



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 October 2017  
EMA/196585/2017  
European Medicines Agency

# European Medicines Agency Brexit Preparedness Business Continuity Plan

## 1. Introduction

Following the outcome of the UK referendum on EU membership the challenges for EMA over the next years as the Brexit discussions progress will be:

- Not to jeopardise EMA's positioning in the pharmaceutical arena in the post-Brexit era.  
To achieve this, EMA should continue to comply as long as possible with its 2017-2019 strategic priorities, whilst also looking for any strategic opportunities that may arise in a profoundly changing environment.
- In parallel, to demonstrate its preparedness for addressing any emerging consequences by taking decisive and timely action when needed to safeguard its core tasks, and by overseeing an effective implementation.

This will require the development of adequate Business Continuity Plans (BCPs) that can help EMA respond to the consequences stemming from this unprecedented situation.

- To provide a balanced communication, both internally and externally, addressing this dual approach.

Such communication, targeted to the various audiences, should be able to provide full transparency to EMA staff on EMA's approach towards Brexit and its consequences for the Agency, whilst also providing targeted information in a timely manner to its partners and stakeholders.

## 2. Aim of this document

The aim of this document is to describe

- the arrangements put in place for launching the EMA Brexit preparedness BCP, and
- how these arrangements will be implemented once it is decided to initiate such BCP.



Following the launch by the UK Authorities of Article 50 on 29 March 2017, EMA's approach towards its functioning is to safeguard continuity of operation. EMA will therefore, as long as possible, operate under a "business as usual" scenario, aiming to comply with its 2017-2019 strategic objectives, initiatives and performance indicators, as adopted by the Management Board in the respective EMA Work Programmes. In case such approach is no longer achievable, a prioritisation of EMA activities will have to be undertaken. This will impact first on the 2017 deliverables as described in the 2017 EMA Work Programme.

### **3. Ensuring continuity of EMA operation**

As stated before, it is EMA's aim to operate as long as possible under a "business as usual" scenario whilst in parallel preparing for the consequences of the outcome of the UK referendum, the latter both in terms of (1) the impact on its operations, as well as (2) the physical move to the new EMA premises in the new host Member State (MS). However, if such "business as usual" scenario can no longer apply, dedicated arrangements have to be put in place as laid down in this EMA Brexit preparedness BCP. Both scenarios are outlined below.

It needs to be emphasised that, whatever scenario will apply, EMA will have to continue in all aspects of its operations to adhere to the high standards which have allowed EMA to become a recognised reference authority in Europe for medicines. It is paramount that such recognition by its stakeholders even in these challenging circumstances is not being jeopardised.

#### ***3.1. Striving for "business as usual" whilst continuing EMA preparedness***

In order to achieve this balance, efforts will focus both on maintaining as much as possible current staffing and on recruiting additional resources to compensate for staff loss, as follows:

##### **3.1.1. Maintaining current staffing**

The primary focus will be on the development of staff retention support measures. Such measures will consist of:

- entitlements under the Staff Regulations for EMA staff and their household, and
- other facilitating arrangements, consisting of other provisions allowed in rules and guidelines, services provided to staff through procured support, services provided to staff through the new host MS.

For some measures the Executive Director will have the authority to take a decision, for other measures EMA will have to liaise first with the European Commission and seek their agreement. In addition, the Management Board may have to be asked to approve some of the envisaged measures.

##### **3.1.2. Recruiting additional resources to compensate for staff loss**

Taking into account the special situation resulting from the outcome of the UK referendum, due consideration is given how EMA can reply faster to extraordinary circumstances which may be characterised by an unprecedented loss of expertise and experience over a rather short timeframe, although such loss also may continue over a prolonged time period (i.e. longer than immediately after the physical move of EMA to its new premises). To achieve this, a dedicated Brexit recruitment and selection strategy is applied.

### **3.2. EMA can no longer apply a “business as usual” approach**

Two situations may arise where “business as usual” is no longer possible, i.e.:

- EMA has to ensure that the necessary human resources are available to work on EMA Brexit preparedness, and
- EMA is no longer in a position in case of an important staff loss to compensate for such loss through the recruitment of replacement resource.

In both situations the EMA Brexit preparedness BCP is invoked. Both situations can exist in parallel and may persist for a longer period. The second situation will most likely only arise after the decision on the new seat for EMA is taken. In addition, the second situation is likely to continue after the physical move has taken place, in a worst case situation even over a prolonged period.

