LIFE SCIENCES AND BREXIT – INTENSIVE CARE NEEDED?

JULY 2017

On 12 July 2017, the Healthcare and Life Sciences team of FTI Consulting's Brussels office hosted an event entitled, "Brexit and Life Sciences: Intensive Care Needed?", bringing together experts from the UK and Brussels to discuss the impact of Brexit on the healthcare sector and what it means for businesses on both sides of the channel. The panel was moderated by FTI Consulting's Patricia Hewitt, who previously served as the UK Secretary of State for Health. Speakers included Mike Bewick, a senior clinical advisor to the Healthcare Solutions team at FTI Consulting, and former Deputy Medical Director of NHS England, Elizabeth Kuiper, Director for European Affairs at the European Federation of Pharmaceutical Industries and Associations (EFPIA), David Earnshaw, head Public Policy Europe & Canada at MSD, and Gian Marco Currado, the social and environment counsellor, overseeing a wide range of areas, including healthcare, at the UK's Permanent Representation to the EU (UKREP).

Katie Brown is Senior Director, and Zachary Burnside is Consultant at FTI Consulting in Brussels

Practical implications of Brexit for the life sciences sector

While Brexit's full effect will take time to emerge, there was a consensus in the room that the healthcare industry is braced for a period of uncertainty. Two key areas of concerns came out throughout the discussion:

- The healthcare sector is expecting a significant impact on market access and potential disruption in the availability of life-saving products to UK and European patients.
- Delays are not only expected due to the relocation of the European Medicines Agency (EMA) out of the UK, but also due to the need for companies to transfer say, UK-located licenses to a EU market, move pharmacovigilance functions, etc. which may be particularly challenging for small and mid-sized pharmaceutical companies.

Such delays could see leading international companies favouring the US Food and Drug Administration rather than the EMA for first authorisation of their products, thus impacting access to EU and UK markets and patients.

Moreover, due to the potential for increases in the cost of production, with trade barriers being put in place on active pharmaceutical ingredients and excipients, certain products, especially generics, may no longer be profitable and could be retired from a number of markets, with consequences for patients and overall healthcare costs.

What can we hope for from the negotiations?

The fact that the EU is insisting on a two-phase approach to Brexit talks: disentangling past ties and commitments, and only then discussing the future relationship, tends to increase the uncertainty for business. To limit any potential damage, a number of points were raised:

- During the negotiations, the goal must be to ensure that as far as possible, the positive elements of the existing healthcare regulatory framework survive intact, for the benefit of companies, but most importantly patients. Ensuring the greatest possible level of cooperation in the healthcare space between the UK and EU-27 will limit the potential damage from the Brexit fallout.
- Moreover ensuring a period of transition for companies to adapt to the new regulatory environment post Brexit will be crucial. Small and medium sized pharma companies, in particular, will need clarity on the future trading relationship, as early as possible, if they are to take decisions that will not cause them unnecessarily harm.

As the negotiations progress, it will be important for healthcare stakeholders to come together to discuss the potential ramifications of Brexit on the healthcare community. With this in mind, the aim of the panel session was to provide individual, company and regulatory perspectives, on the impact that Brexit will have in the life sciences sector across Europe.

The discussion

FTI Consulting's **Mike Bewick**, the former Deputy Medical Director of NHS England, opened the panel discussion pointing out that the UK is in a weakened position that has led to confusion and instability; because of this, research and development has been under threat. He said that a change in attitude is needed as politicians have to have support from Europe in order to forge a successful partnership. He noted, "if we just follow an antagonistic approach, a soft Brexit will not materialise."

> "If we just follow an antagonistic approach, a soft Brexit will not materialise"
>
> *Mike Bewick, FTI Consulting*

The next speaker, **Elizabeth Kuiper**, Director of European Affairs at EFPIA, pointed out that there are several areas of concern with Brexit, particularly with regard to patient safety and the regulation of medicines. The UK contributes heavily to European regulatory policy. Indeed the UK Medicines and Healthcare Products Regulatory Agency (MHRA) currently supports directly about a fifth of all medicine approvals via the centralised authorisation procedure; resulting in a great deal of uncertainty for bio associations, generic associations and industry as a whole. With the movement of EMA, "it is important that there will be no disruption to patient safety and the approval of new medicines' she said. The Council of the EU has put forward six criteria that should be taken into account when selecting the city that will host the EMA post Brexit. EFPIA has called on Member States to take into account all six criteria in order to ensure the vital business continuity. A final decision will be taken by the European Council on the new location in November.

