European Medicines Agency

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9 April 2009

# Minutes of the sixty-second meeting of the Management Board

*London, 4-5 March 2009*

## 4 March 2009

The two-day meeting opened on Wednesday, 4 March 2009, with presentations and discussions on: future global challenges and directions for regulators; challenges linked to the globalisation of clinical trials; risk-based prioritisation of resources.

## 5 March 2009 meeting

### 1. Draft agenda for 4-5 March 2009 meeting

[EMEA/MB/663707/2008] The agenda was adopted. Point 16 on Governance of EU agencies was deferred to the June meeting.

### 2. Start of the term of office of the Management Board members nominated by the Council

[EMEA/MB/87076/2009] The Management Board adopted the decision whereby the term of office of the four members of the Management Board listed in Article 1 of Council Decision No 2009/75/EC commenced on 5 March 2009.

### 3. 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.

### 4. Election of the Management Board Vice-chair

[EMEA/MB/81623/2009] The Management Board elected Mrs Lisette Tiddens-Engwirda as Vice-chair with the following votes:

| **Sole round – 34 votes** | |
|---|---|
| Lisette Tiddens-Engwirda | 27 |
| [redacted] | 7 |

Proxy votes from the representatives of France and Luxembourg were given to Belgium, Malta gave its vote by proxy to Cyprus and the United Kingdom gave its vote by proxy to Denmark. The Chair was notified of each proxy, in writing, in advance of the meeting.

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## 5. Minutes from the 61st meeting, 11 December 2008

[EMEA/MB/671250/2008] The Management Board noted the outcome of the written procedure. Although the minutes are adopted by written procedure, they will continue to appear on the agenda to allow members to raise matters arising from a previous meeting.

## 6. EMEA highlights from the Executive Director

*Collaboration with the FDA*
As part of the EU-FDA confidentiality arrangements, and of increased collaboration and cooperation between the EMEA and the US Food and Drug Administration (FDA), the two authorities have agreed to exchange staff on a defined-term basis. Work is ongoing at the two agencies on arrangements for the reciprocal assignment of staff.

*EMEA corporate-identity project*
In 2008, the Agency launched a project to review its corporate identity. By the end of the process, the Agency expects to have adopted a formal corporate identity, harmonised the presentation of its communications materials and rationalised its use of document templates. Options for adopting a new logo for the Agency are being explored. The Agency will also consider ways to promote use of its official name rather than the acronym 'EMEA', which has limited recognition outside of the Agency's closest stakeholder groups.

*The first centralised vaccine against bluetongue*
In February 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion recommending a marketing authorisation under exceptional circumstances for BTVPUR Alsap 8, intended for the active immunisation of sheep and cattle, to prevent viraemia and to reduce clinical signs caused by the bluetongue virus serotype 8. The EMEA's recommendation is an important step towards the availability of vaccines for use in vaccination campaigns across the EU and the protection of animal health in Europe. The Management Board welcomed the opinion of the Committee as it is of importance to many Member States.

*Review of the remuneration system*
The Management Board was informed that the Court of Auditors will possibly visit the Agency later this year to review the progress of the revision of the remuneration system for the work of (co)rapporteurs.

*Paediatric investigation plans*
The Management Board was notified of the first legal case regarding a paediatric investigation plan-related application.

*Transparency policy*
The Management Board was given a presentation about the Agency's transparency-policy project and associated action plan. The Board nominated Aginus Kalis, Marcus Müllner, Lisette Tiddens and Gro Ramsten Wesenberg as topic coordinators for this project. The public consultation regarding the proposed policy is planned to start in mid June and finish at the end of September 2009.

## 7. EMEA annual report 2008

[EMEA/MB/684002/2008] The Management Board heard a presentation on the implementation of the 2008 work programme. The members welcomed the performance of the Agency and the achievement of substantial milestones in 2008.

The Agency delivered on all core business commitments and implemented its 2008 priorities. The year 2008 saw a further growth in the volume of core activities. The number of applications increased in

the areas of scientific advice, initial evaluation, post-authorisation, paediatrics and other activities. The Agency adopted a record number of positive opinions in the area of initial evaluations. The first switch from prescription-only to non-prescription status of a centrally authorised product took place in 2008. The Agency has also implemented the legislation on advanced therapy medicinal products (ATMPs) and established the Committee for Advanced Therapies. Significant work was carried out in the fields of safety-monitoring of medicines (EudraVigilance, ENCePP projects), communication and transparency, support to innovation, and international activities.

