



11 June 2020
EMA/MB/155342/2020 Adopted
Management Board meeting of 11 June 2020

Agenda for the 108th meeting of the Management Board

Held on 11 June 2020, Room 1C (09:00 – 13:00)

Chairperson: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/155342/2020*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 107th meeting, held on 19 March 2020 adopted via written procedure	For information, EMA/MB/152592/2020*
4.	Update on 30 Churchill Place (<i>in camera</i>)	For endorsement
5.	Proceedings for the nomination of the Executive Director	For adoption, EMA/MB/277313/2020*
6.	Covid-19 <ul style="list-style-type: none">EMA Status ReportPublication of all Clinical Summaries and Reports regarding Covid-19 related and authorised drugs/vaccines	For information/discussion
A	Points for automatic adoption	
A.1	Management Board meeting dates 2021-2022	For information & adoption, EMA/MB/155721/2020*
B	Points for discussion	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Assessment of the Executive Director's Annual Activity Report (AAR) 2019	For information, EMA/MB/265843/2020; EMA/33568/2020*; For adoption, EMA/220995/2020*
B.4	Preparation for written procedure on Amending Budget	For information, EMA/MB/237984/2020



Item		
B.5	Revised implementing rules to the Fee Regulation as of 12 June 2020	For information, EMA/MB/238468/2020 Rev. 1; For adoption, EMA/MB/238467/2020 Rev. 1*
B.6	Implementation Plan - 2018 and 2019 European Medicines Agency Annual Reports on Independence	For information, EMA/MB/226425/2020; For adoption, EMA/176567/2020; EMA/89351/2020*; EMA/89374/2020*; EMA/259494/2016 Rev 3*
B.7	Annual report of internal audit and advisory activities at the European Medicines Agency 2019	For information, EMA/MB/237105/2020; EMA/143243/2020
B.8	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation a) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation b) Report of the EU Clinical Trial Regulation Coordination group	For information, EMA/MB/202071/2020 For information EMA/201952/2020 For endorsement, EXT/267687/2020; For information, EMA/160943/2020; EMA/193987/2020
B.9	Update on the presence of nitrosamine impurities in medicines a) Follow-up to and implementation of the Art 5(3) CHMP scientific review of the presence of nitrosamine impurities in human medicines b) Lessons learnt from the presence of nitrosamine impurities in sartan medicines: outcome of the targeted stakeholder consultation, impact analysis and implementation plan	For information/discussion For information, EMA/MB/306023/2020; For endorsement, EMA/307799/2020*; For information, EMA/INS/GMP/307955/2020* EMA/303870/2020*
B.10	Annual report 2019 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use	For information, EMA/MB/235475/2020; For endorsement, EMA/223363/2020
B.11	Progress report on the drafting paper of the European Medicines Regulatory Network (EMRN) Strategy to 2025	Oral report

Item		
B.12	Update on preparation for implementation of Veterinary Medicinal Products Regulation	Oral report
B.13	Report on the establishment of the Big Data Steering Group	For information, EMA/MB/249685/2020; EMA/251096/2020; EMA/251092/2020
C	Points for information only**	
C.1	Report on EU Telematics	For information, EMA/MB/225113/2020; EMA/225114/2020
C.2	Feedback from the Heads of Medicines Agencies	EXT/312654/2020
C.3	Outcome of written procedures finalised during the period from 21 February 2020 to 26 May 2020	For information, EMA/MB/283295/2020*
C.4	Summary of transfers of appropriations	For information, EMA/MB/201079/2020*
C.5	Summary of implementation of assigned revenue budget	For information, EMA/MB/483727/2019

* 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.