European Medicines Agency

London, 28 January 2009
EMEA/MB/671250/2008 (EN) Adopted

Minutes of the sixty-first meeting of the Management Board

London, 11 December 2008

1. Draft agenda for 11 December 2008

[EMEA/MB/482475/2007] The agenda was adopted.

2. Declaration of interests

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. Draft minutes of 60th meeting, 2 October 2008

[EMEA/MB/529795/2008] The minutes were adopted without changes.

4. Highlights from the Executive Director

Annual hearing at the European Parliament
The Executive Director gave a report on the performance of the Agency in 2008 and on its future plans at the annual hearing, on 4 November, of the European Parliament Committee on Environment, Public Health and Food Safety. The Committee expressed its satisfaction with the performance of the Agency. Some of the topics discussed at the hearing included: safety of medicines, counterfeit medicines, role of the EMEA in providing information for patients, successful implementation of the orphan medicinal products legislation, antimicrobial resistance (possibility of incentives for the industry), herbal medicines, the EMEA's role and interaction with health-technology assessment bodies, and unequal access time to centrally authorised medicines in various Member States. The Committee requested that the Management Board look into the consultation process related to the appointment of members to EMEA scientific committees.

Committee for Advanced Therapies nominations
Nominations by the Member States of members of the EMEA Committee for Advanced Therapies are progressing well. Only two nominations of members are outstanding. Taking into account declarations of the nominated persons, all fields of required expertise are represented. The procedure to nominate civil-society representatives, being run by the European Institutions, is under way.

Summit of heads of regulatory agencies
The third meeting of the forum of international regulators – a series of meetings that began two years ago – was hosted by the Singaporean authorities on 3-4 December. The meeting focused on the future of regulatory agencies. The meeting addressed in greater detail the issue of clinical trials and manufacturing of finished products, as well as active pharmaceutical ingredients, counterfeiting and herbal medicines. The meeting did not intend to reach any definitive conclusions; instead, the chair's notes will be prepared for the participants. The next meeting will take place in Canada, in 2009.

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Antimicrobial resistance
The emergence of antimicrobial resistance remains a great challenge for 2009. DG SANCO and DG Enterprise created a forum for EU scientific bodies (EMEA, EFSA, ECDC and DG SANCO's Scientific Committee on Emerging and Newly Identified Health Risks) to cooperate on a review of the use of antibiotics and of risks associated with their use. Members of the forum will assist DG SANCO as risk managers in considering the need for enhanced risk-management measures with respect to limiting the risk of antimicrobial resistance to man from food and animals.

5. Planning 2009:

- **Work programme**
- **Budget and establishment plan**
- **Staff policy plan**

[EMEA/MB/382635/2008; EMEA/MB/101555/2008;] The Management Board reviewed the planning documents accompanied by the conclusions of the topic coordinators and adopted the EMEA work programme, budget, establishment plan and staff policy plan for 2009.

The work programme largely reflects the preliminary draft work programme adopted in March 2008. However, some shift in focus was needed in order to address rapid developments in the regulatory environment. The changes in the environment include, in particular, the regulatory challenges arising from the move of manufacturing and clinical research to Asia and other territories where contact with the regulators are not yet sufficiently established, and rapid developments in the scientific field (particularly in relation to advanced therapies, biomarkers, relations with health-technology assessment bodies, and work on European initiatives to support innovation). Pressure on the resources of the EMEA and of national competent authorities is mounting, due to the increasing workload in existing areas of responsibility, such as generics, biosimilars, over-the-counter medicines, and authorised medicinal products. The work programme foresees extensive developments in the field of EU telematics, as well as of corporate IT systems. The latter will be developed in line with the reorganisation initiatives of the EMEA.

The EMEA's budget for 2009 is €188,689,000, which includes a Community contribution of €41,890,000. The establishment plan increases staffing numbers by 49 posts, bringing the maximum permissible number of temporary agents to 530.

