The UK pharmaceutical industry braces for Brexit, be it mild, severe, or doomsday

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Abstract

Pharma-Brexit is on its way. The announcement of the European Medicine Agency's move to Amsterdam, various UK government white papers, and comments made by key stakeholders in the UK pharmaceutical industry have led to a wide range of predictions concerning Brexit. While many hope for a Norwegian-type situation where business as usual could continue uninterrupted, others fear that the uncertainty of a "no-deal" outcome has already started a domino effect that could lead to the UK pharmaceutical industry's collapse. This article argues that something inbetween is most likely and looks at what Brexit could mean in each scenario. It explores why and how both the EU and UK might work through a deal and how these challenges might still provide opportunities for medical writers.

Introduction

Since the Brexit referendum on June 23, 2016, there has been a deluge of predictions on the possible ramifications Brexit might bring. Consequences of the impending UK break-up with the EU at midnight on March 29, 2019, range from the conservative to the hyperbolic. Based on currently available information, it is possible to deconstruct the effects of Brexit on the pharmaceutical industry to three scenarios:

- Mild, in which a deal is reached with little disruption to the present situation;
- Doomsday, where no deal is reached, likely leading to the rapid decline of the UK pharmaceutical industry; and
- Severe, which falls somewhere between the two.

As of 2014, the UK has been the sixth largest pharmaceutical producer in Europe.[1] Separation of UK industry away from Europe is likely to be harmful, due to the long-term limitations it would place on information flow, business and trade agreements, and workforce movement. If no deal can be reached, irrevocable damage would be caused by the separation, potentially propelling the UK pharmaceutical industry into a dark age. On the other hand, if a deal similar to the Norwegian model is accomplished, then the UK pharmaceutical industry could end up with a comparable situation to the present.

Even without these decisions being finalised, some effects of Brexit are already being felt. Prominent among these is a profound uncertainty regarding the free movement of people across the EU. Complicating the free movement of the workforce not only threatens a future shortage of workers in the UK pharmaceutical industry, but could also impede further foreign investment into the UK pharmaceutical industry.

Furthermore, while darkness shrouds the Brexit negotiations, uncertainty abounds. Organisations such as the European Federation of Pharmaceutical Industries and Agencies assert that limitations on the free movement of people would have a "negative impact on both the UK and EU academic research and small and medium enterprises". Even the threat of limitations may already be having an effect on potential investors.[2]

The immediate effects of Brexit are impossible to predict and may only become visible once the long-term impacts of separation can be evaluated. The sooner more of the UK government's Brexit plan is revealed, the better the prospects for the pharmaceutical industry in finding stability.

Mild Brexit

Norway model

By far the most desirable outcome for the UK pharmaceutical industry would have been a deal comparable to the agreement reached between Norway and the EU, although it is possible that negotiations have already removed this option. The "Norway model" is arguably the least damaging option and provides the most stability for businesses.[3] It would allow the UK to remain a part of the European Free Trade Association (EFTA) and the European Economic Area (EEA) and therefore the UK would continue to have a similar level of free trade. The EFTA contains four states (Switzerland, Iceland, Norway, and Liechtenstein) and is part of the Schengen Area, but not party to the European Union Customs Union. There are indications that a post-Brexit UK could be accepted into this trading bloc. The EEA is the free-trade area between all the other EU member states. The Norway model of a Brexit deal would be attractive to "soft" Brexiteers, as it does not leave the UK having to renegotiate its trade deals and gives further freedom to make trade deals with other countries.

The pharmaceutical industry and a mild Brexit

Although damage to business would be limited following a mild Brexit, some change would still be inevitable. The European Medicines Agency (EMA) is in the process of moving from London to Amsterdam to continue operations within the EU, as a direct consequence of impending Brexit.[4] This move away from London takes the competitive edge of proximity away from UK

pharmaceutical industry regulatory affairs officials and UK Medicines and Healthcare Products Regulatory Agency (MHRA) personnel. In addition, the European Commission has already outlined the requirement for a European-based Qualified Person and consideration of the UK as a "third country" in the running of clinical studies from the withdrawal date.[5] In a mild Brexit scenario, significant further divergence from the current status quo seems unlikely, other than the UK losing the role of rapporteur status in the market approval process for pharmaceuticals.[6] This would result in the MHRA no longer being involved in EMA decision-making, despite the obligation remaining to follow EMA rules.

