
Brexit – A Hard Landing? Potential Impacts on the UK Pharmaceutical Sector

By Tim Wright and Gurmeet Sidhu

The UK's pharmaceutical sector may have more to fear than other sectors from a possible "hard-Brexit," with the potential for the UK's withdrawal from the EU to impact the entire drug development and commercialization value chain.

The UK hosts a number of major European organizations including, significantly, the European Medicines Agency. It has strong pharmaceutical and life sciences industries, underpinned by access to leading talent and leading universities, and it has benefited significantly from European Research Council funding in the past. The sector employs more than 700,000 people, seven percent of whom are EU nationals, and generates more than 10 percent of UK gross domestic product. UK organizations and researchers play leading roles in the EU's Horizon 2020 research and innovation initiative, which is the world's largest life sciences public-private partnership with over 50 projects currently. By some estimates, as much as £8.5 billion in funding and investment over the next four years is threatened by Brexit.

Patent protection and related challenges are the life blood of the pharmaceutical industry. Presently, the concept of a single Europe-wide patent does not exist and patent disputes have to be conducted at the national level leading to conflicting judgments across the EU. Extensive negotiations among EU member states, covering at least a decade, finally resulted in the Unified Patent Court Agreement (UPCA). The UPCA provides for a unitary EU-wide patent and for patent disputes to be determined centrally, by a Unified Patent Court having its centre in Paris, with a section in London specifically designated to manage and determine all life sciences and pharmaceuticals patent disputes. Under pre-Brexit timelines, the UPCA was due to have been ratified by the UK at the end of 2016, with the London UPC section becoming operational in May 2017. The UK's ratification of the UPCA is a pre-requisite before it can come into force. It is now politically unlikely that the UK Parliament will ratify the UPCA without prior assurances from the EU that it will be allowed to continue to participate in the proposed unitary EU patent and UPC system. In the meantime, other EU member state signatories have started lobbying to replace London as the centre for life sciences and pharmaceuticals patent disputes, with Milan starting the ball rolling by voicing its expression of interest last month.

A View from the Regulators

A few days after the 23 June referendum, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) issued a short statement¹ to the effect that it was "business as usual" in terms of current activities such as the implementation of the new Regulations for Medical Devices and in vitro diagnostic (IVD) devices, and that it was mulling over the outcome of the vote and working with the government to understand the best options and opportunities for safe and effective regulation of medicines and devices in the UK. For the MHRA, continuing to play "a full, active role in European regulatory procedures for medicines remains a priority." The European Medicines Agency (EMA), located in London, also issued a statement following the Brexit vote². Again, the message was business as usual with the EMA underlining that its procedures and work streams would not be affected and that it would not speculate on implications for its seat and future operations.

The UK Intellectual Property Office (UKIPO) has similarly issued a statement stating that the UK remains a signatory state of the UPCA and confirming that it will continue to actively participate in all UPC related meetings³.

Market Authorization

A recent update from the Pharmaceutical & Healthcare Sciences Society⁴ points out that EU and UK pharma regulators have had good productive and cooperative relationships for many years, especially in the fields of product license review, regulatory inspections and information sharing. Other sources suggest that both the EMA and MHRA are already working on ideas for preserving unified European medicines regulations, with substantial UK input, even if the EMA headquarters end up, as we expect, elsewhere. Of course, much will depend on the Brexit model itself.

Perhaps the biggest single impact of Brexit on the pharmaceutical sector will be that of market authorization. Over the past 20 years or so, the UK industry has come to depend on the Europe-wide system run by the EMA in Canary Wharf, London. The EMA can grant pharmaceutical companies a single marketing authorization providing access to the whole EU market, and this has been very attractive for companies looking to access the EU market. Indeed, proximity to the EMA was cited by the Japanese government in its Brexit-related message to the UK and the EU as one of several reasons why many Japanese pharma companies have chosen to locate their main European operations in the UK (see our recent [client alert](#)).

Another potential impact is the UK clinical trial market which, post-Brexit, is likely to shrink because by 2018 a single EU portal for clinical trials will allow for central application and approval to conduct trials across the EU (a much larger and potentially more lucrative market of some 500 million potential patients compared with the UK's 60 million or so). Under that regulatory scheme, companies will not wish to incur the cost of trials in the UK when they already have won EU-wide approval. There may well be a knock on effect in terms of patient access to new medicines, with companies choosing to launch products in the EU in advance of the UK itself.



1 [MHRA and making a success of Brexit](#)

2 [Statement on the outcome of the UK referendum](#)

3 <https://www.gov.uk/government/news/ip-and-brexit-the-facts>

4 [BREXIT—Update on potential impacts on the pharmaceutical industry and its regulation](#)

Pharma sector wish-list

In the run up to the referendum, leaders in the sector warned of the dangers of Brexit. Indeed, senior managers of 50 leading life sciences companies, including AstraZeneca and GlaxoSmithKline, wrote to the *Financial Times* to state the case against Brexit in February this year. Key concerns cited were trade (with the EU accounting for some 56 percent of UK pharma exports worth around £53 billion) and loss of a harmonized approach to European regulation across topics such as intellectual property rights, quality standards, clinical trial rules, and product approval.

