

## Future of the European Medicines Agency

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### Westminster Hall debate

Wednesday 12 October 2016

#### About the BMA

The British Medical Association (BMA) is a voluntary professional association and independent trade union, representing doctors and medical students from all branches of medicine across the UK and supporting them to deliver the highest standards of patient care. We have a membership of over 168,000, which continues to grow each year.

#### Introduction

The European Medicines Agency (EMA) is a key component of the regulatory framework for pharmaceutical research and development. The EMA plays a number of key roles including facilitating development and access to medicines and monitoring the safety of medicines across their life cycle<sup>1</sup>. It is currently located in London and its presence reinforces the position of the UK as one of the leading countries for medical research. It also helps the UK and UK pharmaceutical companies have significant input to consultation processes and thus influence the regulatory framework for pharmaceuticals.

The BMA is concerned about the future of the EMA, and the much wider impact of the UK's decision to leave the EU, on medicine, science and medical research. It is vital that safeguards are put in place to protect research funding, to ensure continued adherence to EU research regulations or mutual recognition of regulations, and the mobility of research staff<sup>2</sup>. The outcome of the EU referendum has created great uncertainty for EU nationals currently living, working, or studying in the UK regarding their future immigration status as well as for UK nationals who are living, working or studying in other EU states. It is vital the government offers these individuals the clarity and reassurance they need regarding their future immigration status.

#### Key points

- Much of the regulation of medicines in the UK derives from EC Regulations and Directives via the EMA<sup>3</sup>. The loss of coverage by these regulations could be hugely damaging for the UK. This loss could require the UK either to re-write significant amounts of UK legislation in this area to cover the gaps arising from the decision to leave the EU or to adhere to regulations over which it has no influence. Even then, differing interpretations of the regulations by UK and EU courts could lead to a divergence
- The presence of the EMA helps underpin the UK's pharmaceutical sector as a market leader and anchor it in the UK
- Safeguards must be put in place to protect research funding, EU research regulations and the mobility of research staff. This is essential for maintaining the UK as an attractive place for pharmaceutical companies to be based, for collaboration between countries and to ensure that the UK continues to have the opportunity to shape the EU's research and innovation agenda
- The UK is a net beneficiary of EU research funding, which has made a significant contribution to UK research. The UK government must act quickly to assure ongoing



participation in such programmes, such as Horizon 2020, to limit any potential damage to the UK's medical research base

### **Regulation of medicines and the future of the European Medicines Agency**

The BMA has significant concerns about the implications of the vote to leave the EU on the regulation of medicines and siting of the EMA. The Agency is currently based in the UK: this not only reflects the size and significance of the UK's pharmaceutical sector, but also helps anchor pharmaceutical and associated companies in the UK.

Furthermore, much of the regulation of medicines in the UK (including those under development, approved products, as well as medical devices and in vitro diagnostic testing) derives from EC Regulations and Directives via the EMA<sup>4</sup>. Following the UK's decision to leave the EU, there are concerns that the loss of these regulations could require the UK to re-write significant amounts of our own legislation to cover the gaps arising from our departure. Unless these are matched by EU regulations or were recognised by the EU, there is a risk that UK-based pharmaceutical companies would be put at a competitive disadvantage compared with their EU competitors in accessing and participating in the Single Market. Alternatively, it could mean that the UK has to adhere to regulations over which it has no influence. Even then, it has been argued that over time, differing interpretations by UK and EU courts over the meaning of the regulations could lead to a divergence and a competitive disadvantage that the UK had sought to avoid.

The Academy of Medical Royal Colleges has also highlighted another worrying concern: the UK's departure from the EU suggests we will not be able to participate in a range of measures relating to the regulation of medicines. This includes the European-wide approval system for new medicines; revisions to already approved products; the Orphan Drug Designation or the Small to Medium Sized Enterprise schemes; the centralised approval process for paediatric drugs; and the process that supports new medicine development for children. The UK also risks losing access to the EU wide Pharmacovigilance networks (whereby the EMA monitors and supervises the safety of medicines that have been authorised in the EU to ensure their benefits outweigh their risks) as well as the EU Clinical Trials Database, to which the UK is a major contributor.