While the current assumption by the EMA is that the UK will become a country outside of the EEA, significant disruption would not happen were the UK to adopt a Norway model.[3] Despite this, it is quite likely that in most mild Brexit scenarios the current regulatory frameworks will be largely maintained and there will be little impact on the UK pharmaceutical industry, aside from losing a certain amount of influence within Europe.

Doomsday

With the prospect of no deal being reached, newspapers from across the political spectrum, within the UK and abroad, have painted very dark possible scenarios. The possible damage has been compared to post-war shortages (e.g. food, medicine, and power shortages[7-8]) within a few days after a no-deal Brexit, due to the UK's dependency on "just in time" supply chains. In this "doomsday" scenario, the knock-on effects on food, travel, IT networks, and availability of personnel could stretch pharmaceutical industry contingency plans to breaking point.

Armageddon and the pharmaceutical industry

The Governor of the Bank of England, Mark Carney, described a no-deal Brexit outcome as being "highly undesirable",[9] but this does not begin to illustrate the potential devastation. The UK pharmaceutical industry, from Research and Development to Sales departments, could easily plunge into complete chaos. No deal could mean a short-term cessation of the free movement of skilled workforce, despite current promises of prioritised entry. There could be an impact on the movement of goods as well. The loss of momentum to cutting-edge research and development programmes could reduce the contribution of UK scientists to progress.

With regards to the free movement of people, issues could include difficulties arranging meetings due to delays with visas, disruption to working conditions due to missing personnel, and resultant interruptions to goods and service chains. Arguably, larger pharmaceutical enterprises will have the capacity to survive long enough for the worst to pass. Smaller enterprises, on the other hand, could face the brunt of the damage, unable to fully secure a large enough skilled UK-based workforce to be financially viable. If so, the UK may experience a mass migration of pharmaceutical industry personnel to EU member states, as the barriers such a Brexit would create could be insurmountable for smaller pharmaceutical enterprises.

Furthermore, as the UK Business, Energy, and Industrial Strategy Committee has suggested, the UK has historically "disproportionately benefited" from EU funding for pharmaceutical research.[10] This is funding that cannot be matched by the UK government, especially under the worst-case doomsday scenario in which the country will already be under tremendous financial strain.

