



11 December 2013
EMA/MB/531192/2013 Version.5 Adopted Corr.*
Management Board meeting of 11-12 December 2013

Agenda for the 82nd meeting of the Management Board

11 December 2013, Room 2A (Wednesday; from 16:00 – 20:30 hours)

Chairperson: Sir Kent Woods

| Item | | |
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| Opening | Guido Rasi, Executive Director | 16:00 – 16:05 |
| Introduction | Sir Kent Woods | 16:05 – 16:15 |
| Session 1 | <i>Pharmacovigilance Fee Regulation – legislative aspects</i> <ul style="list-style-type: none">• <i>Legal framework and impact on the Management Board</i>• <i>Progress of Council discussions</i> | 16:15 – 17:15 |
| <i>Tea and coffee break (2A open area)</i> | | 17:15 – 17:45 |
| Session 2 | <i>Considerations on costing</i> <ul style="list-style-type: none">• <i>European tasks</i>• <i>Understanding costs – EMA/NCAs</i>• <i>Next steps</i> | 17:45 – 19:00 |
| <i>Drinks reception (2A open area)</i> | | 19:00 – 20:30 |

* Document no.corrected on page 3



Agenda for the 82nd meeting of the Management Board

12 December 2013, Room 4A (Thursday; from 08:00 – 15:00)

Chairperson: Sir Kent Woods

| Item | Preliminary draft agenda | Action / Reference |
|----------------|---|--|
| 1. | Draft agenda | For adoption, EMA/MB/531192/2013* |
| 2. | Declaration of conflicts of interest related to current agenda | Oral report |
| 3. | Minutes from the 81st meeting, held on 3 October 2013 adopted via written procedure on 8 November 2013 | For information, EMA/MB/584118/2013* |
| A | Points for automatic adoption/endorsement | |
| A.1 | Financial compensation for Member States' participation in the linguistic checking of product related information | For endorsement, EMA/MB/673504/2013* For information, EMA/673506/2013 |
| A.2 | Amendment no. 2 to the Cooperation agreement relating to linguistic checking – Annex II | For adoption, EMA/MB/688641/2013 |
| B | Points for discussion | |
| B.1 | Highlights of the Executive Director | Oral report |
| B.2 | Report from the European Commission | Oral report |
| B.3 | Roles & Responsibilities of the Management Board | EMA/MB/715306/2013; For endorsement, EMA/MB/186362/2007 |
| B.4 | Draft principles for a revised EMA conflicts of interests policy for scientific committee members and experts | EMA/MB/734303/2013; For endorsement, EMA/734296/2013 |
| B.5 | Revised implementing rules to the Fee Regulation as of 1 January 2014 | Mailing 2 |
| B.6 | Draft principles for implementing rules on publication of and access to clinical trial data | EMA/MB/773284/2013; For endorsement, EMA/743046/2013 |
| B.7 | Work Programme 2014 | EMA/MB/719999/2013; For adoption, EMA/695772/2013* |
| B.8 | a) Draft Budget and Establishment Plan 2014 | EMA/MB/128714/2013; For adoption, EMA/MB/686942/2013* |
| | b) Revision of the budget structure and remarks | For information, EMA/MB/152502/2013 |
| | c) Revision of establishment plan for 2014 | For adoption, EMA/MB/700111/2013 |

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| B.9 | Pharmacovigilance legislation: a) Functional requirements for EudraVigilance to be audited b) Functional requirements for the PSUR repository to be audited | EMA/MB/739742/2013; For endorsement, EMA/626168/2013 EMA/MB/742130/2013; For endorsement, EMA/681848/2013 |
| B.10 | Sixth Annual Report on the Interaction with Patients' and Consumers' Organisations (2012) | EMA/MB/524015/2013; For information, EMA/272219/2013* |
| B.11 | Publication of Agendas and Minutes of EMA Scientific Committees | EMA/MB/745294/2013; For endorsement, EMA/555647/2013* |
| C | Points for information only** | |
| C.1 | Multi Annual Staff Policy Plan MSPP 2014-2016 | EMA/MB/128713/2013; EMA/817331/2012 |
| C.2 | Update on Telematics from the EU Telematics Management Board (EU TMB) | EMA/MB/711217/2013 |
| C.3 | Report from the Heads of Medicines Agencies | |
| C.4 | Outcome of written procedures during the period from 1 September 2013 to 21 November 2013 | EMA/MB/622839/2013* |
| C.5 | Technical adjustment in appropriations for Amending Budget 01-2013 | EMA/MB/641206/2013 |
| C.6 | Summary of transfer of appropriations in the budget 2013 | EMA/MB/703501/2013* |
| C.7 | EudraVigilance Report 2013 for Veterinary Medicinal Products | EMA/718145/2013; EMA/13787/2009* |

* Final documents marked with a star * are intended for publication on the external web site

** Documents in Additional documents for information section are not indented for discussion unless specifically requested