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EMA Brexit Preparedness Business Continuity Plan

Phase 3 implementation plan

1. Introduction

The aim of the EMA Brexit Preparedness Business Continuity Plan (BCP) is to operate "business as usual" as long as possible, while in parallel preparing for the consequences of the UK's exit from the EU, both in terms of the impact on the Agency's operations, as well as the physical move from the Agency's current premises in the UK to the new premises in the Netherlands.

EMA currently is in phase 2 of the BCP. Phase 1 started on 1 May 2017, and phase 2 was launched on 1 January 2018. Each phase is characterised by a temporary suspension/scaling back of a set of EMA activities, starting with the lowest priority activities (category 3), moving to medium priority activities (category 2), even in a worst-case scenario going to the highest priority (category 1) activities if needed[1]. This should allow EMA to protect essential public and animal health activities for as long as possible throughout the Brexit process. So far only category 3 and 2B activities, with in addition some IT work included in category 1, are affected.

As of 1 October 2018 EMA has launched phase 3 of the BCP, the main reason being that the Agency will lose more staff than initially anticipated; staff freed-up as result of a temporary suspension/ reduction of an additional set of EMA activities under phase 3 will allow re-allocation of resources to category 1 activities. Such phase 3 will have to be complemented with an additional set of temporary suspensions/reductions as of 1 January 2019, the latter to be launched as part of phase 4 of the BCP. Temporary suspension/scaling back of activities is currently scheduled to last until 30 June 2019.

2. Additional EMA activities to be subject to business continuity planning

In the context of phase 3 of the BCP a number of category 2B activities have been identified for a temporary suspension/scaling back since they consume a high level of FTEs

- Which should provide for interchangeability of staff following training/ knowledge transfer.

[1] Please refer to annex 1 of the document 'European Medicines Agency Brexit Preparedness Business Continuity Plan' (EMA/196585/2017) for a description of the various categories of EMA activities.

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- Where time spent can be more easily re-allocated.

These category 2B activities relate to the following areas:

- International activities.
- Guideline development.
- Secretariat activities relating to working parties, Working Group on Quality Review of Documents (QRD), Name Review Group (NRG) and GXP meetings.
- Programmes and projects.
- Stakeholder interaction.
- Clinical data publication.

More detailed information on how these areas of activities are affected as of 1 October 2018 is provided below.

It should be noted that EMA is also finalising its review of other meetings planned for Q4 2018, irrespective of the BCP category (1, 2A or 2B). These meetings do not necessarily come within the scope of the activities described below and, therefore, are not included in the current document. These meetings relate to workshops, infodays, training courses, etc.

2.1. International activities: scope of the temporary reduction

- Collaboration at international level is temporarily further scaled back from 1 October 2018 until 30 June 2019.
- International collaboration should during this time period primarily focus on:
  - product-related requests;
  - supply-chain integrity;
  - EUMed4all (article 58) procedures.
- For other international activities EMA involvement is assessed on a case-by-case basis, resulting in an active/supportive/reactive/observer role depending on the precise activity. For instance as regards the harmonisation of global medicine regulation EMA will only take a reactive role. EMA engagement in other global public health issues (such as antimicrobial resistance and vaccines) will be maintained, albeit downsized as considered necessary.
- More specifically as regards clusters (organised as interactions between EMA and one or more of its international partners),
  - All product-related clusters will be maintained but should focus on product discussions (this may be achieved through a shorter duration of the virtual meetings).
  - Non-product related clusters will be temporarily suspended, except for the RWE and the US-EU MRA clusters which will continue to be held, as well as the October 2018 Patient Engagement cluster which will be maintained.
  - Where possible EMA will ask other international partners to manage the secretariat of some clusters.
  - With respect to (V)-ICH guideline development please refer to section 2.2.1. for further information.

2.2. Guideline development: scope of the temporary reduction

- Guideline development is temporarily further reduced from 1 November 2018 until 30 June 2019.
- However, a number of exceptions have been identified, as outlined below.