The staff policy plan was adopted with minor changes. The updated document will be sent to the Management Board for information.

6. Revised EMEA Financial Regulation

[EMEA/MB/442534/2008; EMEA/MB/359871/2008; EMEA/MB/612081/2008] The Management Board adopted the revised EMEA Financial Regulation. The revised Framework Financial Regulation served as a basis for the revised Financial Regulation.

The EMEA has initiated negotiations with DG Budget on two topics, including maintaining the EMEA reserve facility, which allows surpluses from previous years to be used in case of fluctuation of the Agency's fee revenue.

6bis. Financial compensation for Member States' participation in the linguistic checking of product-related information

[EMEA/MB/664754/2008] The Management Board endorsed the adjusted, fixed hourly rate of €40 for 2009, in line with inflation.

7. Revised internal-control standards

[EMEA/MB/278569/2008] The Management Board adopted the EMEA revised internal-control standards (ICSs). The EMEA ICSs follow the standards adopted by the European Commission. The revision aims to change the emphasis in the internal control framework, making it more risk-based and consequently more effective. The changes are also designed to rationalise the current standards, taking into account experience gained, and to ensure that they are made more comprehensible to staff. The new standards are now accompanied by two assessment tools, the 'Requirements' and the 'Effectiveness guidance'.

7bis. Internal Audit Service audit plan 2009-2011

The members noted the Strategic Audit Plan for the EMEA of the Internal Audit Service (IAS) of the Commission. The document contains the IAS audit strategy for the EMEA for the period 2009-2011. The audit planned for 2009 will concentrate on the management of human resources. It will assess the effectiveness, efficiency and compliance of recruitment procedures.

8. Procedure for adoption of Management Board minutes

[EMEA/MB/278569/2008] The Management Board adopted the procedure for adoption of Management Board minutes. The minutes will be adopted by written procedure following a two-week consultation period. The procedure also details how comments to the minutes will be handled. Paragraph 2 of Article 8 of the Management Board rules of procedures will be amended to take account of the adopted changes. The updated rules of procedure will be sent to the Management Board after the meeting, and will be published on the Agency's website.

9. Publication of Management Board meeting documents

[EMEA/MB/440291/2008] The Management Board adopted the decision to publish Management Board meeting documents, effective from the March 2009 meeting. The decision was prepared following initial discussion at the 2 October 2008 meeting. As a general rule, the agenda, meeting minutes, and adopted as well as final Management Board documents agreed for publication by the Board will be published on the EMEA website after each meeting. Documents that are subject to further discussion, amendment, etc., will be published once finalised or approved. The Task Force will report on the experience of the first year's implementation of this policy, together with any recommendations for revision.

10. Reflection paper on procedural advice for classification and incentives for veterinary medicinal products indicated for minor use and minor species/limited markets

[EMEA/460626/2008] The Management Board endorsed the proposal on procedural advice for classification and incentives for veterinary medicinal products indicated for minor use and minor species (MUMS)/limited markets. The proposal clarifies the assistance available to applicants submitting applications for MUMS/limited-market products, and brings together key elements from all of the existing guidance documents relating to such applications. A distinction is made between measures that are available for applicants irrespective of the routes of authorisation and those that are only available to applications eligible for the centralised procedure.

The EMEA has looked at the financial impact of this proposal. Since it depends on how successful the scheme will be in attracting new applications, the impact is difficult to predict at the moment. The current cost of existing measures is well under €100,000. Any increase will happen gradually. However, due to the intrinsic unpredictability of the actual uptake of these measures, the Agency will retain the option to amend the criteria for eligibility if the demands increase exceedingly. The

proposed measures will be introduced through a future amendment to the implementing rules for Regulation (EC) No 297/95.

11. Improving the functioning of the Agency: streamlining the Agency's organisational structure

The Executive Director updated the Management Board on the progress of the 'Improving the functioning of the EMEA' initiative.

