# Amber warning for the UK's access to new medicines post Brexit

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In an editorial to be published on Tuesday 27th June 2017 in the journal *ecancermedicalscience*, Anthony Hatswell of BresMed (an independent health economics consultancy) and University College London, explores the consequences of a British exit from the European Medicines Agency (EMA) as a result of Brexit, and what this will mean for pharmaceutical regulation and future access to medicines for UK citizens.

The EMA is a decentralised agency of the European Union (EU), located in London which is responsible for ensuring that all medicines available on the EU market are safe, effective and of high quality. The future of EMA's headquarters in London is the focus of much speculation at present, as is Britain's future role in the EMA.

The editorial explores how a British withdrawal from the EMA will likely delay the availability of new medicines to the UK market. There is already a reluctance in the UK to fund next generation treatments (for example combination therapies for cancer)1 and the UK has a sketchy track record on handling access such as the much lambasted 'Cancer Drugs Fund'.

The author argues that removal from the EMA jeopardizes access not just to emerging treatment but also their cheaper off brand counterparts once patents expire. In the long term this would be a source of massive harm to patients.

Should the UK leave the European Medicines Agency the author voices

his concern that current calculations of the cost of Brexit have not factored in the cost for duplicating the functions of the EMA - not only in licensing new medicines, but inspecting manufacturing plants worldwide.

The author states: "This is such an important topic, and at the moment there appears to be no policy whatsoever.

"There is a sense that the UK could try and emulate the US model, which has a national system for drug regulation managed by the Food and Drug Administration (FDA) who lead the way in access. However this outcome is unrealistic as the US is a special case due to high prices, a large patient population, few restrictions to access, and direct to consumer advertising. A more likely outcome can be seen with Japan's sovereign regulator, which is despite a market size twice the size of the UK due to both population and GDP, lags the EU (including the UK) in timely access to novel medicines."

Mr Hatswell argues that one potential solution could see the UK's Medicines & Healthcare products Regulatory Agency (MHRA) remaining a part of the EMA, but also given the freedom to adopt decisions from other regulators (such as the FDA). Such an arrangement could actually speed access to medicines and keep the UK at the forefront of medical technology.

On a positive note the author concludes that "With careful planning and collaboration - the UK can maintain or even advance its position as a leader in life sciences. Not only do patients require [this], the life sciences sector is a large source of well-paid employment, and a large net exporter for the UK. As long as ideology does not trump the benefits of cooperation it does not have to be the end of a productive relationship that has done great things for patients across Europe."

**More information:** Hatswell A (2017) *ecancer* 11:ed67 DOI: 10.3332/ecancer.2017.ed67