



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2013
EMA/MB/685719/2012
Management Board meeting of 20-21 March 2013

Agenda for the 79th meeting of the Management Board

20 March 2013, Room 2A (Wednesday 20th; from 14:00 – 19:00 hours)

Final

Chairperson: Sir Kent Woods

Item		Mins
Opening	Sir Kent Woods	14:00 – 14:05
Introduction	Guido Rasi, Executive Director	14:05 – 14:15
Session 1	<ul style="list-style-type: none">A discussion on regulatory science	14:15 – 16:00
<i>Tea and coffee break (2A open area)</i>		<i>16:00 – 16:30</i>
Session 2	<ul style="list-style-type: none">Sustainability of the system	16:30 – 18:00



Agenda for the 79th meeting of the Management Board

21 March 2013, Room 4A (Thursday 21st; from 08:00 – 15:00 hours)

Chairperson: Sir Kent Woods

Item	Preliminary draft agenda	Action / Reference
1.	Draft agenda	For adoption, EMA/MB/685719/2012*
2.	Declaration of conflicts of interest related to current agenda	Oral report
3.	Minutes from the 78 th meeting, held on 13 December 2012 and adopted via written procedure on 6 February 2013	EMA/MB/128819/2013 For adoption, EMA/MB/810387/2012*
4	Decision determining the start date of the term of office of members of the Management Board appointed by Council Decision	For adoption, EMA/MB/82143/2013*
A	Points for automatic adoption/endorsement	
A.1	Amendment I to Annex I of Cooperation agreement relating to linguistic checking	EMA/37940/2013; For information, EMA/21232/2013/rev.1 For adoption, EMA/37307/2013
B	Points for discussion	
B.1	Highlights of the Executive Director	Oral report
B.2	Annual report 2012	EMA/MB/151012/2013 For adoption, EMA/95980/2013*
B.3	Preliminary draft work programme 2014	For adoption, EMA/50749/2013
B.4	a) Preliminary draft budget and establishment plan 2014	EMA/MB/128440/2013 For adoption, EMA/MB/113216/2013
	b) The multi-annual staff policy plan 2014-2016	EMA/MB/128444/2013 For information, EMA/817331/2012
	c) Revision of the budget structure and remarks	For information, EMA/MB/29440/2013
B.5	ICT overall budget 2012-2014	For information, EMA/69347/2013
B.6	Revised Implementing Rules to the Fee Regulation	For adoption, EMA/MB/112878/2013*
B.7	EU Telematics governance model	EMA/MB/117699/2013 For adoption, EMA/795730/2013
B.8	Progress on costing evaluation activities	For discussion, EMA/MB/90210/2013
B.9	a) Report from the European Commission	Oral report
	b) The Commission Roadmap on the follow-up to the Common Approach (outcome of the Inter-Institutional WG on Decentralised Agencies)	
B.10	Report from the Heads of Medicines Agencies	Oral report
B.11	a) Update on the implementation of Pharmacovigilance Legislation	EMA/MB/147218/2013 For discussion, EMA/115971/2013
	b) Public hearing	EMA/MB/172763/2013 For information, EMA/542982/2012

B.12	EMA Code of Conduct	EMA/MB/102832/2013 For information, EMA/385894/2013
B.13	Renewal of the mandate for the Joint Expert Group on 3Rs	EMA/95290/2013 For adoption, EMA/CHMP/CVMP/JEG-3Rs/442724/2012* For information, EMA/521929/2012
B.14	Annual report and review of the operation of the Minor Use/Minor Species (MUMS) scheme for Veterinary Medicines	EMA/MB/114227/2013 For endorsement, EMA/62481/2013* For discussion, EMA/129599/2013
B.15	Annual report on the performance of the Agency's scientific procedures	For discussion, EMA/97787/2013
C	Points for information only**	
C.1	EU Telematics: a) EU Telematics Operations Report b) EU Telematics Projects Report c) Minutes of the Management Board Telematics Committee (MBTC) from 6 December 2012 meeting	EMA/MB/128889/2013 EMA/MB/116611/2013 EMA/MB/113901/2013
C.2	Outcome of written procedures during the period from 22 November 2012 to 27 February 2013	EMA/MB/67488/2013*
C.3	Summary of transfers of appropriations in the budget 2012	EMA/MB/89378/2013*
C.4	First Annual Report on EudraVigilance for the European Parliament, the Council and the Commission	EMA/MB/185063/2013 EMA/127361/2013

* 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