

## Brexit and the Life Sciences Sector

### The Overall Picture

If the UK votes on 23 June to leave the European Union, the consequences for the country would be profound in most sectors as well as for many people themselves.

However, excluding the science industries, the NHS will not be one of these sectors.

This is because EU member governments have jealously protected their own national health services. The NHS health structures and organisations, financial arrangements and staffing will be largely unaffected.

There may be some minor exceptions. The maximum working times for junior doctors, which is governed by EU law, could be amended as could the recognition of EU professional standards, giving doctors the right to work in the UK.

The future of the European Health Insurance Card for UK citizens would be a matter for the negotiations, possibly with a Swiss-style agreement [1].

Yet self-evidently the life science industry cannot be excluded. This blog is designed to focus on a UK sector of considerable strength, with approximately 4,500 companies employing 167,500 people and generating turnover of over £50 billion [2].

### The European Economic Area

The single most important question after a referendum vote to leave is whether the UK would apply to become a member of the European Economic Area (EEA), like Norway.

The advantages for the life sciences industry is that it would retain access to the huge EU market, with free movement of goods and capital, without any tariff or other formal barriers. Furthermore, the UK would remain a member of the European Medicines Agency.

However, EEA membership also requires the free movement of people between the EU to EEA states. Given that immigration from EU countries is one of the main platforms for those opposing EU membership for the UK, it is virtually inconceivable that a post-23 June government would agree to join the EEA. It would make nonsense of the referendum.

Therefore, the working assumption in this paper is that the UK would not join the EEA and instead a series of bilateral agreements would be negotiated between the EU and the UK. The EU constitution allows for two years of negotiation, during which the UK would remain part of the EU but would be excluded from its decisions. However, given that Greenland took three years to negotiate an exit, and all it had to discuss was fish, a more realistic assumption is that UK negotiations would take 5-7 years with the attendant business uncertainty.

A relevant consideration, but very difficult to judge, is whether the EU states would be willing to give the UK a good deal in the negotiations or whether this would be seen as an opportunity to impose some harsh measures to deter other countries from following the UK path.

## Investment in the UK

The majority of the pharma/life sciences industry in the UK is foreign owned, particularly from the USA but also from Switzerland, France and Japan among others.

As has been pointed out *“Many firms invest in the UK in order to sell to the domestic and other EU markets, and for some inward investors, unrestricted access to the EU market is key.... the UK’s fragmented market access schemes and reluctance to pay high prices could compound the situation, making the UK a less attractive launch market.”* [3]

In the event of Brexit, and with new tariff barriers in place, future life science investment from abroad would be increasingly placed in other countries. Germany in particular has a strong life sciences industry and is at the heart of the EU. The UK-based industry would lose some of the ground that it currently occupies.

## The European Medicines Agency (EMA)

Although the European Patent Convention would remain in place, as its membership goes wider than the EU. The Supplementary Protection Certificate, extending patent life by up to five years, is a purely EU matter and would not apply to a Brexit UK. This issue could be part of the renegotiations but, if agreement was not reached, the UK would need to decide whether to introduce its own legislation.

With the UK outside the EEA, the former would have to resign as an EMA member. Germany and other EU member countries would then, quite reasonably, press for the EMA Headquarters to be away from London and a move to a city like Frankfurt would seem logical. Nor would the Unified Patent Court be based in the UK, as currently planned, as the UK would not be a member.

Nonetheless some arrangement between the UK and EMA would be imperative if life science companies wanted to be able to export to the EU market of over 400 million people. Furthermore, the EMA is one of the most influential international institutions regulating medicines and reaching international agreements, along with the US Food and Drug Administration. It may be noted that the EMA encourages innovation in a number of ways, including its special approval system for orphan and ultra-orphan medicines.

The best way forward, assuming that the remaining EMA members give their agreement, would be to reach a Mutual Recognition Agreement with the EMA. There are helpful precedents - Switzerland has done this although it is not an EEA member as has Australia, Canada and New Zealand [4].