Some of the deviations of note related to the implementation of the Product Information Management (PIM) and the EU database of clinical trials (EudraCT) projects. The former was delayed due to some performance issues and stability problems. Following the publication of relevant guidance, the work to extend the EudraCT database in line with the requirements of the legislation on paediatric medicinal products will continue.

The annual report will now be submitted to the members for a three-week consultation period, after which time a written procedure for the adoption will be launched.

## 8. Planning for 2010:

- **Preliminary draft work programme**
- **Preliminary draft budget and establishment plan**
- **Draft staff-policy plan**

[EMEA/MB/632200/2008; EMEA/MB/502942/2008; EMEA/MB/94586/2009; EMEA/MB/579221/2008] The Management Board adopted the preliminary draft work programme, budget and staff-policy plan for 2010. The European Commission made a reservation regarding the level of the Community contribution in the 2010 budget, pending the completion of the budgetary process in the institutions.

*Preliminary draft work programme 2010*

The year 2010 is the final year covered by the current road map. It will be a year marked by further increases in the volume and complexity of activities. The work programme and budget focus on the development of corporate information-technology systems, which aim to increase the efficiency with which procedures are monitored and tracked. However, the funding of information-technology and telematics projects has a structural issue that will be further affected by future legislation in the field of pharmaceuticals (pharmacovigilance, counterfeit medicines and, possibly, information to patients).

It was also stressed that the volume and complexity of procedures exert a lot of pressure on national scientific resources, with scientists having to spend increasingly more time at the Agency. They often contribute to the work of more than one scientific committee and various working parties. The Management Board reiterated the need to find alternative ways of working, including greater use of communication technologies and, possibly, revision of the architecture of the system. This can be considered during the ongoing evaluation of the Agency.

*Preliminary draft budget 2010*

The adopted preliminary draft budget (PDB) for 2010 totals €211.8 million. This includes an estimated fee revenue of €158.3 million and a requested Community contribution of €46 million. The PDB includes an increase in the establishment plan of 37 posts, with a maximum number of 567 temporary agents. The proposed budget is subject to a number of risk factors, including: the difficult global economic climate; the entry into force of the revised variations legislation, which may result in a loss of revenue for the Agency and therefore create the need for an increased Community contribution; revision of the remuneration system for rapporteurships; and risks associated with significant fluctuation of exchange rates.

The European Commission representative requested the Board in the future, to allow that the draft establishment plan be submitted to the Directorate-General for Industry and Enterprise, the Directorate-General for Personnel and Administration and the Directorate-General for Budget ahead of the March Management Board meetings in order to allow the Commission to produce its

consolidated opinion on the draft plan. This would enable the Management Board to take decisions on establishment plans in the knowledge of the views of the European Commission (taking into account that the Commission opinion is transmitted to the budgetary authority). The Board will discuss this proposal at a future meeting.

## 9. Incentives for products for minor uses and minor species or for limited markets

[EMEA/MB/67287/2009] The Management Board endorsed the proposed amendment under paragraph 4.1.4 (MRL applications, including extrapolations) of the procedural advice for classification and incentives for veterinary medicinal products indicated for minor uses and minor species (MUMS)/limited markets. In addition to adoption of the necessary procedures and changes to the fee-implementing rules, the Agency is currently preparing other measures that are necessary to put in place the proposed incentives, such as amendments to guidance, a communication strategy with stakeholders, and an official launch of the scheme, foreseen for later in 2009.

[EMEA/MB/58755/2009] The Management Board also considered the potential financial and budgetary impact of the fee incentives proposed under MUMS/limited markets. At present, the annual cost of support measures for these products is around €100,000. Following the entry into force of the proposed additional measures, the cost may rise to an annual figure of €500,000 and, depending on the actual uptake, may even be significantly higher. In case the Agency's budget is not sufficient to meet the demand, the Agency may introduce additional criteria to make sure that those products of highest benefit, in terms of animal health, continue to receive support. The Board agreed to the common understanding that the fee reductions or waivers will be borne by both the Agency and the national competent authorities that take up the (co)rapporteurships.

