Brexit and balance

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Most of the pharmaceutical headlines regarding the UK’s decision to leave the EU have focused on the negative impacts on the UK and UK economy.1 Few articles have highlighted the significant impact that Brexit will have on the European Medicines Agency’s (EMA) ability to efficiently perform its intended role.

An EMA staff survey indicated that “for 65 percent of staff the new EMA location will be a determining factor in their decision-making to relocate or not”. Although Brexit is scheduled for 29 March 2019, the EMA's accommodation in Amsterdam will not be ready for many months, and staff will be housed in temporary accommodation.2 The EMA indicated in 2017 that even a loss of 19 percent of staff would be serious and could hold up the implementation of other projects, albeit without impacting on the approval of medicines.3 However, the reality is even worse, as the EMA has since indicated that staff losses are currently 30 percent and could be higher; including 135 short-term contract workers who will no longer be able to work for the agency due to Dutch employment laws.4

The EMA faces three inter-related issues as a consequence of Brexit. Firstly, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has historically performed over 33 percent of all central reviews and inspections, and identified up to one third of all drug-related adverse events on behalf of the EMA.5 Secondly, EMA faces significant staffing issues based on a reluctance of London-based staff to relocate to Amsterdam6 and finally, the EMA must reallocate responsibility for 370 centrally authorised products to new rapporteurs and co-rapporteurs within the EU27, with support from Iceland and Norway.4

The loss of MHRA’s extensive expertise and capacity has had significant impact on the EMA's ability to perform its role and has necessitated a scaling back in its workload to focus on "essential activities, such as medicines evaluation and supervision". The measures announced at the beginning of August 20185 include the scaling back of guideline development and placing on hold of all non-product related working parties from the beginning of November 2018. The EMA also indicated that “phase 3 of the business continuity plan will need to be supported with additional temporary suspensions/reductions as of 1 January 2019”6. In addition, EMA stated that "pharmaceutical companies have to plan for the UK becoming a 'third country' out with the EU, which means updating any centrally authorised products marketing authorisations, which have a crucial step registered in the UK".7 Thereby, necessitating yet more regulatory submissions, which the EMA will need to process.

The irony of the EMA’s self-inflicted plight is that the UK is actively seeking to remain a part of EMA after Brexit,7 but the EU will not allow “cherry picking” of sectors for UK involvement. The impact on patients is potentially huge; “45 million packs of medicine are exported to the EU from the UK each month, with 37 million going the other way”.8 Thus, it would appear that EU political expediency trumps common sense ensuring that European/UK patients will needlessly be impacted.

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REFERENCES

2. Taylor P. EMA cuts back as Brexit staff losses top expectations. 01 August 2018. PMLive.
5. EMA. Update on EMA’s Brexit preparedness. Press Release 09 October 2018.
8. Gershlick P. Brexit – will all the medicines get to patients? European Pharmaceutical Review. 2018:23(5);10-12.