Regulatory systems in disarray

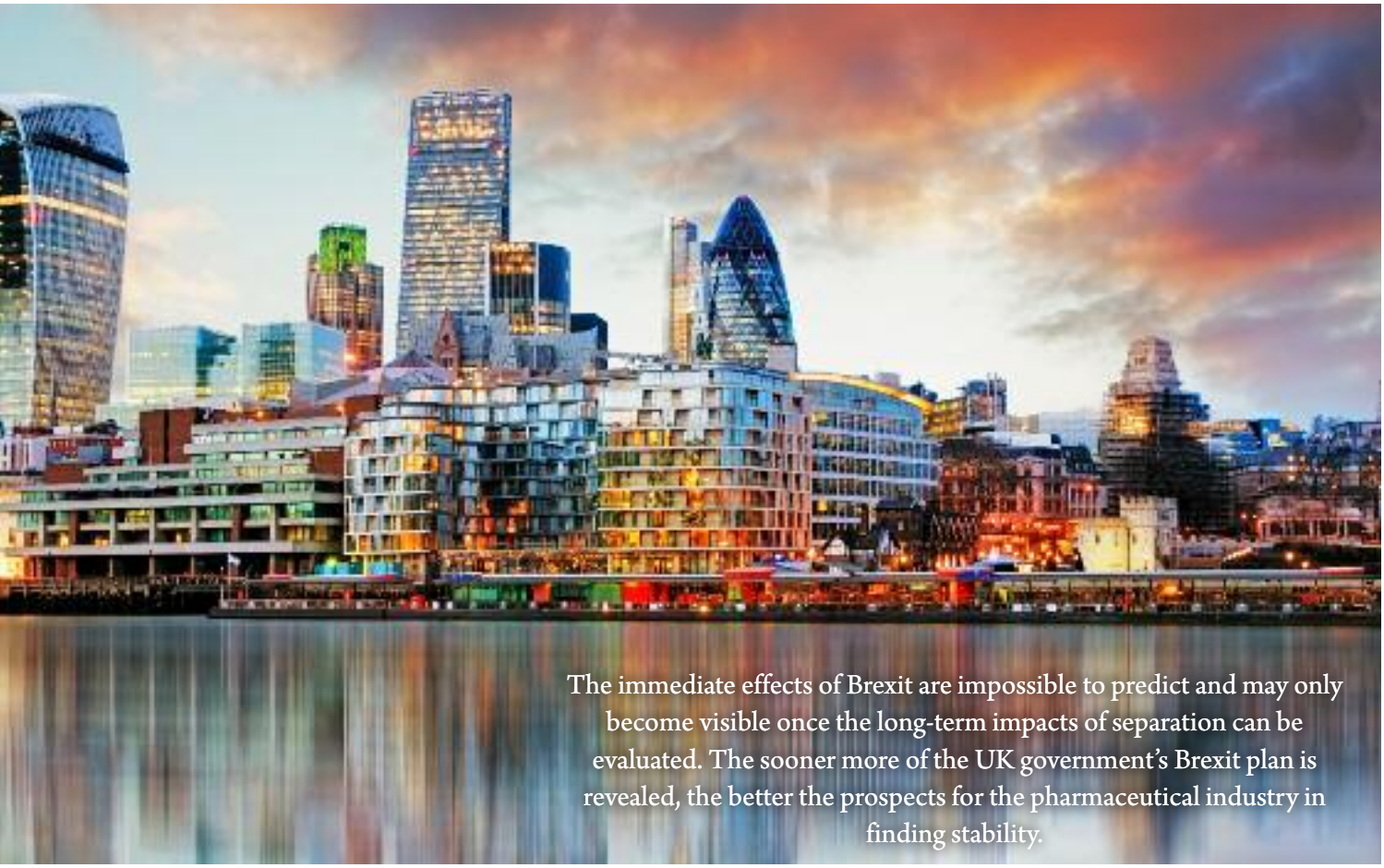
Although UK exports to EU countries were valued at £15 billion as of 2015,[1] EU countries are unlikely to suffer in the long-term due to reduced availability of UK goods if no deal is reached. While short-term damage may be inevitable, given the ramifications to the UK, EU member states would be well-positioned to slowly assume any gap in the market. Although the decline would not be instantaneous in the event of no deal, there could be severe complications to the regulatory process of product development and approval. A marked delay in the UK's access to the EU market, which for an industry brimming with competition from an ever-globalised world, could irreversibly damage a stalled UK pharmaceutical industry.

In the absence of a deal, one of the greater challenges to the UK pharmaceutical industry will be working out how trade could actually continue with the EU. If no deal occurs, the UK Business, Energy and Industrial Strategy Committee states that the UK will no longer be part of any EU agreement on 0% tariffs, and would be reliant on the World Trade Organization's (WTO) Pharmaceutical tariff elimination agreement.[10] This stipulates that all signatories of the agreement are prohibited from the placement of tariffs on pharmaceutical products. In theory this protects the UK pharmaceutical industry, but the list of protected products has not been updated since 2010 (despite the agreement stating it should be updated every three years). Consequently, there are over 1,000 products awaiting introduction to the list.[10] This would greatly disadvantage the UK pharmaceutical industry when competing with EU member states. Without a deal, rapid revisions of the WTO agreement would have to occur for the UK pharmaceutical industry to survive.

Having no deal would, in all likelihood, be disastrous for the UK's pharmaceutical industry, but would probably only dent the EU pharmaceutical industry in the short term.

