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Press release

Brexit preparedness: EMA to further temporarily scale back and suspend activities

Next phase of business continuity plan aimed at securing essential public and animal health activities

The European Medicines Agency (EMA) will launch the next phase of its business continuity plan on 1 October 2018 at the latest. This will allow the Agency to safeguard core activities related to the evaluation and supervision of medicines, while it has to intensify its preparations for the physical move to Amsterdam in March 2019 and cope with significant staff loss.

The temporary cuts in activities are required because it has also become clear that the Agency will lose more staff than initially anticipated. Staff who will not relocate to Amsterdam have already started to leave the Agency and this trend is expected to accelerate. In addition, due to the employment rules in the Netherlands, 135 short-term contract staff will no longer be able to work for EMA. Overall, EMA expects a staff loss of about 30%, with a high degree of uncertainty regarding mid-term staff retention.

EMA has put in place supporting measures to facilitate the relocation of staff to Amsterdam and additional support is provided by the Dutch government. Other mitigating actions, such as a comprehensive staff recruitment programme, are already underway. However, in the short- to midterm EMA will have to reprioritise its resources to fully maintain its core activities related to the evaluation and supervision of medicines to the level of quality and within the timelines expected.

Following the implementation of phase 1 and 2 of the <u>business continuity plan</u>, in phase 3 EMA will start to temporarily scale back or suspend additional activities through to 2019. This contributes to protecting EMA's essential public health activities and allows for training of EMA staff who will be reassigned to new duties ahead of the peak relocation time which will start in early 2019.

Activities initially impacted by phase 3 include:



Collaboration at international level, which will be temporarily scaled back to focus primarily on
product-related requests, supply-chain integrity and procedures under Article 58; in other areas,
such as the harmonisation of global medicine regulation, EMA will only take a reactive role; EMA's
engagement in other global public health issues such as antimicrobial resistance or vaccines will be
maintained as long as possible, but reviewed on a case-by-case basis;

Development and revision of guidelines, which will be temporarily limited to those guidelines that
address an urgent public/animal health need or are necessary to support and facilitate preparations
for Brexit;

 Holding of non-product-related working parties, which will be temporarily reduced as a consequence of the scaling back of guideline development or revision;

 Programmes and projects, where activities in relation to project governance will be reduced in line with the reduction/suspension of projects;

 Organisation and attendance at stakeholder meetings, which will be limited to Brexit-related interactions;

Clinical data publication, for which the launch of new procedures will be temporarily suspended as
of 1 August 2018; data packages submitted for medicines until the end of July 2018 will be
processed and finalised.

The implementation date for phase 3 of EMA's business continuity plan is 1 October at the latest. Detailed plans for the implementation of these measures are currently being developed and will be communicated to stakeholders concerned and the public as soon as they are available.

Notes

1. This press release, together with all related documents, is available on the Agency's website.

2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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