## Research Funding

At present the UK receives more funding than any other EU country from the European Research Council. This funding supports project based research in universities across the UK and accounts for around 16% of universities’ total research funding. It is estimated that Brexit could jeopardise up to \$8.5 billion (~€7 billion) of EU funding for science over the next four years [5], a figure supported by evidence showing that between 2007 and 2013, under the EU’s framework programme, the UK managed to win a disproportionate amount of grants compared to other member states. With a total worth of €7 billion, the UK was second only to Germany in the amount of funding achieved from this EU scheme. Along these lines, a further point to consider is that institutions in the UK also host more researchers who have grants from the EU-funded European Research Council than any other country in the EU [6].

In order to minimise the loss of EU funding, it may be the case that the UK must opt-in to such schemes, the way that other countries, such as Switzerland, Norway and Israel have in the past. These countries have proven that being outside of the EU does not necessarily mean that you are disqualified from becoming involved in EU programmes. Some EU research schemes can be accessed by adopting a number of general EU rules, such as freedom of movement laws (such as the free movement of goods, services, capital and people- which the UK government may be unlikely to adopt for reasons mentioned above) and by paying an additional “inclusion fee” [6].

## Loss of Research Facilities and Collaborative Partnerships

Perhaps more important than the funding grants, is the risk that UK researchers will lose access to scientific facilities across Europe.

A side effect of this is the loss of collaboration across the EU. One example of this is the Innovative Medicines Initiative [7]. This programme is designed to support collaborative research projects in order to build networks of both academics and industry experts throughout Europe, which will inevitably help to improve and encourage pharmaceutical innovation across the EU. With half of the funding for this initiative coming from the EU, if Britain were to leave Europe, it would undoubtedly struggle to maintain its pioneering role in engineering original and ground-breaking pharma-research.

## EMA Regulations

These regulations are often highly criticised for their role in hindering research in the UK. Stuart Pritchard, EU Affairs manager at the Wellcome Trust, told the House of Commons Science and Technology Committee in March 2016 that the problems with the clinical trials directive were eventually addressed and that the delay in effective implementation was simply due to the size of the institutions and the time that it takes to transpose regulation into national law. However, he also agreed that there was a lack of clarity in some definitions and that variation in member state legislation is an issue [8]. Pritchard also acknowledged that the changing medical device regulations concerning in vitro diagnostics could present some problems to the UK, as resources in this department are already stretched.

The proposed changes to the legislation would mean that all genetic testing would need to be supplied by a prescription and that that testing would need to be conducted by medical personnel and have explicit consent and counselling, something that Professor Berne Ferry (representing the Shelford Group) believed could present difficulties with new born screening [8]. Although Dr Jaqueline Barry, Director of Regulatory Affairs, Cell and Gene Therapy Catapult, commented that in terms of the medical advance field there were incentives to remain under the EMA, as it offers a reduction of costs [8].

## Conclusion

The case for continued EU membership seems, on the face of it, a strong one for the life sciences industry. The arguments above are powerful and well supported.

Yet the assumption that “nothing else will change” is a fallacy that also needs to be addressed. With a new Prime Minister and Cabinet (neither David Cameron or George Osborne would continue in office after losing the referendum) and 5-7 years of negotiations, there would be a long period of great political and economic uncertainty. A robust UK Government, faced with losing the UK’s current high tech status, could decide to make the country more attractive for the life sciences industry. It could use the opportunity of Brexit to promote the life sciences industry by substantially easing price controls, speeding up the workings

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of NICE and the NHSE, and reducing company taxation. Those who advocate withdrawal should consider these possibilities.

Of course, the case for and against European Union membership will be decided by broad and emotive issues. But one of these is the future of businesses in the UK, to which the life sciences sector is very relevant. Increasingly, the sector is making its position clearer by seeing advantages in staying within the EU and little to gain by leaving.

## Sources

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