



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Industry stakeholder meeting on Brexit and operation of the centralised procedure for human and veterinary medicinal products

Agenda item 2: Operational preparedness for Brexit and next phase of the BCP
24 September 2018

Presented by Noël Wathion
Deputy Executive Director

An agency of the European Union





EMA Brexit Preparedness BCP in a nutshell (1/3)

- The aim of the EMA Brexit Preparedness BCP is to address a situation where a “business as usual” scenario is no longer possible
 - Either because EMA has to ensure that the necessary human resources are available to work on EMA Brexit preparedness
 - Or because EMA can no longer compensate staff loss through the recruitment of replacement resource
- Both situations can exist in parallel and may persist for a longer period

EMA Brexit Preparedness BCP in a nutshell (2/3)

- To operate the EMA Brexit Preparedness BCP, EMA activities have been grouped in 3 categories which can broadly be described as follows:

Category	Activities covered
Category 1 (highest priority) activities	Core scientific activities and supporting IT applications, corporate/communication/other IT activities necessary for EMA's operation, legal obligations put on EMA
Category 2 (medium priority) activities	Either strategic activities or other core activities, sub-classified into 2A and 2B
Category 3 (lowest priority) activities	Non-strategic activities such as governance and support activities



EMA Brexit Preparedness BCP in a nutshell (3/3)

- Furthermore, activities are temporarily suspended or scaled back (in the latter case the reduced output should continue to the same high standards although it may result in a reduction of volume or a delay in the time to achieve the agreed deliverables)
- A stepwise implementation has been put in place
 - First targeting category 3 (the lowest priority) activities
 - Followed by category 2 (medium priority) activities
 - When needed, targeting category 1 (the highest priority) activities



Current status of the EMA Brexit Preparedness BCP

- Since January 2018, EMA is in Phase 2 of the BCP, whereby
 - Category 3 activities have seen an important scaling back
 - A number of category 2 activities have been temporarily suspended/scaled back as reflected in the 2018 EMA Work Programme



Next phase of the EMA Brexit Preparedness BCP

- As announced on 1 August, the 3rd phase of the BCP will be launched on 1 October 2018, except for one activity which has been temporarily scaled back starting as of 1 August 2018
- The launch of the 3rd phase is needed because EMA will lose more staff than initially anticipated
- The affected activities relate to category 2B activities that consume a high level of FTEs
 - Which provide for interchangeability of staff following training/ knowledge transfer
 - Where time spent can be easily re-allocated
- These activities will either be temporarily suspended or reduced and freed-up staff will be re-allocated to category 1 activities



Identification of additional activities to be temporarily suspended/reduced in Phase 3 of the BCP (1/2)

Activity	Current Phase 2 temporary reductions/suspensions	Additional Phase 3 temporary reductions as of 1 October 2018
International activities	Reduced development of reliance activities with countries with which no MRA nor CA exists, reduced training to non-EU countries which are not a priority and to China and India, reduced fellowships	Reduce to product related activities Reduce to supportive/active role or observer/reactive role as applicable (e.g. in relation to ICH involvement)
Guideline development	Priority given to category 1 activities with an urgent public/animal health need, followed by those that can be finalised or released for public consultation in 1 st half of 2018	Limit to guidelines with an urgent public/animal health need, or necessary in the context of Brexit or for the implementation of new/ revised legislation (to be decided on an <i>ad hoc</i> basis with robust justification)
Secretariat relating to WP, SAGs, QRD, NRG and GXP meetings	Reduced as a result of reduced guideline development and need to achieve budgetary savings	Reduce further in line with the reduction in the number of guidelines



Identification of additional activities to be temporarily suspended/reduced in Phase 3 of the BCP (2/2)

Activity	Current Phase 2 temporary reductions/suspensions	Additional Phase 3 temporary reductions as of 1 October 2018
Programmes and projects	Suspension of projects: Review of WPs and SAGs, Add Value, Veterinary change (except EudraVigilance Vet 3) and Medication errors	Reduce Portfolio Board activities and Portfolio Office activities in line with the reduction of projects
Transparency, information, stakeholder interaction	Reduced number of meetings with patients, HCPs, academia, suspension of bilateral meetings with trade associations (except Brexit related), reduced training of stakeholders and NCAs (except Brexit related) and in other areas such as GxP, general pharmacovigilance and quality topics	Reduce to Brexit and category 1 and 2A activities related interactions only
Clinical data publication	Maintained at a slower pace	Reduce to finalisation of ongoing procedures only Observer/reactive role for further developments in the data anonymisation field



Current environment as regards the available EMA human resources

- Situation in terms of EMA Brexit preparedness is gradually shifting from Brexit preparedness to implementation, although as regards the “relocation to Amsterdam” project itself the focus is still a lot on preparation at this moment in time
- Situation as regards the number of FTEs needed for Brexit preparedness/ implementation is expected to stabilise towards the end of Q4 2018 and only to gradually improve as of Q1 2019
- There remain at this moment several uncertainties which will impact on EMA’s ability to maintain continuity of operation



2019 and 2020 planning: Balancing certainties versus uncertainties

- Planning for 2019 and 2020 remains a real challenge due to a still very unstable situation, characterised by certainties and uncertainties that need to be carefully considered

Certainties	Uncertainties
<ul style="list-style-type: none">• All current short-term contract staff will no longer be available by no later than the end of February 2019	<ul style="list-style-type: none">• Real number of longer term contract staff not relocating, despite a currently more positive picture as regards staff intentions to relocate
<ul style="list-style-type: none">• It is possible to find adequate replacement staff following external selection procedures (in terms of both a sufficient number of successful candidates and their profile)	<ul style="list-style-type: none">• Number of staff on parental leave/unpaid leave throughout 2019 remains very unclear and the extent of decrease in efficiency (e.g. as a result of consecutive TW or the unsettling period for staff whilst also dealing with their private relocation) is currently difficult to quantify• Extent of likely second wave of staff resigning at a later stage once EMA has relocated is currently unknown• EU Budgetary Authorities' decision as regards the EMA request for additional resource to cope with the Brexit consequences is not yet taken



EMA's main challenge in a Brexit preparedness business continuity scenario

- EMA's main challenge is to strike the right balance between achieving:
 - Short to mid-term, ensure continuity of operation by adequately addressing an unprecedented staff loss
 - Longer term (as per EMA's mission statement), continue fostering scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health
- EMA aims to strive for both objectives, acknowledging that this is fully dependent on the ultimately available human resources



EMA 2019 and 2020 planning

- On the basis of current knowledge of anticipated staff loss for 2019 and 2020:
 - 2019 will be a year of transition
 - 2020 will be the year of paving the way for the future



2019: Year of transition

- 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