The Management Board heard that the Agency aims to: formalise a new layer of management in order to reduce the number of staff managed by a single manager; create a function for centralised information management, to replace the existing decentralised approach; reorganise pre- and post-authorisation processes, to avoid duplication of processes and increase the efficiency of underlying procedures; and review the terminology of the functional entities of the Agency.

It is of note that any budgetary and staffing consequences of these changes will be minimal, with no effect on the establishment plan or grading. It is considered that only one additional management position will be needed for the new information-management function. This post has already been foreseen and approved in the 2009 budget.

The full proposal will be presented at the March Management Board meeting.

12. EMEA Implementing Rules on the engagement and use of Temporary Agents

[EMEA/MB/619466/2008] The Management Board adopted the EMEA Implementing Rules on the engagement and use of Temporary Agents. These implementing rules are required under the Staff Regulations, and follow the model provided by the European Commission for all agencies. The rules set out a common standard for the selection of Temporary Agents. The European Commission accepted the EMEA proposal for new minimum years of professional experience required for grades AST 1 to AST 4.

It is of note that, following extensive discussions with DG Admin, the European Commission has accepted the proposal for an inter-agency job market, under which Temporary Agents will retain their grades should they be employed in other EU agencies.

13. Management Board consultation procedure

Scientific qualifications of committee members

The Management Board discussed the profiles of members and alternates appointed to EMEA scientific committees, and the role that the Board can exercise in the nomination process. It was suggested that it was important for the Management Board to receive more information about the academic, scientific and regulatory experience of nominees, which could be achieved through an improved CV template. A possible set of minimum requirements for members might be considered for guidance purposes. However, matching such criteria to the qualifications is, in practice, a challenge. Members also suggested that, following the departure of a scientific committee member, a gap in expertise should be identified and Member States invited to nominate a replacement member. The members stressed that it is important to achieve a balance of expertise in the committees.

In order to look deeper into the consultation process, the Management Board constituted a group of topic coordinators to prepare a reflection paper encompassing all associated issues. The following members and observers agreed to act as topic coordinators: Aginus Kalis, Björn Lemmer, Vasco Maria, Marcus Müllner, Guido Rasi, Lisette Tiddens-Engwirda and Gro Ramsten Wesenberg. The chairs of the committees may be approached during this work. The EMEA will provide secretarial and

legal assistance. The group will draft terms of reference and will provide an update at the March meeting.

Consultation on appointment of CHMP members and alternates
[EMEA/MB/590915/2008; EMEA/MB/658229/2008 Rev.1] The Management Board was consulted on the appointment of:

- Cîrstea Raluca as CHMP alternate, replacing Victoria Subtirica, as proposed by Romania in a letter received 4 November 2008, and
- Jaana Kallio as CHMP member, replacing Pirjo Laitinen-Parkkonen, as proposed by Finland in a letter received 3 December 2008.

The Management Board did not have any objections to these nominations. The mandate of the appointees will start on 12 December 2008.

14. Report from the European Commission

The members noted an update report from the European Commission concerning the pharmaceutical package, which was adopted by the Commission on 10 December 2008. The package contains three legislative proposals, on: pharmacovigilance of medicines; patients' access to high-quality information on prescription-only medicines; and counterfeiting of medicines. The meeting also heard an update on the work of the ICH forum, which related in particular to the guideline on genomic biomarkers, extending ICH cooperation to other countries, and electronic data transfers.

The Commission: adopted a green paper on the EU Workforce for Health, and launched a consultation with stakeholders; adopted a communication and proposal that sets out an EU strategy to support Member States in diagnosing, treating and caring for the EU citizens with rare diseases; convened a meeting of EU scientific committees to address the challenges posed by the growth of antimicrobial resistance. The first-ever European Antibiotic Awareness Day was held across Europe on 18 November, and will become an annual event.