Severe: The most likely scenario

Given the importance of the UK pharmaceutical industry to both the UK and EU, it is most likely that both sides will make every effort to achieve a mutually-beneficial deal. However, the UK Business, Energy and Industrial Strategy Committee advises that there would be "no benefits from regulatory divergence" [10] in the



The immediate effects of Brexit are impossible to predict and may only become visible once the long-term impacts of separation can be evaluated. The sooner more of the UK government's Brexit plan is revealed, the better the prospects for the pharmaceutical industry in finding stability.

pharmaceutical industry. It is difficult to imagine a post-Brexit scenario that would entirely protect the status quo. The most probable outcome of negotiations would likely be a moderate solution: one in which there is limited regulatory divergence, but the potential loss of EU funding and reduction in industry productivity. This depends on the extent to which Britain maintains its position within the single market.

Regulation: An association agreement

According to a white paper produced by the government, the UK is likely to propose an "association agreement" with the EMA.[11] This would involve the UK paying a fee to the EMA to remain under its jurisdiction and thus retaining the ability to apply for EU funding, although the UK would be unable to influence the "direction of these programmes".[12] Moreover, while the white paper provided some clarification on the UK's stance towards the EMA, the policy relating to the Clinical Trial Directive (legislation that guarantees the quality and safety of medicinal products in the EU; soon to become the Clinical Trials Regulation) remains unclear.[13] A move to withdraw the UK from the Clinical Trial Directive, which has been perceived in the UK as being overly bureaucratic, is seen as a real possibility. A report conducted by consultancy firm, PricewaterhouseCoopers, has suggested that this could result in companies choosing not to include the UK in clinical study design, or to include the UK only at a later stage of development.[1]

Funding and investment

Currently, the UK receives significantly more in funding for scientific research and development from the EU than it contributes, and whilst an association agreement with the EMA would protect the UK's right to apply for such funding, it seems unlikely that a favourable funding surplus will remain intact after Brexit. Although the treasury has committed to underwrite funding for projects applied for before the UK leaves the EU, the status of such projects after the UK has left remains unclear.[12] Hence, whatever the outcome of negotiations, the loss of funding that could have otherwise supported new research seems to be inevitable.[14] Furthermore, the UK has also been the greatest recipient in the EU of foreign direct investment, much of which depends on the UK's ability to access the EU market and to attract the best people – both of which could be under threat if the UK does not come to some agreement on the single market.

Free trade

The government has stated that it is committed to the idea of "frictionless trade" between the UK and EU,[11] and it seems likely that the two parties will agree on a "common rulebook". The EU has already rejected the UK government's proposal to impose EU tariffs on goods coming into the UK that are destined for the EU. Furthermore, it seems likely that the UK will have to choose between one of the two following options: either lose any existing free-trade agreements negotiated by the EU, such as those with Israel and South Korea,[1] but gain the ability to negotiate new free-trade agreements; or retain all existing EU-negotiated, free-trade agreements, but be unable to formulate new deals aside from the EU. The cost of any disruption to existing supply chains could be severe and has already prompted large pharmaceutical firms, such as AstraZeneca, to begin stockpiling medicines.[15] Hence, some level of disturbance, especially in the immediate aftermath of the UK's exit from the EU, seems inevitable.

Free movement of people

As with the mild and doomsday options, the free movement of people remains a deep cause for concern. The UK government has said unequivocally that this will end and that it will "be for the UK Government and Parliament to determine the immigration rules that will apply to people coming to the UK from the EU".[11] There has been very little indication as to what these rules may be. Uncertainty regarding the status of EU nationals working in the UK pharmaceutical industry has already prompted some professionals within the sector to leave.[14] The EMA's relocation to Amsterdam in indicative of this concern. Moreover, if the UK is unable to host the best talent from across the EU, this makes the UK less attractive for foreign investment.

