



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Operation and Procedural Preparedness Update

Agenda point 3

Industry Stakeholder meeting on Brexit and operation of centralised procedure for Human and Veterinary Medicinal Products
Presented on 28 January 2019 by:

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An agency of the European Union





Main focus EMA Brexit preparedness

- Main focus at the moment is on:
 - EMA 2019 and 2020 planning
 - Brexit impact on availability of CAPs (see separate slide deck)
 - Preparation for relocation to Amsterdam



EMA 2019 and 2020 planning

- EMA 2019 and 2020 WP adopted by Management Board (MB) in December 2018
- WPs have been drafted on the basis of current knowledge of anticipated staff loss for 2019 and 2020:
 - 2019 will be a year in transition
 - 2020 will be a year of paving the way for the future



2019: Year of transition (1/3)

- 2019 *de facto* will be divided into two parts:
 - January-June: EMA will have to
 - Address an important staff loss
 - Cope with the consequences of the physical relocation to Amsterdam
 - Cope with an important workload increase as a direct result of the Brexit arrangements
 - July-December: EMA will
 - Gradually take-up previously suspended/reduced activities
 - In line with the priorities identified in the Network strategy to 2020
 - Albeit after a reflection on the most efficient way to achieve longer term fit-for-purpose applications/processes/tools
 - Prepare for the future (2020-2025 strategy), with particular emphasis on
 - Regulatory Science Strategy
 - Corporate ICT Strategy

2019: Year of transition (2/3)

- January-June: Launch of phase 4 of the BCP as of 1 January 2019, with the following priorities:
 - Existing category 1 activities to be maintained, with no new activities, except preparation for the implementation of the new veterinary legislation
 - Brexit related activities to be maintained, but gradually less FTEs to be involved
 - Only critical category 2A and 2B activities to be maintained, as well as the minimum required corporate governance activities (category 3)
 - As regards already temporarily suspended/reduced category 2B and 3 activities, no change compared to BCP phase 3
 - All remaining category 2A and 2B activities to be temporarily suspended
 - Specific arrangements to apply during the critical period around the physical relocation from London to Amsterdam Sloterdijk (from 11 February until 15 March 2019 inclusive), whereby the focus will be on maintaining category 1 activities



2019: Year of transition (3/3)

- July-December: Gradually restoring previously suspended/reduced activities:
 - A list of priorities for further consideration will be drawn-up for discussion at the June 2019 MB meeting
 - Before restoring activities, where relevant and feasible, a reflection on longer term sustainability will take place

Preparedness for relocation to Amsterdam

- Only <5 weeks left before the Agency closes its offices in London (1 March); 6 weeks until EMA opens its offices in Amsterdam Sloterdijk (11 March)
- CAT and BWP will meet in February in the Spark building; opportunity to test the new facilities
- As of 15 March all meetings will take place in the Spark building
- Due to the size of the industry lounge in the Spark building a chaperoning system to accompany pharmaceutical companies will be put in place (information will be sent to the Industry Associations and individual pharmaceutical companies)
- Between 4 and 8 March the Agency building is closed; staff are teleworking, with a limited number of staff physically present to deal with emergencies
- Further updates will be provided on the EMA website