It should be noted that the physical move to the new EMA seat will require a second BCP to be invoked addressing business continuity before, during and after the physical move. Such second BCP, the EMA Relocation BCP, will be developed once the decision on the location of the new EMA premises has been taken and more information is available on the timetable for relocation to the new host MS.

## **4. Outline of the EMA Brexit preparedness BCP**

The EMA Brexit preparedness BCP consists of the following elements:

- Methodology for the prioritisation of EMA activities.
- Linking EMA activities to the time recorded by EMA staff in CATS (Cross Application Time Sheet), the EMA tool to record working time.
- Methodology for the implementation of the prioritisation of EMA activities.
- Quantification of the freed-up resources.
- Guiding principles for the allocation of the freed-up resources.

### **4.1. Methodology for the prioritisation of EMA activities**

#### **4.1.1. Principles for the prioritisation of EMA activities**

The following principles apply:

- As a starting point, the already existing BCP prioritisation of EMA activities (currently concentrating on core scientific activities and supporting IT applications) is used, recognising that such BCP prioritisation
  - was designed a few years ago to address other types of scenarios (e.g. pandemic influenza situation), and
  - was originally envisaged for a prioritisation more limited in time.
- All other EMA activities are added and prioritised, in descending order, as follows:
  - those with a fee generating component to ensure a stable income for EMA,
  - those with a legal obligation put on EMA,
  - those which relate to other core activities,

- those of a strategic character, and
- those of a non-strategic character.
- Such BCP scenario will be maintained as long as considered necessary.
- Once the BCP scenario can be lifted, EMA activities will be restored in a stepwise manner starting with those classified as having the highest priority, as outlined above, hence leading to a process of gradual uptake of EMA activities.

#### 4.1.2. Categorisation of EMA activities

Taking into account the aforementioned principles, EMA activities are put into three categories:

- Category 1 (highest priority) activities:

1. Core scientific activities and supporting IT applications as per the existing BCP core tasks	<ul style="list-style-type: none"> <li>• See Annex 1 for more information</li> </ul>
2. Corporate, communication and other IT activities necessary for the operation of EMA	<ul style="list-style-type: none"> <li>• Including IT preparatory work for relocation, as well as the data centres</li> </ul>
3. Fee generating activities not part of 1. to ensure a stable income for EMA	<ul style="list-style-type: none"> <li>• Pharmacovigilance annual fees based on Article 57 data</li> <li>• Inspections fees for routine inspections</li> </ul>
4. Legal obligations put on EMA not part of 1.	<ul style="list-style-type: none"> <li>• Handling of Access to Documents requests</li> <li>• Legal commitments for EMA involvement in ongoing IMI<sup>1</sup>/other research activities</li> <li>• Legal commitments related to ongoing fixed price contracts for IT projects</li> <li>• Handling of court cases</li> <li>• Some projects with legal deadlines (clinical trials, EudraVigilance) as well as other projects (SPOR<sup>2</sup>)</li> <li>• Anti-fraud activities</li> <li>• CMDh/v<sup>3</sup> activities</li> <li>• Enpr-EMA<sup>4</sup></li> </ul>

<sup>1</sup> IMI: Innovative Medicines Initiative

<sup>2</sup> SPOR: Substance, Product, Organisation and Referential master data

<sup>3</sup> CMDh/v: Coordination Group for Mutual Recognition and Decentralised Procedures human/veterinary

<sup>4</sup> Enpr-EMA: European Network of Paediatric Research at EMA

- Category 2 (medium priority) activities:

These are either strategic activities or other core activities not captured in category 1, as follows:

