Brexit and the EMA: what’s next for the UK?

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When Theresa May triggered Article 50 on 29 March, the UK began a two-year process of negotiations to exit the EU, which is likely to include a divorce from the European Medicines Agency (EMA). But what will fill the gap left by the EMA and what will be the impact on new drugs coming to the market?

Breaking up is never easy but Britain’s split from Europe is sending seismic shockwaves through the medical and scientific communities. No one truly knows what the political mantra ‘Brexit means Brexit’ entails but for UK healthcare, it means a brave new world of approving, licensing and monitoring drugs – and, probably, on our own.

The UK is likely to be divorcing itself from the European Medicines Agency (EMA), the London-based organisation that is responsible for monitoring and approving medicines across a bloc of 28 EU member states and 500 million people. In statistical terms, the UK could move from a grouping that accounts for 25% of the pharmaceutical marketplace to an outsider with only 2–3% of the market, as a dog-eared calling card to entice the pharmaceutical industry.

Access to new medicines

This could manifest itself in physicians and patients having to wait up to two years for new drugs while pharmaceutical firms focus on the big markets of Europe, China and the USA before getting round to the UK. Being a free-spirited outsider can have benefits but the fall-out could be lethal, according to some observers. Professor Paul Workman, president of the Institute of Cancer Research, fears lives could be lost. He says: “I worry about the delay of life-saving drugs… and potentially the additional costs. I worry about this being an extra factor in the deprioritisation of the UK not only for making drugs available but research and development as well.”

That concern is echoed across the health landscape. “If we leave the EU we will no longer be part of that magic club and if a company wants to sell its new drug into the UK, it may have to make a separate application whereas before we were covered by one application for the whole of Europe. As we are only 2–3% of the market, why should they bother with us?” explains Professor Sir Alasdair Breckenridge, former chairman of the Medicines and Healthcare products Regulatory Agency (MHRA). “The impact on the public will be that new drugs will be late in coming and we are just not going to get our hands on the huge range of new anticancer drugs, anti-inflammatories...”
and monoclonal antibodies soon enough. Coupled with the fall in the value of sterling, these drugs are going to be more expensive when they do finally arrive.

“Doctors are going to be at the sharp end dealing with patients, who are well read and know what is available, and healthcare is going to suffer. It is looking more like a glass half-empty state for the pharmaceutical and medical devices industry unless there is going to be some fancy footwork with a new regulatory system,” he adds.

Dancing room looks in short supply as access deals to European trade areas come with the conditions of either signing up to the European Court of Human Justice or unrestricted migration — both anathemas to Prime Minister Theresa May and senior Brexit figures.

“The other approach is to wipe the slate clean and say, what do we want for our own regulatory system? But that is a monumental task,” continues Sir Alasdair, who is also emeritus professor of clinical pharmacology at Liverpool University. “The only people who will make money out of establishing that are the lawyers. The fear is that the pharmaceutical industry will be tagged onto some bigger trade deals and we will be swept along in an unpalatable situation. We will not be masters of our own fate.”

Life without the EMA
The EMA is trying to dampen the inflammmation with calm responses but turmoil swirls around its nine floors of offices in a tower block in London’s Canary Wharf. A decision about where it will move to — following a scramble by suitors eager to get its political clout and economic spending power — could be made as early as June.

The EMA, with its mission statement of fostering “scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union”, plays a key role in supporting medicine development, evaluating new medicines and monitoring the safety of medicines across their life span (see Figure 1) but also acts as a magnet for scientific talent and investment. It was set up in 1995 and now employs 890 staff and brings more than 30,000 scientists and academics to London to collaborate across its responsibilities that have grown to include the specialised areas of medicines for rare diseases, children’s medicines, herbal medicines and advanced therapy medicines.

The EMA works closely with regulatory agencies across EU member states and the MHRA plays a big role, taking on 15-20% of the scientific assessments needed before a new medicine is granted a licence (or marketing authorisation). MHRA chairman Professor Sir Michael Rawlins strikes a determined and upbeat note, saying: “Our priority is, and will remain, making sure the UK public have access to the right medicines at the right time. We believe this is best achieved by continuing to contribute to the EMA. This is our preference but this is also a decision that will be made as part of Brexit negotiations. We are investigating the options and are confident that, if needed, we can operate on our own.

“We are currently developing plans for how we will regulate after the UK leaves the EU; whether as part of the EMA or on our own. We know the final negotiations will affect how we operate in the future. However, that does not mean they will affect UK patients accessing important medicines.”

The Department of Health believes there are benefits in a standalone UK authority. “Brexit brings opportunities in this area, and we will be focused on whether we can secure even faster access to the latest innovations for British patients,” comments a spokesperson. “We are already taking action to ensure the UK continues to be a world leader and our cross-agency Brexit task force is considering the future regulatory roles the MHRA could adopt.”

A beefed up MHRA and the government’s Accelerated Access Review is seen as a way of filling the gap left by the EMA and ensuring the fast-paced growth of the nation’s life sciences sector is not blocked.