David Earnshaw, Associate Vice President Public Policy at MSD Europe, started by pointing out that "Brexit is the biggest rupture that has ever hit the European project. It's going to change the shape of Europe for many years." He went on to explain that it's important for Britain to remember that pharmaceutical regulation in the EU is supranational: EU pharmaceutical law was originally about the free movement of goods, about stopping national preference, and creating a level European playing field. He also pointed out the challenges ahead, with EU law applying to all Member States on pharmaceuticals equal to probably 10,000 pages, underscoring the level of detail that the UK will have to enter into when negotiating any

future deal on regulatory cooperation on medicines with the EU.

Earnshaw took the view that there's a 99 to 1 chance against such a partnership being a viable option but "we need to try." He warned, it's not Big Pharma that we need to be concerned about primarily in this transition – "it's the generic and small to medium sized pharma companies who will be hit the hardest if there is not a strong UK-EU27 partnership." Small and medium sized pharma companies do not have the resources to plan for various scenarios in anticipation of the outcome of the negotiations that are due to be concluded by the end of 2018. Uncertainty will force decisions on companies (moving manufacturing, people, supply chain, implementation of recently-adopted legislation, etc.), often based on the worst case scenario. While some of these decisions may turn out to be unnecessary, small and medium companies will find it harder to undo what has already been done.

Gian Marco Currado, Counsellor, social and environment, at UKREP, and former Deputy Director in charge of EU at the MHRA, closed the panel presentations taking a more optimistic approaching, stressing that the UK government is committed to a successful partnership. He said, "the need for collaboration in the interest of public health was very clear" in the Prime Minister's speech in January and that "we have a shared vision." He noted that the UK is focused on patient safety, making sure innovations reach patients quickly and safely, and continuing to promote the life sciences sector in the UK. Backing up his case was a letter sent to the Financial Times on 3 July, by Jeremy Hunt, the UK's health secretary, and Greg Clark, the business secretary, in which they proclaim that "the UK would like to find a way to continue to collaborate with the EU, in the interests of public health and safety".

During the question and answer session Patricia Hewitt stressed the importance of information sharing, explaining that science is international; it's global. "The UK needs to stay a part of the scientific collaboration" she said. Elizabeth Kuiper noted that the free movement of people is critical: "If students can't move, there will be massive consequences for the UK and the EU." The EU negotiating directives call citizens' rights "the first priority", namely the status of British citizens living in the EU and EU citizens living in the UK. However the broader arrangement governing freedom of movement post Brexit will not become apparent until the so called divorce talks are concluded, and an eventual comprehensive free-trade agreement is agreed.

The panellists also agreed that there's little chance of a new UK-EU27 pharmaceutical framework occurring outside a formal negotiation. As David Earnshaw said, "in pharmaceuticals you've got to know who is responsible. It is extremely difficult to create UK-EU27 cooperation in pharmaceuticals informally; it needs to be in a treaty-based setting." Patricia Hewitt pointed out that the ideal situation is to maintain the status quo so the question becomes: how do we get as close as possible to the status quo without it actually being the status quo due to Brexit?

Conclusion

Brexit will have a long lasting impact on the life sciences sector both in the EU and in the UK. Those who had once counted on UK governmental support to make their case in the corridors of power are now likely to look elsewhere, given the almost inevitable decline in the UK's continued influence in Brussels. As Elizabeth Kuiper concluded, all of us now have a responsibility to make the case for life sciences on behalf of patients.

FTI Consulting, with our dedicated Brexit taskforce, situated across both sides of the channel, is well positioned to advise companies throughout the Brexit process and beyond.

Katie Brown
+32(0)2 289 09 54
Katie.brown@fticonsulting.com

Zachary Burnside
+32(0)2 289 0976
Zachary.burnside@fticonsulting.com