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Shock therapy: Can UK life sciences bounce back from Brexit?

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To those predicting calamity for UK pharma after the Brexit decision I have a simple riposte: take a look at Switzerland.

Despite sitting outside the EU and European Economic Area, Switzerland is where some of the world's largest pharmaceuticals companies have placed headquarters, regional hubs, research centres and production facilities. Swiss pharma shows us that British companies and research organisations can survive - indeed thrive - outside the EU.

We can, and should, aspire to the Swiss position. As KPMG in Switzerland shows in its study of Europe's top sites for life sciences, the UK already has the highest number of innovative biotech therapeutic companies in Europe and is second only to Germany for the overall number of life sciences businesses. It has Europe's strongest product development pipeline, raises more money than anywhere else. It also home to nine of the world's top 100 universities - more than France and Germany combined[2].

Even with this incredibly strong base, Switzerland's happy position remains an aspiration. Let's be in no doubt, leaving the European Union will significantly complicate the research, production, sale and distribution of medical products and drugs for those in the UK. It is likely to diminish Britain's influence and reputation in the world as a centre of innovation and learning, all of which is likely to cost the country jobs and investment.

Much rests on a successful transition to the post-Brexit world: the sector employs 73,000 people directly in the UK - 23,000 of them in highly-skilled research and development roles[3]. UK pharma accounted for 20% of all spending on R&D by UK businesses[4] - far more than any other industry. And of course, the UK has pioneered drugs and treatments that have improved millions of lives.

Swift action

At both a company level - and as an industry - we need to act swiftly.

First, life sciences must make its voice heard across Whitehall and in the negotiating halls of Brussels. Government needs to understand the implications of lower funding for innovation or less collaboration with European researchers – just it already appreciates what might happen to the City should UK banks lose their right to passport financial services into the EU.

Up to now the UK has done incredibly well out of funding and collaboration as an EU member. The UK has received 15.4% of all the funding allocated by Horizon 2020[5] - the EU's biggest-ever research and innovation programme that helps finance projects Innovative Medicines Initiative (IMI).

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[1] www.kpmg.com/CH/en/Library/Articles-Publications/Documents/Tax/ch-pub-20151208-site-selection-life-sciences-companies-europe-en.pdf
[2] www.shanghairanking.com/ARWU-Statistics-2015.html#2
[3] www.abpi.org.uk/industry-info/achievements/Pages/pharmaceutical-industry.aspx
[4] www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterpriseresearchanddevelopment/2014#rd-expenditure-by-industry
[5] www.publications.parliament.uk/pa/cm201617/cmselect/cmsctech/158/15804.htm

This €3.3 billion initiative unites universities, pharmaceutical companies and other groups such as regulators to address the whole life sciences value chain, from vaccines and animal health to biomedical imaging industries. So will UK companies and institutions continue to play a part in projects like IMI?

The Swiss experience offers some important pointers. When Switzerland voted to curtail free movement of people, the EU revoked its access to science funding and collaboration. The EU did eventually allow Switzerland back into Horizon, but on much more restricted terms. Most notably, it barred non-EU states from owning the intellectual property of any research conducted with the EU. A similar deal for the UK would seriously diminish its value.

Chilling effect

There is increasing anecdotal evidence that the referendum result is having a chilling effect on collaboration – both the willingness of European scientists to include their UK peers on new projects or at an individual level, to take jobs in the UK when future funding remains so uncertain. As the UK's seven scientific academies made clear in a joint letter on 19 July, "*The current uncertainty is having immediate implications and raises many questions*."[6]

The government will need to quickly plug funding gaps in key areas of research. Britain's Regional Growth Fund has been an important source of funding to new life sciences businesses but nothing more is slated. And while Innovate UK has provided smaller sources of funding and support to life sciences, more will need to be done. Leaving should free up a substantial amount of money previously paid into the EU budget. How much is freed up will depends on the terms of our exit.

The second area of concern is regulation. Life sciences is heavily regulated, so the UK's efforts to extract itself – at least in part – from that complex web will have a range of impacts on the cost of developing and distributing products. The UK is an attractive location for clinical trials for example. This may change if it's no longer covered by the EU Clinical Trials Directive.

Goodbye EMA?

One early consequence for the UK is likely to be the loss of the European Medicines Agency – the largest EU institution based in Britain with over 600 staff. Proximity to the EMA is one of the convenience factors that has encouraged pharmaceutical companies to base themselves here.

Britain was also to have been host to the intellectual-property court running a 'unitary patent system' specialising in drugs and chemicals and due to start work by 2018 – further boosting the country's pharma credentials. That now looks unlikely.[7]

Once the UK has left the EU, its own regulatory authority – the MHRA – will need to gear itself up

[6] www.acmedsci.ac.uk/more/news/joint-academies-publish-statement-on-research-innovation-after-the-eu-referendum/
[7] www.economist.com/news/business/21701811-uncertainty-especially-about-regulation-spreads-among-industries-most-exposed-britain-rules

to handle more applications. That will take time so in the short term there could well be a period of regulatory limbo, and even after that a risk that new medicines will take longer to reach the UK market. After all, most companies would probably prioritise the larger and more lucrative EU market.

No tariffs, but…

UK-based firms will lose the ease of 'passporting' marketing and licensing of drugs across Europe. If you are an EU-based entity, you can sell drugs in any European country. Post Brexit, UK-based businesses may need to set up an EU-based subsidiary.

Likewise, companies need the relevant licence to manufacture, import or hold inventories of drugs in Europe, and to do that they need to have an EU establishment. This is not just a bureaucratic barrier, but potentially a legal one, since the way different countries have interpreted the EU directive varies. The impact of these rules will lessen considerably if the UK joins the EEA, but either way UK pharmaceutical companies will need to review their supply chains carefully.

Tariffs are less of an issue on the face of it since most medical products have tariff-free treatment. However outside the Single Market, every consignment would have to go through border controls - with the requisite paperwork and potential delays. This would not only represent a working capital challenge. Drug producers also have an ethical duty to supply essential medicines to the markets they serve, so they might need to change distribution models and inventory levels to make sure supply wasn't interrupted.

Many of these issues are annoyances rather than deal-breakers for a well-prepared company. The loss of passporting rights for pharmaceutical companies is nowhere near as serious as for an investment bank for example. However, I fear that taken together, these issues will feed a perception that pharma will become more difficult to do in the UK. And so when a company is deciding whether to build a research, production or commercial centre in the UK or elsewhere, that knife-edge decision will go against the UK.

Natural strengths

I've already mentioned some of the UK's great strengths in life sciences such as its R&D institutions and its highly-skilled workforce. These will endure. We have one of the most competitive tax regimes in Europe, both in terms of corporation tax – which former chancellor George Osborne pledged to cut below 15% – R&D tax reliefs and the 'Patent Box' low tax regime covering intellectual property costs and revenues. We have also seen a willingness by the government to champion life sciences. A steering group, established by former life sciences minister George Freeman and chaired by the CEOs of GlaxoSmithKline and AstraZeneca, is currently considering opportunities for the UK life sciences sector outside EU regulation.[8]

The UK's life sciences infrastructure and government backing will be vital if we are to emulate the Swiss. However, the job starts with the companies themselves. They will need to proactively review, and if necessary restructure operations, in light of Brexit. To do that, their first responsibility will be to acknowledge the scale of the challenge and tackle the issue head on.

[8] www.fiercepharma.com/pharma/will-brexit-mean-a-controversial-exit-for-drug-regulation-too-minister-won-t-rule-it-out

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