14 December 2016
EMA/MB/488455/2016 v.4 Adopted
Management Board meeting of 14-15 December 2016

Agenda for the 94th meeting of the Management Board

Held on 14 December 2016, Room 2A (16:00 – 18:45)
Held on 15 December 2016, Room 2A (08:00 – 15:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/488455/2016*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 93rd meeting, held on 6 October 2016 adopted via written procedure on 14 November 2016	For information, EMA/MB/489158/2016*
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/666915/2016 For information, EMA/738889/2016*
A.2	Model rules on non-application of Commission decision on the maximum duration for the recourse to non-permanent staff in the Commission services	For information, EMA/MB/714995/2016; For adoption, EMA/MB/480025/2016 For information, (2016) D/7065
A.3	Decision of the Management Board on setting up a Staff Committee	For information, EMA/MB/714784/2016; For adoption, EMA/MB/438127/2016

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B	Points for discussion	
B.1	Programming 2017-2020 – Programming 2017-2019, including 2017 work programme, budget, establishment plan – Draft programming 2018-2020	For information, EMA/MB/799574/2016; For adoption, EMA/583016/2016*, EMA/MB/740755/2016*; For information, EMA/804060/2016, EMA/679864/2016, EMA/804132/2016
B.2	Highlights of the Executive Director	Oral report
B.3	Report from the European Commission	Oral report
B.4	a) Audit strategy 2017-2019 and annual Audit Plan for 2017 b) Report to the Management Board on Pharmacovigilance audits carried out in the European Medicines Agency from 1 July 2014 to 30 June 2016	For information, EMA/MB/759063/2016; For adoption, EMA/541719/2016 For information, EMA/MB/759561/2016 For endorsement, EMA/506638/2016
B.5	Framework of interaction with Academia	For information, EMA/MB/752841/2016; EMA/753033/2016 For adoption, EMA/578639/2016*
B.6	Revised framework of interaction with healthcare professionals	For information, EMA/752887/2016, EMA/677917/2016; EMA/705066/2016; For adoption, EMA/89918/2016*
B.7	Revised Access to Documents Policy – Release for Public Consultation	For information, EMA/MB/750780/2016; For endorsement, EMA/729522/2016*, EMA/183710/2016*, EMA/127362/2006, Rev. 1*
B.8	Multinational assessment team concept	For information, EMA/MB/765224/2016; For endorsement, EMA/619544/2016*
B.9	Revised EU Telematics governance model	For information, EMA/MB/796830/2016, EMA/MB/790083/2016; For endorsement, EMA/795871/2016

B.10	Pharmacovigilance Programme: Member State access to Art57 data on medicinal products	For information & endorsement, EMA/MB/729634/2016
B.11	Pharmacovigilance Programme: Update on Eudravigilance Auditable Requirements Project	For information, EMA/MB/725773/2016, EMA/452911/2015, EMA/325783/2016, EMA/835422/2016
B.12	Clinical Trial EU Portal and Database	For information, EMA/MB/757803/2016, EMA/753750/2016
B.13	Report by the Steering Group on the Management Board data gathering initiative	For information, EMA/MB/813572/2016
B.14	ADVENT mandate renewal	For information, EMA/MB/734937/2016; EMA/CVMP/ADVENT/630299/2014 – Rev.2*
B.15	Update on the implementation of the Anti-Fraud Strategy	Oral report
B.16	Revision of rules for reimbursement of expenses for delegates attending meetings	For information, EMA/MB/811697/2016
C	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/756656/2016, EMA/731292/2016
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 7 September 2016 to 16 November 2016	For information, EMA/MB/716724/2016*
C.4	Summary of the transfers of appropriation 2016	For information, EMA/MB/707314/2016*
C.5	Pharmacovigilance Programme: Revised Eudravigilance Access Policy	For information, EMA/MB/707899/2016; For information, EMA/759287/2009 Rev. 3*

* Documents marked with a star * are intended for publication on the external website.
** Documents in *Additional documents for information* section are not intended for discussion unless specifically requested.