Non-(V)-ICH guideline development

- Exceptionally, non-(V)-ICH guideline development can continue during this period but only if at least one of the following criteria is met:
  - Necessary due to urgent public/ animal health need.
  - Necessary in the context of Brexit.
  - Necessary for the implementation of new or revised legislation.
- This has resulted in the following 7 non-(V)-ICH guidelines where work will continue:
  - Good Pharmacovigilance Practice: Pregnancy and Breast Feeding.
  - Revision 6 of Note for Guidance on the evaluation of anticancer medicinal products in man.
  - Guideline on the use of minimal residual disease as a clinical endpoint in Multiple Myeloma trials.
  - Revision of Annex 1 of the EU GMP Guide (H/V) – Manufacture of sterile medicinal products.
  - New Annex 21 of the EU GMP Guide (H/V) – Guidance for importers of medicinal products.
  - Reflection Paper of Good Manufacturing Practice and Marketing Authorisation Holders.
  - Guideline on quality requirements of medicinal products containing a device component for delivery or use of the medicinal product.
- Efforts will be made to finalise as many other guidelines as possible before the end of October 2018, either through face-to-face meetings in September or through virtual meetings in October.
- The consultation period for the guidelines that are currently subject to public consultation is extended until the end of June 2019; exceptionally the initial consultation period can be maintained (and not further extended) on condition that only limited work is needed to finalise the guideline and no involvement of EMA staff is necessary to facilitate the work of the rapporteur(s). However, each proposed exception needs to be considered and first agreed by EMA on a case-by-case basis.
- Guideline development that will continue under the above specified conditions can be further processed at GCG (Guideline Consistency Group) and at Scientific Committee level. However, if either the GCG or the Scientific Committees raise issues that need to be further considered by the rapporteur/at WP level, such consideration should be postponed until 30 June 2019, except for the 7 ‘priority’ guidelines described above.
- Work on herbal monographs will continue as planned during this period since such work falls within the scope of product-related activities.

(V)-ICH guideline development

- Exceptionally, ICH guideline development can continue during this period if one of the following criteria is met:

- EMA involvement is as topic lead or rapporteur; this is the case for the following 4 guidelines:
    - E8(R1): Revision of General Considerations for Clinical Trials.
    - E9(R1): Addendum: Statistical Principles for Clinical Trials.
    - M2: Electronic Standards for the Transfer of Regulatory Information.
    - E11A: Paediatric Extrapolation.
- Guideline is of particular interest; this is the case for the following guideline:
    - Q12: Pharmaceutical Product Lifecycle Management.

  For the remaining ongoing guidelines, EMA will switch to an observer role.

- V-ICH guideline development is maintained, albeit that guideline development discussions will not take place at WP level.

2.3. Secretariat activities relating to WP, QRD, NRG and GXP meetings: scope of the temporary reduction

Product-related WPs

- Meetings of product-related WPs (see annex 1 for a list of product-related WPs) will continue as scheduled as per the normal arrangements.
- Non-product related discussions should not take place at these WPs during the aforementioned time period and no other work requiring involvement/support of EMA staff should take place.

Non-product related WPs

- As a general rule, all meetings of non-product related WPs (these are all other WPs not included in the afore-mentioned annex 1) are temporarily suspended from 1 October 2018 until 30 June 2019 in line with the reduction in the number of guidelines to be processed (see also section 2.2.1.), irrespective if such meetings are run as face-to-face or virtual meetings (i.e. via teleconference or webinar).
- An exception is made for those non-product related WPs
    - involved in work on the 7 ‘priority’ non-(V)-ICH guidelines where work will continue (see also section 2.2.1.) and discussions at these WPs will be held virtually;
    - involved in work on other guidelines to be finalised before the end of October 2018 through virtual meetings.

  No other work requiring involvement/support of EMA staff should be undertaken during the aforementioned time period.

- In case the Scientific Committees or the Scientific Advice WPs request product-related input from any of the non-product related WPs, such requests will continue to be addressed as per current practice within the specified time frames, albeit preferably through virtual meetings rather than through face-to-face meetings (the latter for instance can be undertaken if practical arrangements for such meetings have already been made).

Other working/expert groups

- Likewise, all meetings of other working/expert groups are temporarily suspended from 1 October 2018 until 30 June 2019, irrespective if such meetings are run as face-to-face meetings or virtual meetings, with the exception of the following fora:
  - Guideline Consistency Group (GCG).
  - GMDP Inspectors Working Group (GMDP-IWG) *ad hoc* expert group.
  - Compliance Group.
  - SPC harmonisation of old veterinary antimicrobials *ad hoc* expert group.
  - Antimicrobials Advice *ad hoc* expert group.
  - Enpr-EMA working group.
  - EMA-EUnetHTA bilateral.

  The frequency of the aforementioned groups may be reduced or they may be run, where relevant, as virtual meetings.
- In case of product-related discussions these can continue as per current practice within the specified time periods, albeit preferably through virtual meetings rather than through face-to-face meetings (the latter for instance can be undertaken if practical arrangements have already been made).