Severe: How the pharmaceutical industry might fare

Possible effects on the pharmaceutical industry could include reduced investment and funding, and higher costs due to disruption of existing supply chains. In fact, this disruption has already begun; the EMA, having already changed their HQ from London to Amsterdam, have now ended the EU's contract with the MHRA for medicines evaluation. The disruption and dissolution of the UK's role in pharmaceutical supply chains will provide a significant challenge to the future of the industry. It is worth noting that some of the potentially negative consequences of a moderate Brexit solution may be mitigated in the long term by establishing new supply chains and possibly more favourable FTAs.

And what about regulatory medical writing?

We are all hoping that the global nature of regulatory medical writing within a global pharmaceutical industry, coupled with the predominant requirement for delivery in English, will help UK regulatory medical writing weather the storm, if there even is one. But is that a responsible attitude? Awareness of the wider picture within the pharmaceutical industry will help medical writers prepare for cracks that may appear – cracks that medical writing may even be able to assist in patching.

A consideration of the different Brexit threats to the UK pharmaceutical industry and possible opportunities for UK-based medical writing is summarised in Figure 1. Awareness of new UK regulations and learning to include writing to these regulations – in the same way that non-US/EU countries are catered to – will position medical writers favourably if Brexit resolves with mild severity. UK medical writers can also draw from their experience with shifting timelines, working within contingency plans, and their ability to familiarise and work closely with multidisciplinary teams, whatever the outcome of Brexit. On the other hand, stocking up on paracetamol and filling the cupboards with tins of beans might be wise, too.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their affiliated organisations or EMWA.

Conflicts of interest

There are no conflicts of interest.

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Figure 1. Threats from mild, severe, and doomsday Brexit to the UK pharmaceutical industry, and opportunities for UK-based medical writers.

Abbreviations: CSR, clinical study report; eCRF, electronic case report form; EMA, European Medicines Agency; IB, investigator's brochure; MW, medical writer

Outcome	Threats posed to UK pharmaceutical industry	Opportunities for UK-based MWs
Mild	• EMA moves away from London to Amsterdam	• No immediate impact on MWs
	• Fewer study centres in the UK	• MWs used to working within global teams and site location does not affect working practices
Severe	• UK-based companies cease to be the global or European headquarters of Research and Development within global pharmaceutical companies	• MWs familiar with constant restructuring, adapt to global regulatory arrangement, adaptable to new project team structures
	• Regulatory roadmaps for strategy in the UK are not forthcoming in a timely fashion	• MWs adaptable and proactive in keeping to ambitious timelines under pressure
	• Teams or clients unavailable due to relocation commitments and different time-zones adding to the challenge of arranging meeting times	• MWs familiar with working remotely, brokering agreements between team members, facing unexpected project changes, and working hours that adapt to their clients
	• Pharmaceutical industry outsourcing more short-term and sporadic	• Freelance MWs can maintain a variety of clients, ideally based in different continents which leads to a varied client-base and a chance to widen experience
	• More UK regulatory documents required since the UK becomes a separate regulatory territory	• MWs familiar with preparation of non-EU/US documentation leading to increased volume of work for MWs and job security for UK MWs
	• UK suffers from supply problems with knock-on effects on timelines	• MWs used to adapting to timelines and maintain communication with the team
	• IT and communications disruption	• MWs adaptable to all communication methods and contingencies, including paper methods, since some territories still operate this way
Doomsday	• Economic difficulties, e.g. falling pound in the UK, problems with supply chains in the UK pharmaceutical industry, emergency cuts to skilled workforce	• MWs more marketable with cheaper contracts, both globally and for the local market
	• IBs and CSRs threatened with fines for delay in public disclosure due to skilled workforce cuts and communication disruption extending document preparation timelines	• MWs show ingenuity in flexible timeline management
	• Intermitent IT problems lead to problems at the clinic with eCRFs and a knock-on to data cleaning and statistical table compilation as well as other issues	• MWs adapt to using whatever data is available and fitting in with contingency measures
	• UK pharmaceutical industry reduces to a local sales force and the need for UK production of global regulatory documents disappears	• MWs have excellent transferrable skills and many already work from home for global pharmaceutical companies. In desperate circumstances, if the UK-based parts of global pharmaceutical industry completely fold, UK MWs can work remotely for European or US companies, move to a different industry, or move to another country