## 10. Mandate for the Management Board task force on scientific qualification of committee members

[EMEA/MB/673201/2008] The Management Board adopted the proposed mandate of the task force, with a deletion of Point 4, relating to future legislative changes. The task force was set up in response to the Management Board's legal role in the appointment process, with a view to further improving the consultation process. The meeting also noted the discussions to date, and encouraged the task force to take the time necessary to review the various options and liaise with the chairs and members of the scientific committees. A further report will be provided at the June meeting.

## 11. Rules of procedure of the scientific committees:

- **The Committee for Medicinal Products for Human Use (CHMP)**
- **The Committee for Advanced Therapies (CAT)**
- **The draft procedural advice on evaluation of advanced therapy medicinal products (ATMPs)**

[EMEA/CHMP/89672/2009] The Management Board supported the proposed amendments to the rules of procedure of the CHMP. The Board asked to revise the proposed wording of Article 8(7) to make it clear that the CHMP issues an opinion which is transmitted to the European Commission for adoption of a decision. The wording in the rules of procedure will be clarified together with the European Commission, and the document will be submitted for adoption by written procedure. Following the completion of the discussion on the interaction between the CHMP and the CAT, the Management Board will consider whether any further revision of the rules of procedure are necessary.

[EMEA/103390/2009] The Management Board noted the ongoing discussion between the CHMP and the CAT regarding the CAT rules of procedure and the procedural advice on evaluation of ATMPs. The Board supported the amendments proposed by delegations to Articles 2(2) (Responsibilities of chair and vice-chair) and 5(4) (CAT (co)rapporteur and assessment team).

[EMEA/118727/2009] The Management Board considered the present state of the discussion on whether the CHMP also has to endorse milestone documents relating to the evaluation of ATMPs. The Board discussed the topic and offered divergent views. The Board wished to be informed of the outcome of this discussion and the rationale for the future agreement between the CAT and CHMP on this issue.

## 12. Revised organisational structure of the EMEA

The Management Board noted the Executive Director's presentation on the ongoing work to review the Agency's organisational structure. This work is part of the process-improvement work started in 2006.

The main objectives of the intended new organisation include: integration of the human pre- and post-authorisation (line extensions and variations) procedures; more focus on safety-monitoring of medicines through separation of pharmacovigilance and of risk-management activities from post-authorisation work; creation of a new sector for data management. The latter is a new sector with responsibilities for centralising product-information management at the Agency and for improving the interoperability of databases. Overall, the changes of the structure will ensure more accountability at various management levels, and will make the organisation better positioned to operate in the present conditions.

## 13. Updated quality policy of the European Medicines Agency

[EMEA/MB/355781/2007/Rev.1] The Management Board adopted the updated quality policy, which, among other changes, incorporates references to the revised internal-control standards, and clarifies the separation of audit and integrated-quality-management advice functions.

## 14. Preparation for written procedures: changes to the rules for the implementation of Regulation (EC) No 297/95 on fees payable to the EMEA and other measures

The Management Board noted the upcoming written procedures regarding changes to the fee-implementing rules. The written procedures will include fees for veterinary medicinal products indicated for minor uses and minor species/limited markets, and fees for medicinal products to be used in a health pandemic that affects humans.

## 15. Proposal for involvement and participation of patients'/consumers' representatives in the meetings of the CHMP Pharmacovigilance Working Party

[EMEA/261645/2008] The Management Board endorsed the proposal for a pilot project that aims for greater involvement of patients and consumers in the work of the Agency. The pilot will commence in April 2009 and will run for three months. The experience from this pilot will help to develop a general strategy to further involve patients and consumers at different levels of the Agency's work, as well as will help the Agency to acquire experience that will be useful in the context of the future pharmacovigilance legislation. The request to develop similar interactions with representatives of healthcare professionals will be forwarded to the Healthcare Professionals Working Group, and will be discussed during the preparation of the framework for interaction with health care professional organisations.

## 16. Governance of EU agencies

The point was deferred to the next meeting.

## 17. Report from the European Commission

The members noted the update report from the European Commission on a range of topics, including: the guideline setting out what clinical-trial information should be made available to the public; the pharmaceutical package (legislative proposals on pharmacovigilance, tackling counterfeiting of medicines, and information to patients); the evaluation of the EMEA; a recent meeting with Member State representatives on health-technology assessment; the draft Directive on the application of patients' rights with regard to cross-border healthcare; the Commission communication and proposal on patient safety in Europe; and the launch of a public consultation on the future of Europe's workforce for health.