2.4. Programmes and projects: scope of the temporary reduction

- Taking into account projects already temporarily suspended in phase 2 of the BCP, project governance activities (i.e. activities of the Portfolio Board as well as the Portfolio office) will be temporarily reduced from 1 October 2018 until 30 June 2019.

2.5. Stakeholder interaction: scope of the temporary reduction

- In general terms, stakeholder interaction will be reduced to Brexit, category 1 and 2A activities related interactions only, starting from 1 October 2018 until the end of June 2019.
- More specifically this translates into the following temporary suspensions/reductions of activities:
  - Stakeholder meetings (human and veterinary) organised by EMA, including
    - topic driven single stakeholder or multi-stakeholder events *(reduced in BCP phase 3 to a limited number of exceptions in Q4 2018);*
    - interested parties meetings at Scientific Committees/WPs level (*on hold in BCP phase 3*);
    - platform meetings with industry stakeholders (*on hold in BCP phase 3*);
    - clinical data publication quarterly stakeholder webinars (*on hold in BCP phase 3*);
    - SME info days (*reduced in BCP phase 3; the meeting in October 2018 will proceed as scheduled);*
    - bilateral meetings with industry associations *(on hold already as per BCP phase 2).*
  - Face to face meetings of PCWP/HCPWP and implementation of the work plan 2018-2019 and related activities (*on hold in BCP phase 3, with exception of Brexit-related webinars*).

- Annual training session for patients and healthcare professionals for involvement in EMA activities (*on hold in BCP phase 3*).
- Implementation of the framework for interaction with academia (already reduced in *BCP phase 2 and further reduction in BCP phase 3 to focus on the following priority areas*: support the entry of academia for instance to PRIME and scientific advice, engage with academia on the EMA regulatory science strategy, support to the EMA scientific publication strategy).
- Maintenance of stakeholder contacts and reporting:
    - annual report for patients, consumers, HCPs, academia and their organisations (*reduced in BCP phase 3 with no report in 2018, but instead a combined biennial report 2018-2019*);
    - annual report for industry stakeholders (*reduced in BCP phase 3 with no report in 2018, but instead a combined biennial report 2018-2019*).
- EMA representation in external fora with stakeholders *(reduced in BCP phase 3*) to focus on Brexit and category 1 and 2A activities as follows:
    - Events organised by patient organisations/learned societies (e.g. Eurordis, ESMO) – limited to exceptional EMA representation in sentinel role or with active participation on Brexit or another category 1 or 2A topic with priority given to eligible organisations, remote participation where feasible.
    - Events organised by industry organisations (e.g. Medicines for Europe, EBE) - limited to exceptional EMA representation in sentinel role or with active participation on Brexit or another category 1 or 2A topic, with co-ordinated input from the Network where needed.
    - DIA/TOPRA/RAPs etc – exceptional EMA participation to focus on Brexit or another category 1 or 2A topic.

2.6. Clinical data publication: scope of the temporary reduction

Processing of procedures for the publication of clinical data

- No new applications to be submitted as of 1 August 2018.
- All applications submitted before 1 August 2018 to be processed until completion.
- External guidance to be updated before the end of October 2018 taking into account experience obtained, and subsequently to be published.

Activities in the field of data anonymisation

- 2nd Technical Anonymisation Group (TAG) meeting, planned to be held on 23 October 2018, is maintained; no further TAG meeting is scheduled for the 1st half of 2019.
- EMA will for the time being only participate in further developments in the field of data anonymisation either in a reactive role or as an observer (exact involvement to be decided on a case-by-case basis).

Annex 1: List of product-related WPs

The product-related WPs listed below are Working Parties which either meet face-to-face or virtually. In few cases members liaise via email.

- Scientific Advice Working Party (for human and veterinary medicinal products)
- Biologics Working Party
- (Invented) Name Review Group
- Pharmacokinetics Working Party
- Pharmacovigilance Working Party (for veterinary medicinal products)
- ADVENT (*Ad Hoc* Expert Group on Veterinary Novel Therapies)
- Quality Review of Documents Working Group
- Quality Working Party (core group)
- Safety Working Party
- Biostatistics Working Party
- Modelling and Simulation Working Group
- Biosimilar Medicinal Products Working Party
- PDCO Formulation Working Group
- PDCO Non-clinical Working Group