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Brexit: Issues and Opportunities As UK Life Sciences Define A New Relationship In Europe

by Sukaina Virji

It's fair to say that the outcome of the June 23, 2016 referendum on the UK's membership of the EU stunned not only the nation, whether you voted to leave or remain, but sent shockwaves through Europe and beyond. The UK's pharmaceutical industry made no secret of its stance: it was all about remain – but it got a Brexit. *Scrip's* Sukaina Virji gathered a group of pharma industry experts who had spent their summer working on making the best of the situation. Here's an edited recount of their insightful discussion.

Q Sukaina Virji: What do we actually know about the upcoming Brexit?

A Ian Schofield, principal analyst, *Scrip*: We know that we'll have to trigger Article 50 to start the negotiation process for disentangling ourselves from the EU. We don't know what kind of relationship we will have with the EU eventually. Once the Brexit negotiations are finished we'll have to start negotiating trade agreements with the EU. Until then it's very difficult to say what the implications will be for the life sciences as it depends very much on whether we end up with a Norway style agreement, a Swiss type agreement, or a complete withdrawal. Certain things are pretty likely to happen. The European Medicines Agency will probably have to move from London to another EU country, although there are suggestions that there might be some way of working around that by having some operations in the UK and some in another EU country.

It will be very important to try and avoid regulatory divergence between the UK and EU because companies rely to a huge extent on the same regulations across the EU single market. Other considerations to take into account are the UK's participation in the future EU patent system: we could well lose the branch of the new unified patent board that's supposed to be setting up in London.

The one front where there probably won't be much change is pricing and reimbursement, health technology assessments, as they tend to be a member state responsibility.

Q Sukaina Virji: What key concerns did the Brexit result throw up?

A Steve Bates, chief executive, BIA: My main worry was that this was a big degree of uncertainty put into a long scale business that's global in its perspective. From a UK trade association point of view, if you look at big revolutionary moments such as the American declaration of independence or perhaps the French revolution, many things changed but also many things didn't. If you look at the diet of the French peasant between 1750 and 1850, despite the French revolution, it didn't fundamentally change. If you look at the strengths of the UK ecosystem in bioscience, the fantastic science from fantastic universities, the talent and the opportunities, the money that comes from London and beyond into this sector, these aren't likely to be significantly affected by a Brexit.

Harren Jhoti, CEO, Astex Pharmaceutical: My biggest concern was access to talent, to people, because at the end of the day our industry is based on a foundation of being able to access the best scientists, best clinicians, best regulatory folk, from around the world. If that is at risk, then we could see a gradual erosion of the science base in the UK.

Jo Pisani, partner leading the UK pharma and life sciences consulting practice, PwC: We have a global consulting footprint and on June 24 we were overwhelmed with queries from different parts of the world and a lot of it was about uncertainty. The government has underwritten Horizon 2020 commitments but, nonetheless, we have

seen some collaborations fall away. [Horizon 2020 is the EU's €80bn research and innovation program, running from 2014-2020 – ed.] The regulatory framework concerned a lot of our global clients and the view was that if you've got one system for 27 countries and another system for the UK, what does that say about the UK in terms of priorities around market access and launch capabilities? With multinational companies that haven't got a strong presence in the UK, there are different levels of knowledge about what's going on and this can lead to kneejerk reactions. Unfortunately, we have seen some foreign direct investment decisions being reversed at the last minute, we've seen some collaboration agreements being dismantled, and clinical trials locations [changed]. The absolutely critical thing at the moment is to convey confidence and communication about the UK biosciences ecosystem.

Q Sukaina Virji: So it's obvious we need a clear Brexit strategy. What are the key elements from a pharma perspective?

A Steve Bates: The BIA and the ABPI, with support from PwC, have worked hard to produce information for the new UK government to tell them about the needs and priorities of the sector from a global perspective as well as a local perspective in terms of what they need to focus on in the negotiations. We engaged with over 150 companies in 50 hours of workshops; it's been a busy summer, but we are now in a position to be able to help the government with their thinking.

Lindsey Barras, director in global immigration, PwC: The [new] government sees the value of the skilled people that this industry brings in, but at the same time - remember these are people in new roles - they're struggling to create something that gives enough flexibility and makes the EU happy, yet at the same time gives the British public the feeling that they've been heard, because within the vote it was very clear that immigration was a key area of concern - people felt that our borders were too open.

Harren Jhoti: We need in the shorter term to have a position on the EU citizens already here. We have significant numbers of EU staff across the industry; in my company we have around 20% and there is an understandable level of uncertainty in

those people's minds as to what's going to happen.