1. General activities	<ul style="list-style-type: none"> <li>• Secretariat activities related to WPs<sup>5</sup> (i.e. secretariat activities other than activities in the context of a particular procedure which are under category 1), QRD-WG<sup>6</sup>, NRG<sup>7</sup>, GxP<sup>8</sup>, guidelines, data governance and data modelling</li> </ul>
2. Maintenance activities	<ul style="list-style-type: none"> <li>• Activities not linked to specific procedures/processes</li> </ul>
3. Scientific advice and certification	<ul style="list-style-type: none"> <li>• Activities not linked to specific procedures/processes</li> </ul>
4. Paediatrics	<ul style="list-style-type: none"> <li>• Activities not linked to specific procedures/processes</li> </ul>
5. Other public health activities	<ul style="list-style-type: none"> <li>• SME<sup>9</sup> office activities, AMR<sup>10</sup>, HTA<sup>11</sup>, influenza pandemic, innovation and emerging therapies and technologies, regulatory science, availability of human and veterinary medicines, MUMS<sup>12</sup>, ENCePP<sup>13</sup>, EU Institutional and Member States cooperation, enlargement, international cooperation</li> </ul>
6. Programmes and projects (other than those listed under category 1, areas n° 2 and 4)	<ul style="list-style-type: none"> <li>• These relate to both IT (can be part of the EU Telematics Strategy) and non-IT programmes and projects</li> </ul>
7. Transparency, information, communication	<ul style="list-style-type: none"> <li>• Clinical data publication, product and non-product related communication not part of category 1 area n° 2, interaction with stakeholders</li> </ul>
8. Policies and legislation	

<sup>5</sup> WPs: Working Parties

<sup>6</sup> QRD-WG: Quality Review of Documents Working Group

<sup>7</sup> NRG: Name Review Group

<sup>8</sup> GxP: Good x Practice (x = GMP, GCP, GLP and GVP)

<sup>9</sup> SME: Small and Medium-sized Enterprise

<sup>10</sup> AMR: Antimicrobial Resistance

<sup>11</sup> HTA: Health Technology Assessment

<sup>12</sup> MUMS: Minor-Use-Minor-Species

<sup>13</sup> ENCePP: European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Since category 2 contains many, diverse activities, category 2 activities have been classified into 2 subcategories in order to allow activities which support category 1 activities and activities with the highest strategic priority to continue as long as possible, as follows:

- Category 2A: higher medium priority activities.
- Category 2B: lower medium priority activities.

Annex 2 details which activities fall under subcategories 2A and 2B respectively.

- Category 3 (lowest priority) activities:

These are non-strategic activities and not captured in category 1, as follows:

1. Governance and support activities	
2. Transparency, information, communication not part of category 2, area n° 7	<ul style="list-style-type: none"> <li>• Requests for information</li> </ul>

It should be noted that some activities, such as for instance missions, cannot be classified into a single category as these activities are topic specific and will have to be dealt with as part of the activity to which they contribute.

#### ***4.2. Linking EMA activities to recorded time***

In order to measure time spent on a certain activity, the time recorded by EMA staff in CATS is used. Each activity listed in one of the three categories is linked to the respective CATS code. It is understood that staff have completed CATS correctly in accordance with guidance provided.

#### ***4.3. Methodology for the implementation of the prioritisation of EMA activities***

##### **4.3.1. Continuing EMA activities versus temporarily suspending or reducing the output**

Prioritisation of EMA activities results in activities that:

- will either continue, and for which “business as usual” will apply, with the understanding that they will continue to be performed to the same high standards, or
- will be temporarily suspended, or
- for which the output will be temporarily reduced, also with the understanding that such reduced output will continue to adhere to the same high standards, although the reduced output may result in a reduction of volume or a delay in the time to achieve the agreed deliverables.

It should be emphasised that an exception to the temporary suspension or reduced output of an activity is always made if elements of the activity relate to Brexit preparedness and implementation; such Brexit related elements should always continue.

The choice between temporarily suspending an activity or scaling back the output is taken by the EMA Executive Board (EXB) (phase 1 of the BCP) or the EMA Gold Group Directorate (phase 2 of the BCP) on a case-by-case basis depending on the nature and characteristics of each activity, whereby – where

relevant – the strategic nature of the activity, also longer term, is taken into account. Likewise, the extent of any reduced output is decided by EXB for phase 1 of the BCP and the Gold Group Directorate for phase 2 of the BCP, where relevant.

### **4.3.2. Stepwise implementation**

Once the BCP is triggered, it is initiated in a stepwise manner, as follows:

- First targeting category 3 activities, temporarily suspending certain activities, whilst temporarily scaling back the output of other activities.
- Followed by targeting category 2 activities, likewise temporarily suspending certain activities, whilst temporarily scaling back the output of other activities, first looking at category 2B activities, followed by category 2A activities.

Category 1 activities should normally not be affected unless the temporary suspension or output reduction of category 3 and category 2A and B activities is no longer sufficient. At that time category 1 activities will be prioritised. Where there is a choice between meeting a purely legal obligation or the protection of human and animal health, the latter must prevail.