### **EU research funding**

The EMA plays a key role in supporting research and innovation in the pharmaceutical sector as well as promoting innovation and development of new medicines<sup>5</sup>. Continued uncertainty about the future of the EMA, coupled with concerns over the UK's ongoing access to EU research programmes are deeply worrying.

We have major concerns about the future of this research funding following the vote to leave the EU and the implications this will have for science and research in the UK. This is a particular concern because EU research programmes have made a significant contribution to UK research: the UK received €8.8 billion in 2007-2013 having contributed €5.4 billion during the same timeframe<sup>6</sup>; the UK currently has 15% of all awarded grants in Horizon 2020, the greatest share amongst those countries participating<sup>7</sup>. While participation in programmes such as Horizon 2020 is not conditional on membership of the EU (Israel and Switzerland are amongst the highest net recipients) the UK government must act quickly to ensure ongoing participation in such programmes and to limit any potential damage to the UK's medical research base.

The UK government's recent commitment to underwrite EU funding awards secured while the UK remains a member of the EU is a welcome acknowledgement of the importance of this issue. It is, however, insufficient without further detailed commitments on ensuring access to such programmes in the longer term.

### **Free movement of people**

The regulations put in place by the EU, such as the mutual recognition of professional qualifications and freedom of movement, has created an environment which has facilitated and encouraged the exchange of people, data sharing and ideas. The loss of these regulations risks not only having a detrimental impact on the UK's ability to collaborate with our EU partners, to retain research staff, and persuade pharmaceutical and bio-medical research companies to remain and invest in the UK, but also on our ability to maintain our world leading role in research.

As with EU nationals working in the NHS and adult social care, we are seeking reassurances from government that UK-based researchers and staff from other EU nations will be given the right to continue to live and work in the UK. This is vital given that 15% of all academic staff at UK universities are originally from other EU nations<sup>8</sup>. Equally, it is essential that the government seeks to secure opportunities for UK researchers to gain experience in other EU nations: nearly 72% of UK-based researchers spent time at non-UK institutions between 1996 and 2012<sup>9</sup>. Both measures are vital for collaboration and ensure that the UK continues to have the opportunity to shape the EU's research and innovation agenda.

We also believe it is essential for the immigration system to remain flexible once the UK leaves the EU: this will be vital for UK-based research programmes to recruit and retain the best available researchers and medical academics.

### **Rare medical conditions**

A connected, but often overlooked, area is the healthcare of people with rare medical conditions, which are often genetically determined. For example, skeletal dysplasia has many thousands of different conditions. Research into the causes and origins of these problems is leading to the identification of more causes for previously undiagnosed conditions. These individually small patient populations have, overall, presented a massive unmet need from our health care systems but bringing the small patient populations from each member state together at an EU level has meant that their needs can be more effectively addressed and has enabled research to be undertaken. This joint working needs to be maintained for the benefit of these groups of patients.

The EU provides a strong framework for collaboration in these areas. It is worth noting that the Clinical Trial Regulation and the Data Protection Directive support potential for projects covering the total EU population rather than small UK populations, leading to a better understanding of these and other health issues.

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<sup>1</sup> European Medicines Agency <http://www.ema.europa.eu/ema/>

<sup>2</sup> [Academies publish joint statement on research & innovation after the EU referendum](#), 19 July 2016

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<sup>3</sup> Academy of Medical Royal Colleges: [Leaving the EU – What needs to happen to maintain the standards of healthcare in the UK](#), 28 July 2016

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<sup>5</sup> European Medicines Agency <http://www.ema.europa.eu/ema/>

<sup>6</sup> Academy of Medical Royal Colleges: [Leaving the EU – What needs to happen to maintain the standards of healthcare in the UK](#), 28 July 2016

<sup>7</sup> European Commission (2015) *Horizon 2020: First Results*

<sup>8</sup> [Academies publish joint statement on research & innovation after the EU referendum](#), 19 July 2016

<sup>9</sup> Elsevier (2013) *International comparative performance of the UK research base, 2013*