Agenda of the 109th meeting of the Management Board
Held on 1 October 2020, Room 2A (09:00 – 16:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/388242/2020 *
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 108th meeting, held on 11 June 2020 adopted via written procedure	For information, EMA/MB/318294/2020*
4.	Minutes of the Extraordinary Management Board meeting for the nomination of the Executive Director, held on 25 June 2020 adopted via written procedure	For information, EMA/MB/367450/2020*
5.	Update on 30 Churchill Place	Oral report
6.	Covid-19	
	a) EMA Status Report	For information/discussion
	b) Additional safeguards (to be) put in place for securing the robustness and independence of the scientific review process for MAAs for COVID-19 treatments	For information, EMA/MB/505166/2020; Email of 27 August 2020; For endorsement, EMA/MB/506190/2020
	c) EMA COVID-19 BCP: Impact on the EMA Work Programme 2020 and consequences for the EMA Work Programme 2021	For information/ discussion
7.	Update on Brexit	For information
A	**Points for automatic adoption**	
A.1	Management Board Decision - Amendment to rules on leave	For information, EMA/MB/458533/2020; EXT/12715/2014; For adoption, EMA/MB/156327/2020

A.2	Revision of rules on handling declared interests of staff and candidates before recruitment	For information, EMA/MB/458456/2020; EMA/371831/2020; For adoption, EMA/259494/2016, Rev. 4*
B	**Points for discussion**	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	EMA Mid-year report 2020 from the Executive Director (January – June 2020)	For information, EMA/MB/476052/2020; EMA/386447/2020*
B.4	Revision of Internal Audit Charter of the Audit Capability (AF-Audit) of EMA	For information, EMA/MB/404190/2020; For adoption, EMA/209787/2017 Rev.1
B.5	Lessons learnt from the presence of nitrosamine impurities in sartan medicines: Impact Analysis and Implementation Plan	For information, EMA/MB/469318/2020; For endorsement, EMA/INS/GMP/473118/2020; EMA/INS/GMP/473117/2020
B.6	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/472757/2020, Rev.1;
	a) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation	For information, EMA/464240/2020; EMA/276356/2020, Rev.1
	b) Report of the EU Clinical Trial Regulation Coordination group	For information, EXT/505221/2020
B.7	Review of activities of the Working Parties of the EMA	For information, EMA/MB/492845/2020; For endorsement, EMA/491249/2020
B.8	Progress report on the European Medicines Regulatory Network (EMRN) Strategy to 2025	Oral report
B.9	Update on preparation for implementation of Veterinary Medicinal Products Regulation	Oral report
B.10	Introduction to the Union Product Database (UPD) Access Policy under the Veterinary Medicinal Products Regulation (VMP-Reg)	For information, EMA/MB/391703/2020; EMA/198149/2020
B.11	Update on Big Data Steering Group and DARWIN (Data Analytics and Real World Interrogation Network)	Oral report
C	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/396798/2020; EMA/396803/2020

C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 27 May 2020 to 15 September 2020	For information, EMA/MB/474257/2020*
C.4	Summary of transfers of appropriations in budget 2020	For information, EMA/MB/447191/2020*
C.5	Tenth six-monthly report on ex ante and ex post evaluation of projects for the period 1 January to 30 June 2020	For information, EMA/MB/484473/2020; EMA/484474/2020

* 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.