Virginia Acha, executive director, ABPI: We have been trying to bring ministers up to speed on how comprehensive regulatory policy is for working within the life sciences. It shapes the way we do our clinical research, it shapes the way we develop and produce our medicines, the manufacturing process, the way we authorize and provide them to patients, and critically how we follow up with the use of that medicine in practice. A lot of those European laws that shape our sector were British ideas. As I tried to explain to ministers, they are like standards of any sort. The more you diverge from a global standard, the more you need a pretty good reason why somebody would want to do that niche approach. And really the globalization and standards we have were driven there, not because of some sort of trade requirement, but because that's where the science is taking us. So we need to follow the science, and then is it really such a big surprise that this convergence is possible?

Q Sukaina Virji: What kind of positive opportunities does Brexit throw out for UK life sciences?

A Jo Pisani: We shouldn't lose sight of the fact that UK life sciences is tremendously vibrant, so there are three areas of opportunities that I would mention. Innovation, particularly around advanced therapies. Monoclonal antibodies are an example of a technology that we didn't throw our weight behind and we saw a lot of that move beyond the UK's borders. Financing is another one. We have a mature end-to-end system but we need more scale, longer investment cycles and also diversification beyond different therapeutic areas. The third area is the NHS. Looking at the NHS as a single system, effectively looking like a single patient to the outside world, can we encourage rapid uptake in innovation within the NHS? If we look at those three areas, I'd be very positive about the future for UK life sciences but we just need that backing and momentum.

Steve Bates: I look at this from the perspective of the things that have perhaps not gone well for the UK as a member of the EU that could have the opportunity to go well going forwards. One example is the area of cell therapy. There's a case in the EU

Courts called the Bruestle Judgement, well-known to people developing cell therapies, which I think within a UK court might have been decided differently. So perhaps where you have European case law around emerging technologies and how they are patented, there is the potential for there to be a divergence. The second example is what I would describe as the non-scientific approach to GM foods which has been taken by the EU in the last few years. If you look at BIO in the US, the sister organization to the BIA, they have a vibrant and active agricultural biotechnology segment. We don't have that in Europe; there aren't any companies, in a sense the development of that industry has been stifled by EU rules.

Harren Jhoti: What I'd probably think harder about is trying to establish stronger links with the largest pharmaceutical market in the world, North America. We should explore that, as well as some of the emerging markets. The old Commonwealth links, perhaps there's opportunities there. Certainly there's a lot of talent there. India produces thousands of PhD candidates every year and certainly that skill set would be very useful. Also, training our own people; [Brexit] gives us an opportunity to really energize that - persuading the government to think more about science and technology in the education system in the UK because if we are going to be restricted in getting talent from the EU, we'll have to grow our own.

Lindsey Barras: That's one positive from an immigration perspective. Probably one of the biggest challenges over the last five or six years has been a focus on this arbitrary net migration number. Potentially we won't have as many EU people coming, so we can be a little bit more flexible with non-EU migration which will be useful when and when we talk about the trade agreements, if we want people coming from the US or elsewhere, there is opportunity to have a system that works better than it currently does. Even before Brexit there was talk about doing an overhaul of the process and this has reinvigorated that.

Q Sukaina Virji: What happens next on the Brexit front?

A Steve Bates: Much of this discussion is predicated at a political level, so it's important to have an understanding of some of the points in the calendar on the European

political timetable over the next period of time. In the UK, an important moment will be in early October, when the Prime Minister [Theresa May] gives a speech to the Conservative Party Conference, a bit like the State of Nation, where she'll be likely to flesh out some of the thinking. Then there's likely to be further discussions with the EU towards the end of the year, and the triggering of Article 50 could happen early in the New Year. It's also important to look at the context of domestic politics in other European nations. There are elections in the Netherlands due and, significantly, elections for a President in France in the first half of next year. There are significant German elections due next year, which may lead to the biggest countries in Europe's posture for the negotiation later in the year. We will see some of this Brexit discussion through the prism of those political contexts because if those political contexts change, it could change the nature of the debate.

Q Sukaina Virji: What can we tell people about the potential timeframe?

A Jo Pisani: The clock starts when Article 50 is triggered and then we've got two years. It can be extended but you need the other 27 countries to agree unanimously, which will take two years in itself. So we're advising companies around scenario planning. What are the different scenarios both in terms of velocity and impact? How does it impact your business and how do you mitigate the risks? The other important thing to mention is that other sectors are going through similar challenges as well. We as a sector have got a lot to learn from other sectors. For regulation look at aerospace. Life sciences' life blood is venture capital for which passporting is absolutely key and that's the number one agenda point for financial services. It is important for the sectors to remain aligned because there are a lot of interdependences that go on there.

Harren Jhoti: We also need to remind ourselves that we are working in a ferociously competitive sector. So while the executives running the companies are distracted by this huge issue, they're not building the company. All our competitors around the world are building their companies. There's no answer to that, it is what it is, but we all know the EU doesn't move very fast.

Steve Bates: So for those planning for 2017, the UK will still be in the EU, the regulatory processes will be as they are now, and people should get on with their work.