Pascal Soriot, chief executive of AstraZeneca, is also geared to the opportunities. “I can tell you the industry, and us as a company, have had very rich dialogue with the government... There is a very good and strong collaborative spirit, and from our point of view in the science and regulatory sense, I think we can do great things.”

A hostile market?
But the rallying calls cannot dispel all the gloom and Professor Breckenridge, who spent a decade at the MHRA, remains less enthused and believes that regulatory delays could also impinge on developing healthcare devices, which are an increasingly important tool in tackling ris-

![Graph showing GVA per employee of manufacture of pharmaceutical products](https://example.com/graph.png)

**Figure 2.** Direct gross value added (GVA)* per employee of manufacture of pharmaceutical products, 2014 prices (£’000s)

* GVA is a linked measure to gross domestic product (GDP) and is commonly used to measure the contribution of an individual company or sector. It is equivalent to GDP excluding taxes and subsidies on products.
ing NHS demands. “The government is in a difficult place. It was caught with its pants down over Brexit and it has made a brave attempt to say this going to end up to the UK’s advantage. Who is to say whether that will turn out right or wrong, but in any case, there are going to be casualties along the way. The man in the street is going to suffer, paying more for medicines and not getting the new drugs early enough. It is a worry as, especially in cancer, we have new drugs coming off the production line just when things may fall apart for a considerable time.”

Dr Philippa Whitford, Scottish National Party (SNP) MP for Central Ayrshire, who is also a member of the House of Commons select committee on health, says: “Delays will be inevitable and even once a drug is licensed, we may have a battle to get it funded. With the NICE constitution and NHS England now putting in an extra layer of financial approval, some firms, particularly in rare medicines, are talking as if they perceive the UK as a hostile market, which could make us fall disproportionately behind.

“We are a bigger market than Australia and Canada, so you would hope we won’t slide that far down the scale but some manufacturers might say: ‘Why rush? The NHS won’t pay for it for five years anyway so let’s approach everyone else and then go to the UK’.”

Dr Whitford, a consultant surgeon and SNP shadow health minister, adds that decoupling from the EMA would also impact clinical research and the UK’s ability to keep its position as a world force in life science. “There were no contingency plans and not having them when you call a referendum is irresponsible. If they’d scratched the surface and seen the complexity then it might have brought other things into the debate, the many things that we get from Europe, such as Horizon 2020 (an €80 billion European research and innovation fund).”

“Some companies may also be questioning how beneficial it is to produce drugs in the UK if they have to pay a tariff to export them to Europe. Hopefully, British companies will stay and keep their strong links with universities and life sciences. But the real need is to get these issues high on the government agenda. It needs to be setting out to fix these things and find solutions. Some things will be awkward and some we will lose but we should be trying to get as much social protection as we can, adds Dr Whitford.”

A smooth divorce
The Association of the British Pharmaceutical Industry (ABPI), which represents companies that supply more than 80% of all branded medicines used by the NHS, is pressing the government to make the EU split as smooth as possible. Dr Virginia Acha, the ABPI’s executive director research, medical and innovation, comments: “Good regulation is in everyone’s interest and we have that after decades of development so we don’t want the fact of leaving the EU to send us backwards in standards and quality of regulation. We need to do it in a smooth and frictionless fashion so there are no problems on day one – a lady in Manchester or a child in Norwich shouldn’t even know that it has happened. There is a recognition from government that no one wants a giant speed bump. But companies have to prioritise filing in the biggest markets to reach the most patients possible. We won’t go to the back of the queue but we will go out of the first tier.”

The government is unlikely to abandon the pharmaceutical sector in the UK. The life sciences sector contributed £30.4 billion to the economy in 2015, providing an estimated tax return of £8.6 billion to the treasury, according to a report by PwC commissioned by the ABPI, and supported by the Association of the British Healthcare Industry (ABHI), the BioIndustry Association (BIA), and the British In Vitro Diagnostics Association (BIVDA). The report adds that the sector supports 482,000 jobs, either as direct employees, in supply chains or by induced effects. It concludes: “UK pharmaceutical manufacturing is the most productive of any of the major European nations. GVA [gross value added] per employee in 2014 was 40% higher than in Germany and Italy, 50% higher than Spain and almost twice the level achieved in France [see Figure 2].”

Dr Acha adds: “The UK’s strength in life sciences will still drive investment, collaboration and partnerships. Big science projects are by their nature collaborative and we think the government is aware of this. But we are very concerned that the government doesn’t mishandle this important juncture for the UK.

“For the last 20 years, they have been building networks in Europe and it is very difficult to suddenly find new friends. But doctors and patients should be assured that a lot of people are working on this and it is not necessary to raise the level of panic. We have made considerable strides over the last six months but we need to ensure everyone is aligned as this is going to be a considerable change.

“We need to be sure how everything fits and joins; a bit like finding the wiring in the walls, which is something we have not had to think about before.”

References

Declaration of interests
See http://www.mjauk.org/author/bucklandd/

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