### **4.3.3. Triggers for launching the EMA Brexit preparedness BCP**

As already described under section 3.2. of this document there are two possible triggers for launching the EMA Brexit preparedness BCP, i.e.:

- EMA has to ensure that the necessary human resources are available to work on EMA preparedness.  
  
Parts of these resources also have to be available for implementing the BCP and overseeing such implementation.
- EMA staff loss can no longer be compensated through the recruitment of replacement resource.  
  
The extent of such staff loss will highly depend on the ultimate decision with respect to the new MS hosting EMA.

Although the need for freeing-up the necessary resources for EMA preparedness must be addressed first, both situations can exist in parallel and may continue for a longer period, considerably exceeding the date of the physical relocation of EMA.

## **4.4. Quantification of the freed-up resources**

Temporarily suspending or reducing the output of EMA activities allows staff to be freed-up. These are expressed in terms of Full Time Equivalents (FTEs). The extent of freed-up resources that can be achieved is of course dependent on the timing of introduction of the temporary suspension or reduced output of the activity. For further information see section 5.1.1.

#### ***4.5. Guiding principles for the allocation of the freed-up resources***

Any resources freed-up as a consequence of the temporary suspension or reduced output of an activity are directed

- in a first phase to work on EMA preparedness, and
- in a second phase to address staff loss which can no longer be compensated through recruitment, giving priority to category 1 and 2A activities as described under section 4.1.2. to ensure continued operation of EMA's core activities.

### **5. Implementing the EMA Brexit preparedness BCP**

#### ***5.1. A phased approach***

The first aim of the launch of the EMA Brexit preparedness BCP is to ensure that the necessary human resources are available to work on EMA preparedness, and subsequently that activities with the highest priority will continue to operate "business as usual", without interruption and to the same high standards. As a consequence, a phased implementation is envisaged. As already explained this is achieved through a temporary suspension or scaling back of EMA activities, starting from those activities with the lowest priority as outlined before.

##### **5.1.1. First phase**

As stated before the aim of the first phase is to free-up the necessary resources to prepare for the UK exiting the EU and the resulting consequences for EMA. It is anticipated that by temporarily suspending or reducing the output of category 3 and some category 2B activities enough resources are freed-up until the end of 2017 to undertake EMA preparedness. The first implementation date was set for 1 May 2017. For those activities where deliverables are specifically captured in the 2017 EMA Work Programme, the earliest timing of introduction was 3 July 2017 following discussion at the 14-15 June 2017 Management Board meeting.

As regards the allocation of the freed-up resources the following applies:

- Firstly, resources freed-up are directed towards those EMA organisational entities working on EMA preparedness, using internal mobility (either within the same organisational entity (e.g. a Division) or between organisational entities (e.g. between Divisions)). The decision on internal mobility between Divisions is taken by EXB. Training is provided to the staff member(s) concerned as needed.
- Secondly, EMA organisational entities (e.g. the scientific Divisions) not directly involved in EMA preparedness, should keep remaining freed-up resources on standby in order to participate without delay and, where needed, even at short notice, in EMA preparedness activities (e.g. procurement procedures, selection procedures) when requested.
- In addition, freed-up resources which are not (yet) involved at this stage in EMA preparedness should be directed by the HoDiv concerned to category 1 and category 2A activities
  - to speed-up as much as possible deliverables for 2017, and
  - to create a "buffer" in case an important staff loss which can no longer be compensated through the recruitment of replacement resource would affect these activities at a later stage.

Annex 3 provides more information on the implementation of phase 1 of the BCP.

### **5.1.2. Second phase**

The second phase, whilst focusing on freeing-up additional resources for EMA preparedness for 2018 and 2019, also aims at ensuring that activities with the highest priority as described before can continue in a situation where staff loss can no longer be compensated through recruitment. To achieve this, category 3 activities will be further reduced before moving to category 2 activities, and only in a worst case scenario to (certain) category 1 activities as outlined in section 4.3.2.

Further details about the arrangements applicable to the second phase will be provided at a later stage.

### **5.2. Consequences of implementing this BCP**

The temporary suspension or reduced output of EMA activities has consequences as regards the current “business as usual” operation of EMA. Although the deprioritisation of activities under phase 1 is mainly affecting internal governance and support activities with few activities impacting on EMA partners and stakeholders, the deprioritisation of the large majority of activities under phase 2 will impact the deliverables, including KPIs, as described in the EMA Work Programme. The use of Management Board topic coordinators to facilitate discussions at the Management Board will be considered.

