



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 March 2014  
EMA/MB/2712/2014 Version 4, Adopted  
Management Board meeting of 19-20 March 2014

## Agenda for the 83<sup>rd</sup> meeting of the Management Board

Held on 19 March 2014, Room 4A (14:00 – 19:00)

Chairperson: Sir Kent Woods

Item	Preliminary draft agenda	Action / Reference	Mins
Opening & introduction	Sir Kent Woods		14:00 – 14:10
Session 1	Management Board data gathering initiative	For endorsement, EMA/MB/49036/2014; For adoption, EMA/MB/49037/2014	14:10 – 15:50
<i>Tea and coffee break (4A open area)</i>			15:50 – 16:20
Session 2	New building and new structure - what will be different Review & Reconnect Update		16:20 – 18:00
<i>Drinks reception</i>			18:00 – 19:00



# Agenda for the 83rd meeting of the Management Board

Held on 20 March 2014, Room 4A (08:00 – 15:00)

Chair: Sir Kent Woods

Item	Preliminary draft agenda		Action / Reference
1.	Draft agenda		For adoption, EMA/MB/2712/2014*
2.	Declaration of conflicts of interest related to current agenda		Oral report
3.	Minutes of the 82nd meeting, held on 11-12 December 2013 adopted via written procedure on 7 February 2014		For information, EMA/MB/723234/2013*
<b>A</b>	<b>Points for automatic adoption/endorsement</b>		
A.1	Revised Management Board rules of procedure		EMA/MB/91953/2014 For adoption, EMA/MB/115339/2004/en /Rev.5 Draft *
A.2	Revision of PRAC Rules of Procedure following the implementation of Pharmacovigilance Legislation in the European Economic Area		EMA/MB/130072/2014 For adoption, EMA/PRAC/567515/2012 Rev.1*
A.3	Implementing rules to the Financial Regulation applicable to the budget of the European Medicines Agency		EMA/MB/100697/2014; EMA/61802/2014; For adoption EMA/MB/99010/2014*
<b>B</b>	<b>Points for discussion</b>		
B.1	Highlights of the Executive Director		Oral report
B.2	Report from the European Commission		Oral report
B.3	Annual report 2013		EMA/MB/145678/2014 For adoption, EMA/88206/2014*
B.4	Amending Budget 01-2014		For adoption, EMA/MB/45191/2014*
B.5	EMA preliminary draft work programme 2015		EMA/MB/121028/2014; For endorsement, EMA/80156/2014
B.6	a) Preliminary draft budget and establishment plan 2015		EMA/MB/120006/2014; For endorsement, EMA/MB/651/2014
	b) Multi-annual Staff Policy Plan 2015-2017		EMA/MB/120236/2014; For endorsement, EMA/120424/2014
B.7	Revised implementing rules to the Fee Regulation as of 1 April 2014		EMA/MB/785541/2013; EMA/MB/153694/2014; For adoption, EMA/145687/2014*

B.8	a) Update on the implementation of Pharmacovigilance Legislation <ul style="list-style-type: none"> <li>– Proposed principles for improving the RMP process</li> </ul> b) PSUR single assessment procedure for NAPs	Oral report  For information, EMA/MB/141196/2014; For endorsement, EMA/146102/2014
B.9	Report by the CHMP Chair	Oral report
B.10	Draft revised EMA policy on the handling of declarations of interests of scientific committees' members and experts	EMA/MB/144336/2014; For information, EMA/145339/2014; For endorsement, EMA/513078/2010*
B.11	Draft EMA policy on the publication of and access to clinical trial data	Oral report
B.12	4th Annual Report Veterinary MUMS/limited market	EMA/MB/102900/2014; For endorsement, EMA/14945/2014*
<b>C</b>	<b>Points for information only**</b>	
C.1	Update on Telematics from the EU Telematics Management Board (EU TMB)	EMA/MB/130082/2014
C.2	Report from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 22 November 2013 to 21 February 2014	EMA/MB/9624/2014*
C.4	Summary of transfer of appropriations in the budget 2013	EMA/MB/85740/2014*
C.5	EudraVigilance report 2013 for Human Medicinal Products	EMA/MB/143919/2014; EMA/145085/2014 *
C.6	Overview of Staff Regulation implementing rules signed by the MB Chair during the period from 16 November 2012 to 26 February 2014	EMA/MB/121745/2014*

\* 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