



CRA Insights: Life Sciences

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The impact of Brexit on the life sciences industry: separating fact from fiction

Overview

Following the results of the UK's referendum on 23 June, the life sciences industry needs to prepare for the impact of a change in the relationship between the UK and EU. Although the shape of the relationship remains a topic of considerable debate, and the impact will differ from company to company, it is possible to shed light on the extent, the timing and who in the industry will be affected, by considering the different activities in the industry value chain and the role of European rules and regulation.

Consultants with Charles River Associates (CRA), were commissioned by the European Federation of Pharmaceutical Industries and Associations (EFPIA) to conduct an independent and objective assessment of the impact on the life sciences industry in Europe of a withdrawal of the United Kingdom from the European Union (commonly described as British exit from the EU or "Brexit"). The broad goal of this project was to identify, from both a UK and a European perspective, the positive and negative impact that a change in the relationship might have upon activities along the industry's value chain.

Approach

To investigate the impact of the UK developing a new relationship with the EU, we need to consider how this relationship might work in practice. At a high level, there are four different scenarios:

- European Economic Area (EEA) membership (similar to Norway);
- Multiple sectoral bilateral agreements with the EU (similar to Switzerland);
- "Comprehensive" Free Trade Agreement with the EU (similar to Canada); and

- Full Break model governed solely by World Trade Organization (WTO) free trade rules, i.e. no specific agreement with the EU.

We considered each of the above examples and conducted 30 interviews involving industry trade associations, large multinational companies, small biotech companies based in the UK, specialist research organisations located in the UK, UK universities with researchers involved in collaborative projects with the life sciences industry, and charities involved in funding R&D.

Key findings

It is important from the outset to highlight that a change in the UK's relationship with the EU will not change all of the rules governing life sciences in the UK. The life sciences industry is a global industry, and this has implications for how it is regulated and how trade is conducted. Whichever scenario occurs, we do not envisage tariffs being applied to active ingredients (AIs) or finished pharmaceutical products or the UK departing from international agreements on how medicines are regulated.

Learning from the experiences of Norway, Switzerland and Canada

One way to look at the impact of a change in the relationship between the UK and the EU is to look at other countries and the relationships they have with the EU. We have considered the experience of the life sciences industries in Norway, Switzerland and Canada and the extent to which lessons are applicable to the UK.

- **Participation in EU science programmes:** A number of countries outside the EU have succeeded in negotiating access to all or some parts of the EU research programme. Norway benefits from full participation in EU science programmes, like Horizon 2020, in return for a substantial financial contribution. In contrast, Switzerland has only partial access. The proposed limitations on freedom of movement, following the February 2014 referendum on curbing immigration, have led to restrictions on Swiss access to European funding through Horizon 2020 and uncertainty regarding how this will evolve in the future. Under a Canadian type bilateral agreement model, the UK would have even less access to the EU research programme.
- **Compliance with EU regulations:** EEA members such as Norway are bound by EU regulations (although in practice there are a number of exceptions where Norway does not comply with EU rules) but have no influence on the legislative process. The result of this is that Norway adopts marketing authorisations issued by the EU. In Switzerland, there is an ongoing dialogue with the European Medicines Agency (EMA) but Switzerland maintains much of its own regulatory framework for issuing product licenses for pharmaceuticals under the control of the national medicines agency (Swissmedic). Similarly, Health Canada is solely responsible for evaluating drug approval packages and issuing Canadian product marketing licenses, although there is a collaboration programme with EMA allowing some exchange of information on pre- and post-authorisation applications. Collaboration is possible under all the models, but where countries have separate regulatory processes, there is a delay. Our analysis shows that marketing approvals in Switzerland and Canada often occur later than those

in the EU, on average 157 days after EMA approval for Switzerland and 144 days later for Canada.

- **Ability to conduct trade deals:** Trade deals independent of the EU have little or no impact on the life sciences sector. For Norway and Switzerland, the ability to sign their own trade deals does not appear to have led to any significant benefits for the life sciences industry. In addition, individually negotiating these deals takes time. Looking at the experience of the Comprehensive Economic and Trade Agreement (CETA) and other Canada FTAs, we find that a bespoke UK-EU trade agreement would be complex to negotiate and would take many years.

Implications of Brexit

To look at specific issues for the UK and the EU, we interviewed current participants in the life sciences value chain and asked them what would happen to the industry and their organisation under different Brexit scenarios.

Looking along the value chain, the impact is most significant for the basic research, then for product development and approval, then for manufacturing and trade, with only a minor impact on market access. Our conclusions for each stage of the value chain are as follows.