Annex 3 also provides details on the actions to be taken following a decision on a temporary suspension or output reduction of an activity.

### **5.3. Monitoring of the implementation**

The implementation of this BCP is continuously tracked and monitored and, where needed, remedial action will be taken. Where necessary, emerging issues are escalated to EXB (phase 1) or the Gold Group Directorate (phase 2) for decision.

Once the BCP scenario can be lifted, EMA activities will be restored in a stepwise manner starting with those classified as having the highest priority, as outlined before, hence leading to a process of gradual uptake of EMA activities.

### **5.4. Internal and external communication**

It is paramount that full transparency is provided to all EMA staff on the implementation status of this BCP and that staff is informed on a regular basis. Likewise, for any activities impacting on the EMA Work Programme deliverables as adopted by the Management Board, full transparency and a targeted, regular and timely communication to EMA's partners and stakeholders is needed following discussion at the Management Board on the deprioritisation and its consequences.

## Core scientific activities and supporting IT applications as per the existing BCP core tasks

This annex describes those category 1 activities which relate to the core scientific activities and supporting IT applications as per the existing BCP core tasks<sup>14</sup>. It should be noted that these activities listed below are ranked as per the ranking order of the existing BCP core tasks (described in the document dated 24 April 2015). However, such ranking order is without prejudice to any future prioritisation of category 1 activities within the context of the EMA Brexit preparedness BCP.

Core scientific activities	Supporting IT applications
<ol style="list-style-type: none"> <li>1. Urgent and significant public health threats relating to the safety and quality of medicinal products for human and veterinary use in the EU               <ol style="list-style-type: none"> <li>1.1. Provision of urgent pharmacovigilance or quality defect information to EMA and the European medicines regulatory network, in particular the systems and structures needed to provide such information</li> <li>1.2. Suspension or withdrawal of a CAP<sup>15</sup> or a non-CAP including those due to quality defects, in particular the activities relating to the scientific committees to achieve this</li> <li>1.3. Urgent safety restrictions or urgent variations, in particular the activities relating to the scientific committees to achieve this</li> <li>1.4. Detection of safety issues (signal detection) for CAPs and provision of analyses to Member States for signal detection for non-CAPs</li> <li>1.5. Access and operational availability of supply of medicines on the market</li> <li>1.6. Sampling and testing/inspections in support of areas n° 1.1. and 1.2.</li> </ol> </li> </ol>	<p>All IT applications supporting the core scientific activities listed under area n° 1 (such as SIAMED, EudraVigilance human/veterinary, EudraCT, EPITT, Corporate GxP, EVDAS, EudraGMDP,...)</p>

<sup>14</sup> The existing BCP core tasks are described in the document "Prioritisation of scientific core tasks for business continuity planning" (EMA/277023/2009), dated 24 April 2015

<sup>15</sup> CAP: Centrally Authorised Product

Core scientific activities	Supporting IT applications
<p>2. Legal deadline activities related to the safety and quality of medicines on the market, and the availability/maintenance of supply of critical medicines to address an immediate public health urgency</p> <p>2.1. Activities as specified under area n° 1.1.</p> <p>2.2. Urgent safety issues, safety procedures (including safety referrals), the authorisation of emergency medicines, urgent variations, in particular the activities relating to the scientific committees and WPs to achieve this</p>	<p>All IT applications supporting the core scientific activities listed under area n° 2 (such as PedRA, Referrals database, ...)</p>
<p>3. Legal deadline activities with no immediate public health urgency, and not covered under area n° 2.</p> <p>3.1. Applications for marketing authorisation, post-authorisation procedures, pharmacovigilance, MRLs<sup>16</sup>, in particular the activities relating to the scientific committees, WPs and SAGs<sup>17</sup> to achieve this</p>	<p>All IT applications supporting the core scientific activities listed under area n° 3 (such as Orphan drugs database, Experts database, ...)</p>
<p>4. All other medicinal product related activities with no legal deadlines and no public health urgency</p> <p>4.1. The activities relating to the scientific committees and WPs to achieve this</p> <p>4.2. Preparation of certificates</p> <p>4.3. Handling of parallel distribution notifications</p>	<p>All IT applications supporting the core scientific activities listed under area n° 4 (such as Scientific Advice database, SME database, Certificates database, Parallel distribution OR database, ...)</p>

<sup>16</sup> MRLs: Maximum Residue Limits

<sup>17</sup> SAGs: Scientific Advisory Groups

### Subclassification of category 2 (medium priority) activities

This annex relates to category 2 activities. It excludes

- some projects with legal deliverables (clinical trials, ADRs),
- some other projects (SPOR), and
- some IT activities necessary for the operation of EMA (including IT preparatory work for relocation, as well as the data centres).

