EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 December 2019
EMA/MB/547838/2019 Adopted
Management Board meeting of 18-19 December 2019

Agenda for the 106th meeting of the Management Board

Held on 18 December 2019, (14:30 – 18:30)
Held on 19 December 2019, (09:00 – 16:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/547838/2019*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 105th meeting, held on 3 October 2019 adopted via written procedure	For information, EMA/MB/542228/2019*
4.	EMA Preparedness on Brexit 4.1. Update on EMA Brexit preparedness 4.2. Update on EMA-NL collaboration for relocation to Amsterdam	Oral report For information/discussion For information/discussion
5.	Update on 30 Churchill Place	Oral report
A	**Points for automatic adoption/endorsement**	
A.1	Financial compensation and workload estimation of the EMA organisation of translations of product related information	For information, EMA/MB/602870/2019; For endorsement, EMA/607478/2019
A.2	Management Board decision – on request for authorisation not to apply Commission Decision C (2019) 4231 final of 12 June 2019	For information, EMA/MB/461610/2019, Ares (2019)3845058 – 17/06/2019; For adoption, EMA/461615/2019

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A.3	Corrigendum to the Financial Regulation applicable to the budget of the European Medicines Agency from 1 July 2019	For information, EMA/MB/598412/2019; For adoption, EMA/MB/911312/2019*
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	Oral report
B.4	Review of activities of the Working Parties of the EMA	For information/endorsement EMA/681159/2019
B.5	EMA Regulatory Science Strategy to 2025 a) Draft plan and proposals	Oral report
B.6	Development of European Medicines Regulatory Network (EMRN) Strategy to 2025	Oral report
B.7	Programming a) Programming 2020-2022, including 2020 work programme, budget, establishment plan b) Draft programming 2021-2023	For information, EMA/MB/559448/2019, EMA/MB/533088/2019 For adoption, EMA/282/2019*, EMA/193731/2019*
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/572768/2019-Rev.1, EMA/572767/2019 For endorsement EXT/671952/2019; For information, EMA/666659/2019
B.9	Mandatory use of the ISO/ICH E2B(R3) format for ADR reporting in the EU	For information, EMA/MB/567037/2019; For confirmation & announcement, EMA/561671/2019*
B.10	HMA-EMA Joint Big Data Taskforce Phase II report	For information, EMA/MB/663219/2019; For endorsement, EMA/584203/2019*

B.11	HMA-EMA Task Force on the Availability of Medicines – Terms of Reference – SPOC system: report on phase 1 of the pilot – Metrics for shortages: Key information for shortage management and monitoring by EU regulators	For information, EMA/MB/672653/2019; For adoption, EMA/857232/2016 Rev1; For information, EMA/410297/2019; For adoption, EMA/548142/2018; For information, EMA/605066/2019
B.12	Update on preparation for implementation of Veterinary Medicinal Products Regulation	Oral report
B.13	Yearly revision of the EMA Information Management Strategy and Information Management Strategic Plan	For information, EMA/MB/647746/2019; For endorsement, EMA/410709/2019*, EMA/410763/2019
B.14	Audit Strategy and Annual Audit Plan a) Audit Strategy 2020 – 2022	For information, EMA/MB/615428/2019; For adoption, EMA/MB/533310/2019
B.15	Electronic product information (ePI): key principles and roadmap	For information, EMA/MB/600460/2019; For endorsement, EMA/240743/2019, EMA/503860/2019
B.16	EMA implementation of medical devices and in-vitro diagnostic regulations	Oral report
B.17	Annual report on the implementation of the EMA's Anti-Fraud Strategy	Oral report
B.18	Report on the implementation by EMA of the EU Data Protection Regulation	Oral report
B.19	Management of Nitrosamine presence in medicines	For information, EMA/MB/687292/2019; For endorsement, EMA/MB/678452/2019
C	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/578488/2019, EMA/578489/2019
C.2	Feedback from the Heads of Medicines Agencies	EXT/682256/2019
C.3	Outcome of written procedures finalised during the period from 17 September 2019 to 22 November 2019	For information, EMA/MB/638477/2019*
C.4	Summary of the transfers of appropriation 2019 and Summary report on implementation of assigned revenue	For information, EMA/MB/582178/2019*

C.5	Revised Executive Directors decision on rules governing tuition fees for dependents of secondment of national experts to the EMA	For information, EMA/MB/596721/2019; EMA/596711/2019*
C.6	European Ombudsman's (EO) decision on pre-submission activities; update of the Procedural Advice on the CHMP/CAT/PRAC (Co)-Rapporteur appointment	For information, EMA/MB/651058/2019, EMA/654264/2019 Rev.4

* 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.