



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 June 2014
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Management Board meeting of 12 June 2014

Agenda for the 84th meeting of the Management Board

12 June 2014, Room 4A (Thursday; from 08:00 – 15:00 hours)

Chairperson: Alternate chair

Item	Preliminary draft agenda	Action / Reference
1.	Draft agenda	For adoption, EMA/MB/22128/2014*
2.	Declaration of conflicts of interest related to current agenda	Oral report
3.	Election of the Chair of the Management Board	EMA/MB/222355/2014 By ballot

Chairperson: Elected chair

4.	Minutes from the 83rd meeting, held on 19-20 March adopted via written procedure on 5th May 2014	For information, EMA/MB/169928/2014*
A	Points for automatic adoption/endorsement	
A.1	Management Board meeting dates 2015	For adoption, EMA/MB/226104/2014 *
B	Points for discussion	
B.1	Highlights of the Executive Director	Oral report
B.2	Assessment of the Executive Director's Annual Activity Report (AAR) 2013	For information, EMA/MB/286545/2014; For discussion, EMA/145663/2014; For adoption, EMA/262020/2014*
B.3	Report from the European Commission	Oral report
B.4	Two addenda to Cooperation Agreement between EMA and NCAs	For information, EMA/MB/258645/2014; For adoption, EMA/MB/292242/2014; For adoption, EMA/MB/337289/2014



B.5	a) Revision of rules for reimbursement for delegates and experts attending meetings	For information, EMA/MB/270653/2014; For adoption, EMA/MB/270654/2014*
	b) Compensation of employers of the Committee Chairperson	For endorsement, EMA/MB/349441/2014
	c) Harmonisation of payments to NCAs for applications with fee reductions	For adoption, EMA/MB/150667/2014
B.6	EMA Internal Audit Charter	EMA/MB/264031/2014 For adoption, EMA/145450/2014
B.7	IAS consultancy report on IT Project Management	For information, EMA/272472/2014; Ref. Ares(2014)951143 - 27/03/2014
B.8	2013 annual reports of Audit Activities at the Agency a) Annual Internal Audit Report (IAS-EC) 2013	For information, EMA/MB/272800/2014; Ref.Ares(2014)1119073 - 09/04/2014
	b) Annual Report of the Internal Audit of EMA 2013	For information, EMA/MB/272889/2014; EMA/76509/2014
B.9	EU Telematics Strategy 2014-2016	For information, EMA/MB/325379/2014; For endorsement, EMA/289808/2014
B.10	Proposal for the establishment of an AD hoc expert group on VETERINARY Novel Therapies (ADVENT)	For information, EMA/299310/2014; For endorsement, EMA/CVMP/139369/2014*
B.11	Report by the Steering Group on the Management Board data gathering initiative	For information, EMA/MB/333172/2014; EMA/MB/333935/2014; For adoption, EMA/MB/49037/2014
B.12	Update on the implementation of Pharmacovigilance Legislation – New proposal for improving the RMP process	For information, EMA/MB/329595/2014; EMA/37444/2014
B.13	EMA policy on the publication of and access to clinical trial data	For information, EMA/MB/333011/2014; For discussion/endorsement, EMA/240810/2014
B.14	Annual report on the performance of the Agency's scientific procedures	Deferred

B.15	<p>Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA "eligibility"</p> <p>a) Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA eligibility</p> <p>b) Criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency activities</p> <p>c) Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency (EMA) activities</p>	<p>For information, EMA/MB/247583/2014;</p> <p>For adoption, EMA/566453/2012*</p> <p>For adoption, EMA/24913/2005 rev. 2*</p> <p>For adoption, EMA/161137/2011 – Rev 1*</p>
B.16	<p>a) Opinion on the Agency's annual accounts for the financial year 2013</p> <p>b) Mandate for the Executive Director to sign the lease and all associated documents for 30 Churchill Place</p>	<p>For information, EMA/MB/291478/2014;</p> <p>For adoption EMA/MB/292607/2014;</p> <p>For information, EMA/277014/2014; EMA/292683/2014; EMA/14575/2014</p> <p>For information, EMA/MB/340709/2014;</p> <p>For adoption, EMA/343507/2014</p>
C	Points for information only**	
C.1	Update on Telematics from the EU Telematics Management Board (EU TMB)	EMA/MB/273776/2014
C.2	Report from the Heads of Medicines Agencies	
C.3	Outcome of written procedures during the period from 22 February 2014 to 12 May 2014	EMA/MB/190422/2014*
C.4	Summary of transfer of appropriations in the budget 2014	EMA/MB/268686/2014*

* 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