will follow this proposal. Measures for the implementation of the policy will be reflected annually in the Agency's work programme. An operational task force for the implementation of the transparency policy will be considered.

10. EMEA policy and procedure on the handling of conflicts of interests of EMEA scientific committees' members and experts

- **Report on experience covering the period 2006–2008**
- **Reflection paper on the way forward**
- **Review of EMEA policy on Handling of Conflicts of Interests of EMEA Scientific Committees**

[EMEA/MB/138548/2009; EMEA/MB/305863/2009; EMEA/MB/356427/2009] The Board heard a presentation on the experience with the policy on the handling of conflicts of interests at the EMEA committees and working parties. The experience shows that the current low level of permissible conflicts of interests restricts the involvement of valuable scientific expertise, which impacts on the work of the scientific committees.

The Management Board considered that it is feasible to increase the level of allowable conflicts of interests, but this needs to be matched with increased transparency to assure the public that opinions and decisions will continue to be reached with utmost independence. Experts with a higher level of conflicts of interests than permitted under the present policy could be allowed to provide their recommendations, but they would not participate in the decision making. Necessary mitigating actions need to be implemented and their conflicts of interests should be made public. These changes would ensure that a future policy would not limit the availability of the best expertise for robust decision making. The permissible level of conflicts of interests of rapporteurs and co-rapporteurs should remain at the present level (level 1).

The Board thanked the EMEA and Management Board topic coordinators (Jean Marimbert and Lisette Tiddens-Engwirda) for their contributions. A proposal taking into account the Board's views will be submitted in December 2009.

11. Simplification of the contractual arrangements between the EMEA and the National Competent Authorities of the Member States: development of a cooperation agreement

[EMEA/MB/284297/2009/Rev.1] The Management Board discussed the first proposal on simplification of contractual arrangements in December 2006. The presented proposal takes into account Management Board comments. The document also includes provisions regarding performance indicators and quality assurance.

The Management Board is invited to send additional written comments to the EMEA by the end of July. The proposal will then be submitted to the Heads of Medicines Agencies for discussion. A revised version will be resubmitted for adoption in October and the signature of the contracts is expected by the end of the year. The topic coordinators (Jean Marimbert and Marcus Müllner) were thanked for their contributions.

12. Amendments to the Fee implementing rules

[EMEA/MB/170391/2009/Rev.2] The Management Board adopted the revisions to Articles 3(2) and 4 of the Fee implementing rules. The revisions concern applications made under Article 29 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use. The amended rules will be published on the Agency's website.

13. Developing the European Medical Information network

[EMEA/MB/306935/2009] The Management Board discussed the proposal to establish a European medical information network. The members invited the Agency to elaborate more on the mandate and role of the coordinating group of the proposed network, the composition of this group and expected competencies of members. Also, further reflection is needed as to the type of support, information and overall added benefit such a network will provide. The proposal will be further reflected upon at the October meeting.

14. Staffing issue

Closed session.

15. EMEA/FDA liaison exchange

The Management Board noted the update report on progress of the preparations for exchange of staff between the EMEA and the US FDA. The FDA colleague will join the EMEA in June. The assignment of the EMEA counterpart is in progress.

16. Rules on attachment of staff

[EMEA/MB/295158/2009] The Board discussed the EMEA rules on attachment of staff. The rules will be submitted for adoption after a positive opinion of the European Commission. The proposed rules transpose the rules that are applied in the European Commission for secondment of their staff to organisations outside the EU.

17. Changes to the Mission rules

[EMEA/MB/694348/2008] The Management Board adopted the rules on missions. The rules follow those of the European Commission with derogation regarding the calculation of the duration of the mission for departure and arrival times from London stations and airports.

18. Resource requirements of the CVMP

[EMEA/MB/301036/2009] The members heard EMEA concerns that due to high number of referrals, the ability of the Committee for Medicinal Products for Veterinary Use (CVMP) to handle these procedures is reaching capacity. This may impact on the Committee's ability to conduct its normal work.

The Agency is preparing proposals on how to manage this increase in workload (some referrals are very large, complex and include some 300-800 products). The procedures are not remunerated, which also impacts on national competent authorities' ability to volunteer for the work.

The proposals, including scheduling of referrals in line with the ability of the Committee to manage them, will be submitted to the Management Board and the Heads of Medicines Agencies.