## 18. Report from the Heads of Medicines Agencies

The Management Board noted the report from the Heads of Medicines Agencies (HMA), which included: information on the election of Johannes Löwer as the new chair of the HMA management group, replacing Jytte Lyngvig; discussions regarding the EudraPharm database; resources of the network; work on antimicrobial resistance.

## 19. Points for information

*Documents for information*
The Management Board noted the following documents for information:

- [EMEA/MB/30754/2009] Survey 2008 on the performance of EMEA scientific procedures for medicinal products for human use.
- [EMEA/MB/20870/2009] Update report on EMEA implementation of the EU telematics strategy.
- [EMEA/86607/2009; EMEA/MB/45112/2009] Reports on EudraVigilance implementation for human medicines and medicines for veterinary use.
- [EMEA/MB/81661/2009] Outcome of written procedures on consultation on changes in the membership of the CHMP and CVMP committees.
- [EMEA/MB/649766/2008] Summary of transfers of appropriations in the budget, 2008 and 2009.

*Additional documents tabled*

- Presentation 'Future challenges and directions for regulators'.
- Presentation 'Building on a risk-intelligence framework'.
- Presentation 'Challenges linked to globalisation of clinical trials'.
- Presentation 'EMEA annual report 2008'.
- Correspondence from Germany and France relating to agenda item 11, specifically the CAT rules of procedure and the procedural advice on evaluation of ATMPs.
- Presentation 'Improving the functioning of the EMEA'.
- Presentation 'Revised CHMP Rules of Procedure and Interaction between CHMP and CAT'.

**Participants at the sixty-second meeting of the Management Board**

London, 4-5 March 2009

**Chair: Pat O'Mahony**

| | Members | Alternates and other participants |
|---|---|---|
| Belgium | Xavier De Cuyper | |
| Bulgaria | Emil Ivanov Hristov | |
| Czech Republic | Lenka Balážová | |
| Denmark | Jytte Lyngvig | |
| Germany | Walter Schwerdtfeger | |
| Estonia | Kristin Raudsepp | |
| Ireland | | Rita Purcell |
| Greece | Vassilis Kontozamanis | |
| Spain | Cristina Avendaño-Solà | |
| France | | Pierre-Henri Bertoye |
| Italy | Guido Rasi | Silvia Fabiani |
| Cyprus | Panayiota Kokkinou | |
| Latvia | Inguna Adoviča | |
| Lithuania | Mindaugas Būta | |
| Luxembourg | Apologies | |
| Hungary | Tamás Paál | |
| Malta | Apologies | |
| The Netherlands | Aginus Kalis | |
| Austria | Marcus Müllner | Christian Kalcher |
| Poland | Apologies | |
| Portugal | Vasco A J Maria | |
| Romania | | Rodica Badescu |
| Slovenia | Martina Cvelbar | |
| Slovakia | Jan Mazag | |
| Finland | | Pekka Järvinen |
| Sweden | Christina Åkerman | |
| United Kingdom | | Sean Gallagher |
| European Parliament | Giuseppe Nisticò | |
| | Björn Lemmer | |
| European Commission | | Georgette Lalis |
| | Isabel de la Mata | Lenita Lindstrom-Rossi |
| Representatives of patients' organisations | Mike O'Donovan | |
| | Mary G. Baker | |
| Representative of doctors' organisations | Lisette Tiddens-Engwirda | |

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| Representative of veterinarians' organisations | Henk Vaarkamp | |
| Observers | Gro Ramsten Wesenberg (Norway) | |
| | Brigitte Batliner (Liechtenstein) | |
| EMEA | Thomas Lönngren | Tony Humphreys |
| | Patrick Le Courtois | John Purves |
| | David Mackay | Agnès Saint Raymond |
| | Andreas Pott | Vincenzo Salvatore |
| | Hans-Georg Wagner | Bo Aronsson |
| | Noël Wathion | Mario Benetti |
| | Riccardo Ettore | Claus Christiansen |
| | Beatrice Fayl | Arielle North |
| | Martin Harvey Allchurch | Nerimantas Steikūnas |