The aforementioned projects are classified as category 1 (highest priority) activities.

Furthermore this annex details which activities fall under subcategories 2A and 2B respectively.

#### **1. Subcategory 2A: higher medium priority activities**

- Innovation and emerging therapies
- Secretariat activities relating to WPs, ORD-WG, NRG and GxP meetings – product related (but for WPs not in the context of a particular procedure since these activities are under category 1)
- EU institutional cooperation – general aspects
- EU cooperation with Member States
- SME Office
- AMR
- ESVAC<sup>18</sup>
- HTA
- EU NTC<sup>19</sup>
- EU institutional cooperation – support to new legislation
- Transparency – product related, not captured in category 1
- Preparation for new legislation and revision of legislation
- Availability of human and veterinary medicines, MUMS
- Success factors
- Customer Relationship Management (CRM) in cloud (orphans only)
- EudraVigilance Vet 3
- Joint Action on Vaccination

---

<sup>18</sup> ESVAC: European Surveillance of Veterinary Antimicrobial Consumption

<sup>19</sup> EU NTC: EU Network Training Centre

## 2. Subcategory 2B: Lower medium priority activities

- Data governance
- Data modelling
- EnCePP
- Influenza Pandemic
- Regulatory science and registries
- Clinical data publication
- Guideline development
- International cooperation
- Secretariat activities relating to WPs, ORD-WG, NRG and GxP meetings (non-product related)
- Transparency – stakeholder interaction
- Transparency – information/communication (non-product related)
- Scientific Advice and certification (modelling and simulation of clinical studies, geriatrics, adaptive pathways and specialised disciplines' contribution to scientific advice)
- Maintenance activities (maintenance of product oversight and committee discussion oversight)
- Development of new internal policies and revision of existing policies
- Development of new external policies and revision of existing policies
- GRIP
- IMI-Advance, IMI-Adapt Smart, IMI-FluCop
- Product registries
- Review of WPs and SAGs
- Add Value
- Veterinary change (except EudraVigilance Vet 3)
- Medication errors

# Implementation of phase 1 of the EMA Brexit preparedness BCP

This annex provides information on the implementation of phase 1 of the EMA Brexit preparedness BCP. Phase 1 aims to provide the resources needed for EMA to prepare for Brexit. This annex describes the decision taken for each activity affected under phase 1, the implementation date, as well as the impact. In addition, it distinguishes between affected activities detailed in the 2017 EMA Work Programme and other affected activities not mentioned in such Work Programme.

## 1. List of affected activities as per the 2017 EMA Work Programme

### 1.1. Category 3 activities

Activity	Current status	Implementation date	Impact
<ul style="list-style-type: none"> <li>IQM related activities</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily suspended</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>Identified actions to align EMA's quality management system with the new ISO 9001: 2015 standard is postponed until further notice</li> </ul>
<ul style="list-style-type: none"> <li>Audits</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>03/07/2017</li> </ul>	<ul style="list-style-type: none"> <li>2 non-legally required audits are postponed until further notice</li> <li>ECA<sup>20</sup>, IAS<sup>21</sup> and legally required audits (clinical trials and EudraVigilance) are maintained</li> </ul>
<ul style="list-style-type: none"> <li>Self-assessment activities and BEMA</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>2 already scheduled BEMA assessment visits (Paul Ehrlich Institute – 9/2017 and Czech Institute Vet – 10/2017) are maintained as well as the 14/9/2017 BEMA<sup>22</sup> seminar at EMA</li> <li>2018 EMA BEMA assessment as well as EMA participation in 2018 assessments are postponed until further notice</li> </ul>

