14 June 2017
EMA/300951/2017 Endorsed
Executive Director

EMA working group on committees' operational preparedness for human medicines

Mandate, endorsed by the Management Board at its 14 June 2017 meeting

1. Background

In view of the formal notification by the UK of Article 50 to the European Council on 29 March 2017, DG SANTE clarified, both at the meeting of the EMA Management Board on 16 March 2017 and at the Information meeting that took place at the EMA on 27 April 2017, that the scenario to be considered is the one by which the UK membership will cease to exist as of 30 March 2019.

As of that date, the UK will therefore be considered a "third country" and, as a consequence, the MHRA will no longer be able to engage in centralised regulatory procedures which are expected to finalise after 30 March 2019. With this in mind DG SANTE strongly recommended that centralised regulatory procedures should be managed in a pragmatic manner before 30 March 2019.

In view of this, preparatory work should start to allow the remaining 27 NCAs to ensure business continuity and maintain the quality and robustness of the scientific assessment while complying with legal deadlines. Furthermore, it is of utmost importance to ensure knowledge retention, either by building on existing knowledge, or through knowledge transfer whilst assuring that an easy implementation and medium- and long-term sustainability can be achieved, and strive to allow all NCAs to participate in EMA activities, as per the capacity and capability of each NCA, so as to ensure an optimised and robust allocation of the workload across the Network. Such key principles were agreed upon at the meeting on 27 April 2017 and endorsed at the 14 June 2017 Management Board meeting, and are reflected in the objective criteria described below.

2. Scope

In order to ensure that EMA is ready to face the above described scenario and to comply with the European Commission's indication, it is necessary to establish a working group which will explore options for a reasonable and robust allocation of the workload related to human medicines across the Network. The working group will also explore ways to streamline the work by increasing efficiency in order to further increase capacity in the Network.

In light of the foregoing key principles, the working group will follow the objective criteria and working methodology set forth below.

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Objective criteria for (re)-distribution of workload

The approach to workload (re)-distribution for human medicines, veterinary medicines and inspections can be different since each area has its own characteristics and complexity. Even within the same area of activity the approach can be different for different Scientific Committees, unless there is a significant level of interaction between Scientific Committees, e.g. the CHMP and PRAC. However, the (re)-distribution of workload in all areas should follow a common set of objective criteria based on the aforementioned agreed principles. In particular, it should:

- ensure business continuity and proportionality in the distribution of workload taking into due account other elements including but not limited to the deadline of 30 March 2019 and the average timelines of the various procedures;
- ensure knowledge retention, either by building on existing knowledge, or through knowledge transfer (if the latter applies this should be accommodated);
- allow to comply with the legally required timelines and maintain the quality of the output;
- be as easy as possible to implement and, in addition, should be sustainable (both short/medium term to address the more immediate Brexit consequences, as well as longer term);
- strive to allow all NCAs to participate in EMA activities, as per the capacity and capability of each NCA, so as to ensure an optimised and robust allocation of the workload across the Network.

In addition:

- The current appointment process which foresees as the main determining factor for assigning the lead role "the best available expertise", should be maintained in any redesign.
- Approaches such as the Multinational Assessment Team (MNAT) concept should be further encouraged and, once more experience has been obtained, further adjustments should be introduced, if needed.

3. Composition, membership and secretariat

The working group is composed by representatives from EMA, CHMP, PRAC, CAT, SAWP, CMDh and NCAs (preferably it should include representatives from both smaller and larger NCAs and NCA representatives should be appointed at the level of Heads of Agency also being members of the EMA MB).

Membership of the group consists of:

- CHMP chair and two additional CHMP members appointed by the CHMP Chair;
- PRAC Vice-Chair and two additional PRAC members appointed by the PRAC Vice-Chair;
- CAT Chair ;
- SAWP Vice-Chair;
- CMDh Chair;
- Four members of the MB appointed by the Chair of the MB who are also Heads of Agencies and may act as Topic Coordinators, as required;

- EMA's Deputy Executive Director and two additional staff members appointed by the Executive Director.

EMA's Deputy Executive Director will chair the working group. The EMA ORP Task Force will provide administrative secretariat to the working group.

The initial term of the working group will be two (2) years.

4. Mandate and objectives

Based on the general principles and objective criteria set forth above, the working group will assess the different options for workload distribution and put forward proposals for endorsement by the MB. The focus of the group will be on:

- Redistribution of UK product portfolio
- Distribution of workload for initial marketing authorisation applications, including reassignment of procedures not yet started but currently assigned to the UK
- Distribution of workload for scientific advices
- Distribution of workload for PRAC procedures, for which the contribution of the CMDh is required concerning national authorised medicinal products

All the proposals for redistribution in the areas mentioned above will take into consideration the outcome of the surveys on capacity building in the Network. The group will also explore potential operational adjustments, including processes and assessment support structures, to further streamline EMA procedures.

The working group will develop an implementation plan with specific timelines for the (re)-distribution of the workload in advance of 30 March 2019. A communication plan will be drafted to ensure coherent and targeted communication to the Scientific Committees, the network and stakeholders.

5. Working approach

Work will be conducted as far as possible by means of virtual meetings and teleconferences. It is expected that the working group will convene bi-monthly by teleconference.

Face to face meetings will be held in the margins of Management Board and/or Scientific Committee meetings.

The Chair of the working group will provide regular reports to the Executive Director. Updates on the activity of the working group will be provided during subsequent information meetings hosted by EMA. The working group will prepare a proposal for (re)-distribution of the workload which will subsequently be agreed by the Executive Director and will be submitted by the Executive Director to the Management Board for endorsement.

Working methodology

a) Mapping of capacity and expertise

b) Implementation of the general principles and objective criteria

c) Decision-making process

d) Communication to stakeholders

a) Mapping of capacity and expertise

To better understand the current and future capacity in the network and to identify expertise gaps as well as NCAs' willingness and possibilities to invest, the working group will analyse the mapping of current and future capacity and expertise across the Network. This will be done based on the results of the surveys to be conducted on each individual NCA.

b) Implementation of the general principles and objective criteria

In order to implement the aforementioned general principles and objective criteria various scenarios can be designed. The working group will agree on the best possible scenario following a SWOT analysis of the different options.

c) Decision-making process

Proposals put forward by the working group and agreed by the Executive Director will be submitted by the Executive Director to the Management Board for endorsement.

d) Communication to stakeholders

Communication will ensure coherent and targeted information to the Network, to the Scientific Committees and Working Parties, and to stakeholders.