19. Recommendations from the Management Board group on the consultation of nominations to the committees

[EMEA/MB/300234/2009] The topic coordinators presented three proposals to improve the consultation procedure: the revision of the CV template to obtain more information on scientific qualifications of nominees; a pre-selection panel listing its advantages and disadvantages; and amendments to the request for nomination letter. The group will continue its work presenting the proposals at a Heads of Medicines Agencies meeting. In addition, the members enquired whether it would be useful to determine the level of conflicts of interest of new nominees during the nomination procedure, raising potential issues with the nominating authority. This agenda item will be further discussed at the October meeting.

20. Report from the European Commission

The members noted the update report from the European Commission on a range of topics, including: work on novel influenza and the Council's conclusions regarding strategy for vaccine development; pharmaceutical package and good progress with pharmacovigilance and anticounterfeiting proposals, as well as Member States' concerns over the proposal for drug information provisions.

21. Report from the Heads of Medicines Agencies

The members noted the written report.

22. Preparation for written procedures:

- **Request for opinion on Agency's annual accounts for the year ended 31 December 2008**
- **Preparation for written procedure on amending budget 1/2009**

[EMEA/MB/246063/2009; EMEA/MB/251948/2009] The members noted the information on upcoming written procedures.

Documents for information

- [EMEA/MB/287743/2009] Update report on EMEA implementation of EU telematics strategy.
- [EMEA/MB/282675/2009; EMEA/MB/317275/2009] Reports on EudraVigilance. implementation for human medicines and medicines for veterinary use.
- [EMEA/MB/174828/2009] Revision timing for Implementing Rules to EMEA Financial Regulation.
- [EMEA/11007/2009; EMEA/18113/2009] Annual audit-related reports: Audit advisory committee; EMEA internal auditor; Internal Audit Service of the Commission.
- [EMEA/MB/321843/2009] Outcome of written procedures on: Consultation on changes in the membership of the CHMP and CVMP committees; Fee implementing rules; Annual Report 2008; Fee implementing rules relating to MUMs; Fee implementing rules relating to Pandemic situations.
- [EMEA/MB/90876/2009] Summary of transfers of appropriations in the budget 2009.

Participants at the sixty-third meeting of the Management Board
London, 11 June 2009

Chair: Pat O'Mahony

	Members	Alternates and other participants
Belgium	Xavier De Cuyper	
Bulgaria		Meri Borislavova Peytcheva
Czech Republic	Lenka Balážová	Jiří Bureš
Denmark	Jytte Lyngvig	
Germany	Walter Schwerdtfeger	
Estonia	Kristin Raudsepp	
Ireland		Rita Purcell
Greece	Vassilis Kontozamanis	
Spain	Cristina Avendaño-Solà	
France	Jean Marimbert	Miguel Bley
		Patrick Dehaumont
Italy	Guido Rasi	Silvia Fabiani
Cyprus	Panayiota Kokkinou	
Latvia	Inguna Adoviča	
Lithuania	*Apologies*	
Luxembourg	*Apologies*	
Hungary		Beatrix Horváth
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	*Apologies*	
Portugal		Fernanco Manuel d'Almeida Bernardo
		Hélder Mota Filipe
Romania	Daniel Boda	Rodica Badescu
Slovenia	Martina Cvelbar	
Slovakia	*Apologies*	
Finland		Pekka Järvinen
Sweden	Christina Åkerman	
United Kingdom	Kent Woods	
European Parliament	Björn Lemmer	
European Commission	Heinz Zourek	Irene Sacristan - Sannchez
	Isabel de la Mata	
Representatives of patients' organisations	Mike O'Donovan	

Representative of doctors' organisations	*Apologies*	
Representative of veterinarians' organisations	Henk Vaarkamp	
Observers	Rannveig Gunnarsdóttir (Iceland)	Johannes Löwer (HMA Group)*
	Gro Ramsten Wesenberg (Norway)	
	Brigitte Batliner (Liechtenstein)	
EMEA	Thomas Lönngren	Agnès Saint Raymond
	Patrick Le Courtois	Vincenzo Salvatore
	David Mackay	Mario Benetti
	Andreas Pott	Claus Christiansen
	Hans-Georg Wagner	Emer Cooke
	Noël Wathion	David Drakeford
	Riccardo Ettore	Arielle North
	Beatrice Fayl	Frances Nuttall
	Martin Harvey Allchurch	Nerimantas Steikūnas
	Tony Humphreys	Spiros Vamvakas
	John Purves	

*As part of the cooperation between the Management Board and the Heads of Medicines Agencies, Mr Johannes Löwer, the chair of the HMA management group, participated in the Board meeting as an observer. Mr Johannes Löwer's invitation as an observer is extended to all future meetings of the Management Board.