



The European Medicines Agency on the Move

BY DOMINIKA MISZTELA, SENIOR DIRECTOR, REGULATORY POLICY EUROPE, PPTA

On March 29, 2017, the United Kingdom (UK) notified the European Council of its intention to withdraw from the European Union (EU).¹ On March 30, 2019,² the UK will cease to be a member of the EU — a process also known as “Brexit.” One of the many consequences of Brexit is the physical relocation of the EU’s medicines regulatory authority, the European Medicines Agency (EMA), from London, UK, to Amsterdam, the Netherlands.³

This is a major move for one of the most important agencies of the EU: EMA is responsible for the scientific evaluation of many medicines in the EU and the European Economic Area (EEA), serving a market of about 500 million people. Since its inception in 1995, the EMA has been based in London.

The planned relocation carries significant consequences for EMA’s day-to-day activities. Apart from the practical difficulties of relocating the agency, a key concern is the relocation of 890 full-time staff and minimizing staff loss, which could be as high as 30 percent.⁴ According to EMA’s Brexit Preparedness Business Continuity Plan (BCP),⁵ a minimum of 65 percent staff retention is needed to ensure “core activities” related to pharmacovigilance, quality, safety, and supply of medicines are adequately maintained.

On Jan. 23, 2019, the EMA implemented phase 4 of its BCP, including the physical relocation from London to Amsterdam and restricting activities to those deemed highest priority⁶ until at least the end of June 2019. On Jan. 29, 2019, EMA officially closed its doors at its London headquarters, with the shutdown of all activities in London planned for March 1, 2019. EMA

staff is expected to move gradually to Amsterdam and resume work as of March 15, 2019. The move to the agency’s permanent headquarters is planned for November 2019.

EMA stressed that the restriction or suspension of activities to mitigate staff loss and the practical consequences of moving will be temporary. However it remains to be seen if there are any longer-term effects on the agency’s operations.⁷ ●

References:

1. EU (Notification of Withdrawal) Bill. <https://services.parliament.uk/bills/2016-17/europeanunionnotificationofwithdrawal/documents.html>
2. ‘Treaty on European Union’ (=Maastricht treaty, TEU), 1992. https://europa.eu/european-union/sites/europaeu/files/docs/body/treaty_on_european_union_en.pdf
3. European Medicines Agency to be relocated to Amsterdam, the Netherlands, 20 November 2017. <http://www.consilium.europa.eu/en/press/press-releases/2017/11/20/european-medicines-agency-to-be-relocated-to-city-country>
4. EU drugs agency to see 30% staff losses over Brexit move. 02 August 2018, updated 27 August 2018. <https://www.euractiv.com/section/health-consumers/news/eu-drugs-agency-to-see-30-staff-losses-over-brexit-move/>
5. European Medicines Agency Brexit Preparedness Business Continuity Plan - EMA/196585/2017 - 13 October 2017. https://www.ema.europa.eu/documents/other/european-medicines-agency-brexit-preparedness-business-continuity-plan_en.pdf
6. EMA activities, other than the highest priority activities (category 1 activities), that will continue in 2019 - EMA/30394/2019 – 23 January 2019. https://www.ema.europa.eu/documents/work-programme/ema-activities-other-highest-priority-activities-category-1-activities-will-continue-2019-annex-1_en.pdf
7. EMA Brexit Preparedness Business Continuity Plan, Phase 3 implementation plan - EMA/701082/2018 – 09 October 2019. https://www.ema.europa.eu/documents/other/ema-brexit-preparedness-business-continuity-plan-phase-3-implementation-plan_en.pdf