EUROPEAN MEDICINES AGENCY
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Press release

Update on EMA's Brexit preparedness

Phase 3 of business continuity plan enters into force

The European Medicines Agency's (EMA) Brexit preparedness business continuity plan (BCP) entered into its third phase on 1 October 2018, as announced at the beginning of August 2018.

The temporary suspension or reduction of additional activities in this phase allows the Agency to safeguard core activities related to the evaluation and supervision of medicines while the Agency prepares for the consequences of the United Kingdom's (UK) exit from the European Union (EU) - both in terms of the impact on the Agency's operations, as well as its physical move to Amsterdam. It will also help the Agency cope with anticipated staff loss.

"EMA will now temporarily suspend or scale back additional activities to ensure that resources can be redeployed so that its core activities can continue without interruption and to the same quality," commented Noël Wathion, EMA's Deputy Executive Director. "Over the next few months, EMA will continue to carefully monitor staff intentions to relocate and the anticipated impact on its activities whilst planning for the critical time period when the Agency will be moving to its new premises in Amsterdam."

The measures announced on 1 August included, among others, the scaling back of guideline development and revision and the putting on hold of non-product related working parties from 1 November 2018. The Agency has now drawn up priority lists of those guidelines and working parties, which will exceptionally continue during BCP phase 3:

- Work on seven guidelines which address either an urgent public/animal health need, or are necessary to support and facilitate preparations for Brexit or the implementation of new or revised legislation, will continue beyond 1 November 2018;
- Meetings of product-related working parties will continue as scheduled;
- All meetings of non-product related working parties have been temporarily put on hold in line with the reduction in the number of guidelines to be processed.

Detailed information is available in the BCP phase 3 implementation plan.

The Agency anticipates that phase 3 will have to be complemented with additional temporary suspensions/reductions as of 1 January 2019, which will be launched as part of phase 4 of the BCP, in order to put in place the necessary arrangements for the physical move to the Netherlands.

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Temporary suspension and scaling back of activities is currently scheduled to last until 30 June 2019, but will be reviewed in April 2019, once the Agency has completed its move to its temporary building in Amsterdam.

Practical guidance for companies on cut-off dates for UK rapporteur appointments

EMA has also published new information for pharmaceutical companies on cut-off dates for appointments of (co)-rapporteurs from the UK for both pre- and post-authorisation activities for centrally authorised medicines (CAPs).

In preparation for the UK's withdrawal from the EU as of 30 March 2019, all medicines for which the UK's Medicines & Healthcare products Regulatory Agency (MHRA) and Veterinary Medicines Directorate (VMD) are acting as rapporteurs or co-rapporteurs in centralised procedures will need to be transferred to new rapporteurs and co-rapporteurs from the EU27 Member States, plus Iceland and Norway. The cut-off dates were established based on the average length of a specific procedure, from submission to outcome.

For full initial marketing authorisation applications the process is complete and new rapporteurs have been assigned for all CAPs.

For line extensions and extensions of indication, the cut-off dates have already passed and therefore procedures starting after 1 October 2018 will already be taken care of by the new (co)-rapporteurs.

All other post-authorisation procedures will be allocated to new (co)-rapporteurs as follows:

- Quality, safety and efficacy type II variations submitted after 26 October 2018;
- Renewal applications submitted after 24 October 2018;
- Periodic safety update reports (CAPS only) submitted after 6 November 2018;
- Type IB variations submitted after 16 January 2019;
- For veterinary medicines the above cut-off dates apply with the exception of renewals (November 2018) and periodic safety update reports (PSURs) (December 2018).

Companies are reminded to submit their applications for any necessary changes allowing their marketing authorisations to remain valid in the EU, Iceland and Norway after Brexit as soon as possible and in consideration of the procedural timelines foreseen in the regulatory framework.

More information is available here.

Change in format of pre-submission meetings

All pre-submission meetings[1] for human and veterinary centralised initial applications requested as of 1 October 2018 will be held remotely (i.e. either via teleconference or virtual meeting) until the Agency is fully operational in its new permanent premises at the end of 2019.

No pre-submission meetings for human and veterinary centralised initial applications will take place between 11 February and 15 March 2019, when the Agency's physical move to its new premises will take place.

As of September 2018, pre-submission meetings for scientific advice are only held by teleconference, which has already been the case for most of these meetings since 2017.

[1]Pre-submission meetings aim to provide marketing authorisation applicants with information that will assist them in the finalisation of their upcoming marketing authorisation applications.

Notes

1. This press release, together with all related documents, is available on the Agency's website;
2. More information on EMA's preparations for Brexit is available here;
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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