



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

3 October 2013  
EMA/MB/197800/2013 Version 5, Adopted  
Management Board meeting of 3 October 2013

## Agenda for the 81st meeting of the Management Board

Held on 3 October 2013, Room 4A (08:00 – 15:00)

Chair: Sir Kent Woods

| Item     | Preliminary draft agenda  | Action / Reference   |
|----------|---|--|
| 1.       | Draft agenda  | For adoption,<br>EMA/MB/197800/2013*   |
| 2.       | Declaration of conflicts of interest related to current agenda  | Oral report  |
| 3.       | Minutes from the 80th meeting, held on 13 June 2013 adopted via written procedure on 1 August 2013                    | For information,<br>EMA/MB/367978/2013*  |
| <b>A</b> | <b>Points for automatic adoption/endorsement</b>  |  |
|          |   |  |
| <b>B</b> | <b>Points for discussion</b>  |  |
| B.1      | Highlights of the Executive Director  | Oral report  |
| B.2      | Internal reorganisation of the EMA  | Oral report  |
| B.3      | Report from the European Commission   | Oral report  |
| B.4      | EMA mid-year report 2013 from the Executive Director (January - June 2013)  | For information,<br>EMA/MB/503866/2013*  |
| B.5      | Update on the progress of Project 2014  | For information  |
| B.6      | Amending Budget   | For adoption,<br>EMA/MB/415538/2013*   |
| B.7      | Preparation of written procedure for adoption of EMA's financial regulation   | For information,<br>EMA/MB/557966/2013<br>EMA/MB/559920/2013   |
| B.8      | Report by the PRAC Chair<br>"Reflections one year on from the establishment, composition and functioning of the PRAC" | Oral report  |
| B.9      | Principles for Publication of Agendas and Minutes of EMA Scientific Committees  | EMA/MB/555575/2013<br>For endorsement, EMA/127582/2010<br>For information, EMA/391939/2013,<br>EMA/434574/2013 Rev. 4 CONFIDENTIAL |
| B.10     | Role of the Management Board in the discussion on the Introduction of Pharmacovigilance Fees                          | For discussion   |



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|----------|--|--|
| <b>C</b> | <b>Points for information only**</b>   |  |
| C.1      | Update on Telematics from the EU Telematics Management Board (EU TMB)              | EMA/MB/549873/2013,<br>EMA/523568/2013 |
| C.2      | Report from the Heads of Medicines Agencies  |  |
| C.3      | Outcome of written procedures during the period from 24 May 2013 to 30 August 2013 | EMA/MB/378130/2013<br>V.2*             |
| C.4      | Summary of transfers of appropriations in the budget 2013                          | EMA/MB/537811/2013*                    |

\* 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