<sup>20</sup> ECA: European Court of Auditors

<sup>21</sup> IAS: Internal Audit Service of the European Commission

<sup>22</sup> BEMA: Benchmarking of European Medicines Agencies

Activity	Current status	Implementation date	Impact
<ul style="list-style-type: none"> <li>Meeting management enlargement</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily suspended</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>Although EMA's commitment with the European Commission (DG SANTE, DG NEAR) and the Beneficiaries will be finalised end of Q4 2017 (shortening the 2 years implementation to 18 months), EMA participation in the next implementation phase is postponed until further notice</li> </ul>
<ul style="list-style-type: none"> <li>Transparency – requests for information</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>03/07/2017</li> </ul>	<ul style="list-style-type: none"> <li>Increased response time for some requests for information depending on the risk level allocated, although still within the set timelines</li> </ul>

## 1.2. Category 2 activities

Activity	Current status	Implementation date	Impact
<ul style="list-style-type: none"> <li>Development of new external policies/ revision of existing external policies</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>Publication for public consultation of the draft EMA Transparency Roadmap is postponed until further notice</li> <li>Technical Anonymisation Group (TAG) related work in the context of EMA Policy 0070 (publication of clinical data for human medicines) implementation will continue, however the assessment of the implementation of Policy 0070 and subsequent publication of a report is postponed until further notice</li> </ul>
<ul style="list-style-type: none"> <li>Online programme</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>03/07/2017</li> </ul>	<ul style="list-style-type: none"> <li>Work on corporate website to continue</li> <li>Extranet/intranet work temporarily suspended</li> <li>EMWP (European Medicines Webportal) work temporarily suspended with the following 2017 work postponed until further notice:</li> </ul>

Activity	Current status	Implementation date	Impact
			<ul style="list-style-type: none"> <li>- Develop preliminary business case for approval</li> <li>- Begin work on interface design</li> <li>- Develop implementation plan to publish Article 57 database online</li> </ul>
<ul style="list-style-type: none"> <li>• e-submission project</li> </ul>	<ul style="list-style-type: none"> <li>• Temporarily suspended</li> </ul>	<ul style="list-style-type: none"> <li>• 03/07/2017</li> </ul>	<ul style="list-style-type: none"> <li>• e-submission work temporarily suspended with the following 2017 work postponed until further notice: <ul style="list-style-type: none"> <li>- Environmental analysis to examine eCTD4 tools</li> <li>- Impact assessment to provide an estimation of cost for adapting EMA systems to eCTD4</li> </ul> </li> <li>• Provide centralised business subject matter expertise for integration of the H-initial MAA form in CESP via the existing EU TCT, and EMA master data and controlled terminology, will continue</li> </ul>
<ul style="list-style-type: none"> <li>• Publication of clinical data under Policy 0070 project – further development work</li> </ul>	<ul style="list-style-type: none"> <li>• Temporarily suspended</li> </ul>	<ul style="list-style-type: none"> <li>• 01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>• Development of a workflow and case management tool is postponed until further notice</li> </ul>

## 2. List of other affected activities

Activity	Current status	Implementation date	Impact
<ul style="list-style-type: none"> <li>Other IQM related activities</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>The number of 2017 ex post controls is reduced from 13 to 4, maintaining:               <ul style="list-style-type: none"> <li>DoIs<sup>23</sup> checking</li> <li>Checking of handling of whistle-blower process</li> <li>Correct fee calculations for extensions of marketing authorisation and for scientific advice procedures</li> </ul> </li> <li>No process improvements will be done except in the context of Brexit</li> <li>Creating/updating SOPs/WINs is postponed until further notice except for category 1 activities where a risk based approach will be applied</li> </ul>
<ul style="list-style-type: none"> <li>Corporate governance and support activities</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>Reduced by 25%, prioritising core activities and Brexit related aspects</li> </ul>
<ul style="list-style-type: none"> <li>Training for EMA staff</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>Focusing on training in the context of Brexit, specialist IT knowledge, language training</li> </ul>
<ul style="list-style-type: none"> <li>Non-product related translations</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>Reduced by 50%</li> </ul>
<ul style="list-style-type: none"> <li>Corporate risk management</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>Only focusing on Brexit related aspects, and as required for the programming document</li> </ul>
<ul style="list-style-type: none"> <li>Development/revision of internal policies</li> </ul>	<ul style="list-style-type: none"> <li>Temporarily reduced</li> </ul>	<ul style="list-style-type: none"> <li>01/05/2017</li> </ul>	<ul style="list-style-type: none"> <li>A risk based approach will be applied</li> </ul>

<sup>23</sup> DOIs: Declarations of Interests