- **Basic research:** With bilateral agreements or a full break, it could be expected that access to EU research funding would be limited, whether partially or completely. This would diminish the UK's reputation for life sciences, and although collaboration would continue, it would be negatively affected. UK academic researchers and Small and Medium Enterprises (SME) report that it would be more challenging to collaborate with EU experts without EU collaborative frameworks. Based on past performance, it seems reasonable to conclude national funding would not replace the lost European research funding. Limitations on the free movement of people would have a negative impact on UK and EU academic research and SMEs.
- **Product development and approval:** With bilateral agreements or a full break, the UK would not be bound by EU regulation and would need to develop its own regulatory framework for pharmaceuticals. If the UK did not comply with the European Clinical Trials rules, then the attractiveness of the UK, and to a much lesser extent also the EU, as a location for later-stage clinical trials (Phase II, Phase III) would be reduced. In terms of product approval, it is unlikely that the UK would develop regulations that are significantly different from the current EU standards, although over time some differences would no doubt emerge. Most companies interviewed stressed that there would not be any advantage for the UK in developing a market authorisation process that was divergent from the EMA. This would be likely to cause delays in marketing authorisation (even if the process itself was faster), incur additional costs and would adversely affect access to medicines, especially products that are not subject to the health technology assessment process (for example, some orphan medicinal products). In this case, the UK and EU would lose some of the benefits of sharing expertise in drug regulatory processes.
- **Manufacturing and trade:** How Brexit would affect manufacturing and trade would depend largely on the type of agreement that the UK is able to negotiate in terms of

mutual recognition of manufacturing regulations and arrangements as well as limitations on labour market mobility. Mutual recognition of GMP inspections is an important issue and saves the pharmaceutical industry significant costs; it is likely (although not certain) that the UK would be able to negotiate such a deal over time. In terms of freedom to negotiate FTAs with other countries (under a bilateral agreement or a full break), we do not anticipate any significant effects for the life sciences industry. However, as both the UK and EU life sciences industry rely on each other for skilled staff (including managerial and operational), a limitation on the free movement of people, would have a negative impact on manufacturing (as well as other activities along the value chain).

- **Market Access:** Brexit would have little direct impact on the rules determining price, reimbursement and market access. Under bilateral agreements or a full break scenario, the UK would no longer be subject to the EU Transparency Directive or part of ongoing initiatives to improve access. However, this is unlikely to have a significant impact. There would be more freedom regarding the application of rules on state aid and the rules governing parallel trade, which could be beneficial to the industry in the UK and patients. Nonetheless, we do not believe these benefits will be significant. In other areas it is likely that the UK would continue to comply from outside the EU—for example, with the Falsified Medicines Directive. The delay in marketing authorisations, however, could delay access to some products. For example, a six-month delay seems likely given the experience of other countries.

The transition

Trade agreements typically take years to negotiate. Even though regulation affecting the life sciences industry would be aligned (as the UK applies those rules today), issues affecting other industries will lead to complex negotiation and delay. It seems reasonable to conclude that there would be considerable uncertainty over the first two years and potentially for 5 to 10 years.

The life sciences industry is unusual in that investments occur periodically, in terms of the location of research hubs, clinical trial programmes and manufacturing plants, but these decisions determine the location of activity for many years; once the decision is taken, it is difficult to change. Drawing on economic theory, empirical analysis and the interviews, we find that although the long-term outcome of the transition might not have a significant impact on the attractiveness of the UK for locating life sciences activities, the uncertainty during the transition will lead to a reduction in investment in R&D and manufacturing that will have consequences for many years.

More broadly in terms of the life sciences in Europe, leaving aside the macroeconomic impact, the biggest impact during the transition will be the need to relocate the EMA. This will have a number of consequences including the disruption during the physical move, the loss of staff, the loss of capacity to undertake reviews, and the loss of experience. We conclude that as the reputation and expertise of the EMA is now well established, relocation after a sensible transitional period should not constitute a serious threat to the EMA continuing to grant timely access for innovative medicines to all EU markets. However, it is

possible that the transition could lead to delays. For example, if the transition reduced the capacity of the EMA to review products in line with loss of UK capacity, this could result in a delay of 2 to 3 months for two years.

Conclusions

Brexit will add a number of barriers to undertaking activities in the UK along the value chain for life sciences and add considerable uncertainty during the transition. In the case that the free movement of people is restricted, the UK life sciences industry would also face additional challenges to accessing EU staff for scientific, managerial and operational positions, as well as consequences for EU research funding. As a global industry, the life sciences industry would not stop investing in the UK, but it is clear from our analysis that depending on the way Brexit unfolds, this will have short and long-term consequences in terms of the competitiveness of the UK.

Over the next few years, Brexit will turn from a theory to a reality. Refining this high level analysis so that it sheds light on the impact for different types of companies, allowing the negative impacts to be mitigated and opportunities to be identified, will be important for UK and European policymakers, for life sciences companies and ultimately for patients.

To read a copy of CRA's full report, entitled "Assessing the impact on the life sciences industry of a change in the UK relationship with the EU" click [here](#).

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