



11 June 2015  
EMA/MB/170636/2015 V.3 Adopted  
Management Board meeting of 11 June 2015

## Agenda for the 88th meeting of the Management Board

Held on 11 June 2015, Room 2A (08:00 – 15:00)

Chair: Sir Kent Woods

Item	Preliminary draft agenda	Action / Reference
1.	Draft agenda	For adoption, EMA/MB/170636/2015 *
2.	Declaration of conflicts of interest related to current agenda	Oral report
3.	Minutes of the 87th meeting, held on 19 March 2015 adopted via written procedure on 28 April 2015	For information, EMA/MB/178925/2015 *
<b>A</b>	<b>Points for automatic adoption/endorsement</b>	
A.1	Management Board meeting dates 2015-2016	For adoption, EMA/MB/239247/2015*
<b>B</b>	<b>Points for discussion</b>	
B.1	Highlights of the Deputy Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Amendment to Work programme 2015-2016 Annex 4: Operational procurement decisions	For information & adoption, EMA/MB/297623/2015
B.4	Assessment of the Executive Director's Annual Activity Report (AAR) 2014	For information, EMA/MB/333954/2015; EMA/95858/2015*; For adoption, EMA/277613/2015*
<del>B.5</del>	<del>Update on the Implementing rules to the Fee Regulation</del>	<del>Oral report</del>
B.6	Draft guiding principles for a revision of the EMA Col policy for the Management Board	For information, EMA/MB/332272/2015, For endorsement, EMA/332353/2015



B.7	Update on the EU Telematics Strategy and Implementation Roadmap 2015-2017	For information, EMA/MB/334709/2015; For discussion, EMA/322556/2015
B.8	Response to outcome of the public consultation on public hearings at the PRAC	For information, EMA/MB/332804/2015; For discussion, EMA/332813/2015
B.9	PSUR Repository  a) Outcome of the audit and PRAC recommendation  b) Plan for further functionality  c) Decision on mandatory use	For information, EMA/MB/290716/2015  For discussion, EMA/321731/2015; EMA/PRAC/233445/2015  For information, EMA/312973/2015; EMA/681848/2013; EMA/313926/2015  For adoption, EMA/MB/303824/2015
B.10	Management Board liaison process for PRAC composition – Liaison after the first 3 years of PRAC in 2015	For information, EMA/MB/330972/2015; EMA/324491/2015; For discussion, EMA/525507/2014 For adoption, EMA/330665/2015
B.11	Update on the development of CT Portal and Database	For information, EMA/MB/331420/2015
B.12	IAS Mission Charter	For information, EMA/MB/271124/2015; For adoption, Ares(2014)3984092
B.13	2014 annual reports of Audit Activities at the Agency a) Annual Internal Audit Report (IAS-EC) 2014  b) Annual Report of the Internal Audit of EMA 2014	For information, EMA/MB/281256/2015;  For information, EMA/668428/2014
B.14	Amendment of audit strategy 2015-2017 and annual audit plan 2015	For information, EMA/MB/281376/2015; For adoption, EMA/427639/2014
B.15	Report by the Steering Group on the Management Board data gathering initiative	For information, EMA/MB/344426/2015

B.16	Annual report on the performance of the Agency's scientific procedures	For information, EMA/MB/320899/2015 For endorsement, EMA/268699/2015
<b>C</b>	<b>Points for information only**</b>	
C.1	Report on EU Telematics	For information, EMA/MB/325307/2015; EMA/MB/273417/2015
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 19 February 2015 to 8 May 2015	For information, EMA/MB/233602/2015*
C.4	Summary of transfer of appropriations in the budget 2015	For information, EMA/MB/279870/2015 *
C.5	IAS Strategic Internal Audit Plan 2016-2018	For information, EMA/MB/281871/2015; Ares(2015)1769698
C.6	Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2014	For information, EMA/MB/322505/2015

\* 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