Since 23 June, the two main trade bodies, the Association of the British Pharmaceutical Industry (ABPI) and UK BioIndustry Association (BIA) established a task force which is jointly chaired by Pascal Soriot, CEO of AstraZeneca, and Andrew Whitty, CEO of GlaxoSmithKline. Following an extensive consultation with their members, the task force identified four priorities for the sector post-Brexit:

- continued ability to trade and move goods and capital across borders
- continued access to the best international talent
- long-term, predictable government funding for scientific research, and the continued ability to collaborate at scale across Europe and the world
- a regulatory co-operation agreement with Europe “to bring innovative, effective and safe medical technologies to UK patients quickly”

Others have also stepped in. Erik Nordkamp, UK general manager for US-based Pfizer, has called for the UK government to “take a more holistic approach to industrial policy” and has called for the global pharmaceutical industry to be given “a seat at the table so we can help to find solutions to the challenges in the UK health system”.

Whatever the model for Brexit, the concern remains that the UK will become a significantly less attractive launch market especially if additional hoops and hurdles which companies must navigate are introduced.

The Swiss model

Brexiters will no doubt point to Switzerland’s pharmaceuticals industry (the biggest in Europe by market capitalization) as evidence that UK pharma companies can do well outside the EU. However, the Swiss are in something of a unique position – it is a member of EFTA but is outside of the European Economic Area (the EEA). Whereas the other three EFTA members (Iceland, Liechtenstein and Norway) are all inside the EEA, Switzerland instead relies on a number of bilateral agreements with the EU, including one regarding the free movement of labour.

But it is by no means clear that the European governments will grant the UK similar privileges to those afforded to Switzerland. And that model is under some strain with a recent Swiss referendum voting to impose quotas in order to restrict EU immigration in 2017. The EU has refused to accept this decision and has threatened to suspend all six bilateral agreements. Other models for Brexit include EEA membership as well as the so-called “hard Brexit” model of falling back on the World Trade Organization rules.

Silver lining

A few items worthy of mention:

- AstraZeneca and GSK have been quick to give reassurance that they remain committed to the UK and are not looking to up sticks. AstraZeneca is in the midst of a huge £330 million project developing a new R&D hub and headquarters in Cambridge, and GSK came out quickly after the vote and announced a £275 million investment at its sites at Barnard Castle, in County Durham, at Montrose, in Scotland and Ware, and in Hertfordshire in order to boost production and support delivery of its latest respiratory and large molecule biologic medicines.
- In a move which has been cautiously welcomed by UK scientists and academics, Chancellor Phillip Hammond outlined a government commitment to guarantee EU funding for British research projects made before Britain leaves the EU even if they continue for several years afterwards, including Horizon 2020.
- Alnylam Pharmaceuticals, a Massachusetts-based biotech group, announced that it would be setting up its European HQ in the UK, to hire more than 100 people in Maidenhead, after early clinical trials which took place in the UK, including at the Royal Free Hospital in London. According to chief medical officer Akshay Vaishnav, this “decision shows that the threat of Brexit has not eliminated Britain’s attractiveness as a home for the life sciences industry”. Alnylam, which is developing drug candidates using RNAi (RNA interference) technology, which makes it possible for disease-causing genes to be “silenced,” cited the UK’s strong academic and clinical research sector, the NHS, as well as regulatory bodies which constantly strive to be more streamlined and efficient in support of its decision. Asked about the likelihood that the EMA will relocate, Vaishnav said that his company would simply look to set up a “small extra office in whatever European city the EMA moves to.”
- With sterling recently hitting a 31-year low since the Brexit vote and with significant revenue sourced in the U.S., UK companies across the sector have reaped a short term currency boost to earnings.

Next Steps

Much depends on how the UK government and the EU handle the withdrawal negotiations with the EU and the model the UK government determines to pursue. With Prime Minister Theresa May announcing a new industrial strategy that would help ensure that UK pharmaceutical industry jewels such as AstraZeneca are not lost to a hostile foreign takeover—such as Pfizer’s unsolicited attempt in 2014—the industry would appear to have a real opportunity to achieve its aims through a meaningful lobbying campaign. However, with George Freeman moved on from his post as minister for life sciences in the recent cabinet reshuffle, the sector – for the time being at least – is without a dedicated minister at this critical time.

Despite this, there is still optimism that the UK pharmaceutical industry will be fine once the dust settles. The UK remains far ahead of most EU countries in terms of innovation and entrepreneurship—both necessities for scientific advancement and creativity—and most EU pharmaceutical companies will undoubtedly desire a means for promoting their products in a market as large as the UK. Thus, any EU move that makes it more difficult for UK pharma to receive EU clinical approval would ultimately hurt more than help.

If you have any questions about the content of this alert, please contact the Pillsbury attorney with whom you regularly work, or the authors below.

Tim Wright **(bio)**
London
+44.20.7847.9505
tim.wright@pillsburylaw.com

Gurmeet Sidhu **(bio)**
London
+44.207.847.9500
gurmeet.sidhu@pillsburylaw.com

This publication is issued periodically to keep Pillsbury Winthrop Shaw Pittman LLP clients and other interested parties informed of current legal developments that may affect or otherwise be of interest to them. The comments contained herein do not constitute legal opinion and should not be regarded as a substitute for legal advice.

© 2016 Pillsbury Winthrop Shaw Pittman LLP. All Rights Reserved.