EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 March 2020
EMA/MB/1404/2020 Adopted
Management Board meeting of 19 March 2020

Agenda for the 107th meeting of the Management Board

Held on 19 March 2020, Room 1C (09:00-10:30)

Chairperson: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/1404/2020*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 106th meeting, held on 18-19 December 2019 adopted via written procedure	For information, EMA/MB/542228/2019*
4.	~~EMA Preparedness on Brexit~~	~~Oral report~~
5.	~~Update on 30 Churchill Place~~	~~Oral report~~
A	**Points for automatic adoption**	
A.1	Model rules on the non-application of the Commission Decision on the maximum duration for the recourse to non-permanent staff in the Commission services	For information, EMA/MB/12651/2020; Ares(2019)6057171; C(2019) 6929; For adoption, EMA/MB/23627/2020
A.2	Revision of budget remark for budget 2020	For information & endorsement, EMA/MB/36206/2020
B	**Points for discussion**	
B.1	~~Highlights of the Executive Director~~	~~Oral report~~
B.2	~~Report from the European Commission~~	~~Oral report~~
B.3	Future-proofing of the EMA	For information, EMA/MB/91553/2020
B.4	Preparation for the proceedings for the nomination of the Executive Director	For information, EMA/MB/88036/2020
B.5	EMA Annual Report 2019	For information, EMA/MB/83673/2020; For adoption, EMA/68349/2020*

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B.6	2018-2019 EMA Annual Reports on Independence	For information, EMA/MB/85003/2020; For information/endorsement, EMA/425399/2019
B.7	a) Revised implementing rules to the Fee Regulation as of 1 April 2020 including amendment to Annex I of Cooperation Agreement b) Renewal of the Cooperation Agreement between EMA and National Competent Authorities	For information, EMA/MB/516696/2019; For adoption, EMA/MB/332998/2019*; EMA/MB/686213/2019 For information & discussion, EMA/MB/677663/2019
B.8	Update on the presence of nitrosamine impurities in medicines a) Proposed approach for the management of nitrosamine presence in medicines b) Lessons learnt from presence of N-nitrosamine impurities in Sartan medicines	For information For information, EMA/MB/91583/2020; EMA/INS/GMP/91551/2020; EMA/INS/GMP/91552/2020; For endorsement, EMA/93691/2020
B.9	Review of activities of the Working Parties of the EMA	For information, EMA/MB/74978/2020; EMA/72861/2020; For adoption, EMA/675923/2019; For endorsement, EMA/100564/2020
B.10	EMA Regulatory Science Strategy to 2025	For information, EMA/MB/100523/2020; For endorsement, EMA/68752/2020*
B.11	~~Progress report on the drafting paper of the European Medicines Regulatory Network (EMRN) Strategy to 2025~~	~~Oral report~~
B.12	Potential impact of the Coronavirus infection on the availability of human and veterinary medicinal products – status report	For discussion

B.13	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) Audit methodology	 For information, EMA/MB/40090/2020; EMA/40089/2020 For information, EMA/MB/92568/2020; For endorsement, EMA/65000/2020
B.14	~~Update on preparation for implementation of Veterinary Medicinal Products Regulation~~	~~Oral report~~
B.15	10th Annual Report Veterinary MUMS/limited market	For information, EMA/MB/66702/2020 For endorsement, EMA/371094/2019*
B.16	Big Data: update on establishment of the Steering Committee	For information, EMA/MB/95793/2020; EMA/95333/2020
B.17	Amendments to the existing Rules of Procedure of EMA Management Board and scientific Committees	For information, EMA/MB/138850/2020; EMA/144543/2020 For adoption Annex to EMA/MB/138850/2020
C	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/687822/2019; EMA/687823/2019
C.2	Feedback from the Heads of Medicines Agencies	For information, EXT/138162/2020
C.3	2019 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2019	For information, EMA/MB/67255/2020; EMA/640614/2019*
C.4	Report on ex ante and ex post evaluation of projects for the period 1 January to 31 December 2019	For information, EMA/MB/54359/2020; EMA/54360/2020
C.5	Outcome of written procedures finalised during the period from 23 November 2019 to 20 February 2020	For information, EMA/MB/91576/2020*
C.6	Summary of transfers of appropriations in budget 2019	For information, EMA/MB/60088/2020*
C.7	Adoption by analogy of Commission decisions on the duties of Commission drivers and Commission decision on procedures for dealing with professional incompetence	For information, EMA/MB/48438/2020; Ares(2019)6989184; O/97/2004; Ares(2019)6254121

C.8	Strategic internal audit plan 2020-2022 by the Internal Audit Service	For information, EMA/MB/62989/2020; Ares(2020)465850
C.9	Follow-up of outstanding recommendations from past audits in the European Medicines Agency (EMA) by the Internal Audit Service– Note on audit conclusions	For information, EMA/MB/63039/2020; Ares(2020)608953
C.10	Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2019	For information, EMA/MB/69538/2019

* 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.