



European Medicines Agency

EMEA/MB/663707/2008Adopted
Version: 3.0, CURRENT, Adopted

Sixty second meeting of the Management Board

*4 March 2009 (Room 4A)
3pm – 8pm*

Agenda

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| 1. Introduction | <i>Chairman</i> | <i>3:00pm – 3:15pm</i> |
| 2. Future challenges and directions | <i>Thomas Lönngren</i> | <i>3:15pm – 4.00pm</i> |
| 3. Risk-based prioritisation of resources | <i>Chris Verdonck, Sophie Janssens
and Michel De Ridder
Deloitte</i> | <i>4.00pm – 5:00pm</i> |
| 4. Tea and coffee break (4 th floor open area) | | <i>5:00pm – 5:15pm</i> |
| 5. Challenges linked to the globalisation of clinical trials | <i>Charles S. Mgone,
European & Developing Countries
Clinical Trials Partnership</i> | <i>5.15pm - 6.15pm</i> |
| 6. Dinner (3rd floor function room) | | <i>6.30pm-8.00pm</i> |

5 March 2009 (Room 4A)

9am to 4pm

Draft Agenda

1. Draft agenda *For adoption, EMEA/MB/663707/2008**
2. Start of the term of office of the Management Board members nominated by the Council *For adoption, EMEA/MB/87076/2009**
3. Declaration of conflicts of interest *Oral report*
4. Elections of vice-chair *Oral report*
5. Minutes from the 61st meeting, held on 11 December 2008, adopted via written procedure on 28 January 2009 *For information, EMEA/MB/671250/2008**
6. EMEA highlights from the Executive Director *Oral report*
 - 6.1. Outcome of the EMEA transparency policy workshop *Oral report*
7. EMEA annual report 2008 *For discussion, EMEA/MB/684002/2008*
 - 7.1. Preparation for written procedure for adoption of the EMEA annual report 2008
8. Draft EMEA work programme and budget for 2010: *For adoption, EMEA/MB/632200/2008*
 - 8.1. Preliminary draft work programme *For adoption, EMEA/MB/502942/2008*
 - 8.2. Preliminary draft budget - Information technology *For information, EMEA/MB/94586/2009*
 - 8.3. Staff policy plan *For adoption, EMEA/MB/579221/2008*
9. Incentives for MUMS/limited markets products
 - 9.1. Analysis and risk assessment of the financial and budgetary impact of the fee incentives proposed under MUMS/Limited market *For information, EMEA/MB/67287/2009*
 - 9.2. Procedural Advice for Classification and Incentives for Veterinary Medicinal Products Indicated For Minor Use Minor Species (MUMS)Limited Markets *For endorsement, EMEA/MB/58755/2009*
10. Draft mandate for Management Board task force on scientific qualifications of committee members *For adoption, EMEA/MB/673201/2008**
11. Rules of procedure for:
 - 11.1. the Committee for Medicinal Products for Human Use *For discussion, EMEA/CHMP/89672/2009*
 - 11.2. the Committee for Advanced Therapies *For discussion,*
 - 11.3. Draft procedural advice on evaluation of Advanced Therapy Medicinal Products *EMEA/103390/2009*
EMEA/118727/2009
12. Revised organisational structure of the EMEA *Oral report*
13. Updated EMEA Quality policy *For endorsement, EMEA/MB/355781/2007Rev1**
14. Preparation for Written procedure on changes to The Rules for Implementation of Regulation (EC) No 297/95, as amended, on Fees Payable to the EMEA and other measures, in particular:
 - 14.1. Fees relating to Veterinary Medicinal Products Indicated For Minor Use Minor Species (MUMS)Limited Markets *Oral report*
 - 14.2. Fees relating to Medicinal Products to be Used in a Human Pandemic situation
15. Proposal for involvement and participation of patients'/consumers' representatives in the meetings of the CHMP PhVWP *For endorsement, EMEA/261645/2008**
16. Governance of the EU agencies *For discussion*
17. Report from the European Commission *Oral report*

18. Report from the Heads of Medicines Agencies

Oral report

19. Points for information:

19.1. Survey 2008 on the performance of EMEA scientific procedures for medicinal products for human use

*For information,
EMEA/MB/30754/2009**

19.2. Update report on EMEA implementation of EU telematics strategy

*For information,
EMEA/MB/20870/2009**

19.3. Report on EudraVigilance implementation:

- Veterinary

- Human

*For information,
EMEA/86607/2009*
EMEA/MB/45112/2009**

19.4. Outcome of written procedures on consultation on changes in the membership of the CHMP and CVMP committees

*For information,
EMEA/MB/81661/2009*

19.5. Summary of transfers of appropriations in the budget 2008 and 2009

*For information,
EMEA/MB/649766/2008**

Documents marked * are intended for publication on Management Board external web site.