15. Report from the Heads of Medicines Agencies

The members noted the report from the Heads of Medicines Agencies management group. The report covered: the endorsement of the Incident Management Plan (IMP), including the start of a pilot at the beginning of 2009; the adoption of recommendations for implementing transparency of agendas and minutes in the field of assessment of marketing-authorisation applications across the EU; and a discussion on ways to minimise and prevent antimicrobial resistance resulting from the use of antibiotics in animals.

16. Management Board meeting dates 2009

[EMEA/MB/547459/2008] The Management Board adopted the meeting dates for 2009 and took note of the suggested dates for 2010. The Board agreed to focus on the following topics during the 4 March 2009 meeting:

- Future challenges and directions;
- Risk-based prioritisation of resources;
- Challenges linked to the globalisation of clinical trials.

The 2009 meeting dates are:

- Wednesday 4 March & Thursday 5 March;
- Thursday 11 June;
- Thursday 1 October;
- Thursday 10 December.

The proposed 2010 meeting dates are:

- Wednesday 3 March & Thursday 4 March;
- Thursday 10 June;
- Thursday 7 October;
- Thursday 16 December.

17. Points for information

Documents for information
The Management Board noted the following documents for information:
- Report on EMEA implementation of the EU Telematics strategy;
- Status report on EudraVigilance implementation (Human medicines; Veterinary medicines);
- Outcome of written procedures (on consultation on changes in the memberships of the CHMP and CVMP scientific committees);
- Summary of transfers of appropriations in the budget 2008.

Additional documents tabled
- Summary of the discussions of the topic coordinators on work programme, budget, corporate IT and Telematics.
- Press release from the European Commission on launch of the pharmaceutical package.

Participants at the sixty-first meeting of the Management Board
London, 11 December 2008
Chair: Pat O'Mahony

	Members	Alternates and other participants
Belgium	Xavier De Cuyper	
Bulgaria	Emil Ivanov Hristov	Meri Borislava Peycheva
Czech Republic	Eva Niklíčková	
Denmark	Jytte Lyngvig	
Germany	*Apologies*	
Estonia	Kristin Raudsepp	
Ireland		Rita Purcell
Greece	Vassilis Kontozamanis	
Spain	Cristina Avendaño-Solà	
France		Miguel Bley Patrick Dehaumont
Italy	Guido Rasi	Silvia Fabiani
Cyprus	Panayiota Kokkinou	
Latvia	Inguna Adoviča	
Lithuania	Mindaugas Būta	
Luxembourg	*Apologies*	
Hungary	Tamás Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	*Apologies*	
Portugal	Vasco A J Maria	
Romania		Rodica Badescu
Slovenia	Martina Cvelbar	
Slovakia	Jan Mazag	
Finland	Hannes Wahlroos	
Sweden		Anders Broström
United Kingdom		Steve Dean
European Parliament	Giuseppe Nisticò	
	Björn Lemmer	
European Commission		Georgette Lalis
	Isabel de la Mata	Lenita Lindstrom-Rossi
Representatives of patients' organisations	*Awaiting nomination*	
Representative of doctors' organisations	*Awaiting nomination*	Lisette Tiddens-Engwirda
Representative of veterinarians' organisations	*Awaiting nomination*	
Observers	Rannveig Gunnarsdóttir (Iceland) Gro Ramsten Wesenberg (Norway) Brigitte Batliner (Liechtenstein)	Mike O'Donovan (Representative of patients' organisations) Lisette Tiddens-Engwirda (Representative of doctors'

		organisations)
EMEA	Thomas Lönngren	Riccardo Ettore
	Patrick Le Courtois	Martin Harvey Allchurch
	David Mackay	Isabelle Moulon
	Andreas Pott	Xavier Luria
	Hans-Georg Wagner	Frances Nuttall
	Noël Wathion	Agnès Saint Raymond
	Tony Humphreys	Vincenzo Salvatore
	Marijke Korteweg	Arielle North
	Emer Cooke	Nerimantas Steikūnas
	Hans-Georg Eichler	Mario Benetti