



16 December 2015
EMA/MB/169416/2015 Version 4 Adopted
Management Board meeting of 16-17 December 2015

Agenda for the 90th meeting of the Management Board

Held on 16 December 2015, Room 2A (16:00 – 18:45)

Held on 17 December 2015, Room 2A (08:00 - 15:00)

Chairperson: Sir Kent Woods

Item		
1.	Draft agenda	For adoption, EMA/MB/169416/2015 *
2.	Declaration of conflicts of interest related to current agenda	Oral report
3.	Minutes of the 89th meeting, held on 2 October 2015 adopted via written procedure on 10 November 2015	For information, EMA/MB/313663/2015 *
A	Points for automatic adoption	
A.1	Financial compensation and workload estimation of the revised EMA organisation of translations of product related information	For endorsement, EMA/MB/711738/2015*; For information, EMA/742260/2015
B	Points for discussion	
B.1	Strategy for EU Medicines Network to 2020 – working together to improve health	For information, EMA/MB/778307/2015; For adoption, EMA/MB/151414/2015* For information, EMA/667824/2015*; EMA/670072/2015 – Annex 1*; EMA/441188/2015 – Annex 2*
B.2	a) Programming document – Multi-annual programming 2017-2019 – Work Programme 2016 – Work programme 2017 – Annexes to multiannual programming Programme and project plans	For information, EMA/MB/792303/2015-Rev.1; For adoption EMA/693305/2015* For information, EMA/610297/2015



Item		
	b) Budget and Establishment Plan 2016	For information, EMA/MB/577439/2015 For adoption, EMA/MB/596380/2015*
	c) Non-automatic carryover 2015 to 2016	For adoption, EMA/MB/615629/2015*
	d) Delegation of non-substantial amendments to the Work Programme to the authorising officer	For adoption, EMA/MB/768568/2015*
B.3	Audit strategy 2016-2018 and annual Audit Plan for 2016	For information, EMA/MB/718643/2015; For adoption; EMA/363099/2015
B.4	Highlights of the Executive Director	Oral report
B.5	Report from the European Commission	Oral report
B.6	a) Revised Policy on the Handling of Conflicts of Interests of the EMA Management Board b) Breach of trust procedure	For information, EMA/MB/774793/2015; For adoption, EMA/MB/715362/2015,* EMA/MB/309079/2012, Rev. 1*
B.7	Report by the Steering Group on the Management Board data gathering initiative	For information, EMA/MB/803492/2015; For endorsement, EMA/841279/2015; EMA/841290/2015
B.8	Timelines for the implementation of the EU Portal and Database and Clinical Trial Regulation	For information, EMA/MB/744249/2015; For endorsement, EMA/760345/2015*
B.9	Revised EudraVigilance Access Policy	For information, EMA/MB/748121/2015-Rev 1 For adoption, EMA/759287/2009 Rev 2*
B.10	Pharmacovigilance Programme: EudraVigilance high level audit plan	For information, EMA/MB/727947/2015; EMA/452911/2015
B.11	Member State access to Art57 data on medicinal products: functionality for Qualified Person for PhV and location of PhV master file	For information, EMA/MB/632566/2015; For adoption, EMA/MB/730957/2015
B.12	EMA Anti-fraud strategy: progress report	Oral report
B.13	EMA Information Management Strategy	For information, EMA/MB/764735/2015; EMA/768940/2015*

C	Points for information only**	
C.1	Report on EU Telematics	For information, EMA/MB/752101/2015; EMA/712432/2015
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 2 September 2015 to 2 November 2015	For information, EMA/MB/653272/2015 *
C.4	Summary of the transfers of appropriation 2015	For information, EMA/MB/776950/2015 *
C.5	An action plan to improve the perception and use of the Article 58 procedure	For information, EMA/MB/762330/2015-Rev 1; EMA/756676/2015-Rev 1*
C.6	Overview of Staff Regulation implementing rules signed by the MB Chair during the period from 13 February 2015 to 2 October 2015	For information, EMA/MB/737283/2015 *

* 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