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Brexit Implications: Life Sciences

On 24 June 2016, the UK voted to leave the European Union (EU), marking the beginning of a difficult journey towards official exit from a bloc it has belonged to since 1972.

The UK withdrawal from the EU – commonly referred to as "Brexit" – will have a significant and extensive impact on the medical devices, pharmaceutical and biotechnology sectors in the life sciences industry. Exactly how this will play out is yet to be seen. The UK is home to operations of all of the top 20 global pharmaceutical companies, as well as many smaller ones, including a flourishing bioscience industry and innovative startups.

There are numerous ways in which this decision will indirectly impact the industry, such as trade and customs, trade secrets, patenting and trademarks (which could impact on the ability to parallel trade), product labelling, immigration and research funding, to name a few.

From a trade perspective, upon withdrawal, the UK might be out of the Customs Union, which means re-imposition of trade barriers in the form of customs clearance procedures would be almost inevitable. In terms of customs duty, and unless agreed otherwise with the EU before formal withdrawal, the UK will lose the benefit of the duty rates afforded by being an EU Member State under the existing EU trade agreements with third countries, or by way of its membership to the World Trade Organisation (WTO). This is likely to result in an increase in the landed cost of many goods, which may also be affected by any volatility of exchange rates. Those considerations should be carefully catered for in advance at the contractual negotiations stage, starting now. Also, it is likely that the UK will need to begin renegotiating separate trade deals with the roughly 800 international trade agreements currently in place through the UK's membership of the EU. One of the proposed benefits of the Transatlantic Trade and Investment Partnership (TTIP) currently being negotiated between the US and EU is that it would allow for wider EU/US pharmaceutical convergence, in particular around biogenerics. With the UK outside of the EU, the future of TTIP is being questioned given the UK's influence in EU trade negotiations.

The second central area of change will be in relation to the regulation of the life sciences sector. The EU provides a single framework for regulating and approving pharmaceutical products, and the UK is currently home to the European Medicines Agency (EMA). The EU also provides uniform rules governing standards for medical devices.

Upon withdrawal, the UK will need to determine which regulations and directives it wants to continue to apply and, if not, it will need to create its own. All this would depend on the model chosen to form the basis of the EU-UK future trade relationship. If Britain were to follow the EEA trade model, it would abide by existing EU standards in return for access to the EU's single market. However, it is unlikely that this option is politically acceptable.

If the EU pharmaceutical regulations are not applied in the UK because of non-membership of the European Economic Area, the UK (via consultation coordinated by the Medicines and Healthcare Products Regulatory Agency) would need to create its own regulations for the acceptance and marketing of pharmaceuticals. Additionally, in relation to new drugs coming onto the market, the commercial incentives to use any new UK marketing authorization procedures might change. This would depend on whether the UK stays within the EU's authorization procedures and, if not, the nature of any changes and whether these are still on par with the EU regime.

On an institutional and research level, the EMA is based in London and is expected to move elsewhere following Brexit. Timing on this could be impacted by the location of specialist advisors working on applications with EMA and practical matters, such as timelines for such applications. UK researchers will soon start facing issues relating to access to EU life sciences grants due to the uncertainty of their entitlement to the funds post-withdrawal and there are arguments about how this will be balanced by new grants that may originate from the UK to make up for these. Given the UK's input into many specialist EU advisory groups on medical devices, pharmaceuticals and biotechnology, the Brexit consequences cannot be ignored.

As a result, many pharmaceutical trade associations and international companies are already starting to engage in discussions with their government to assess the possible scenarios post-withdrawal. The Association of the British Pharmaceutical Industry, BioIndustry Association, British Generic Manufacturers Association and Association of British Healthcare Industries are all issuing statements noting the advantages of the existing EU regulatory framework. One immediate issue that some will be considering is what to do with regards to implementation of the new Falsified Medicines Directive. The UK pharmaceutical industry is in the process of setting up a body to implement this directive which is to apply from early 2019. The pharmaceutical sector will need to grapple with how to take this forward given the regulatory uncertainty in the life sciences sector.

The UK MHRA has also issued a statement indicating that, "working closely with government, we will consider the implications for the work of the Agency. We will continue to make a major contribution globally to improving public health through the effective regulation of medicines and medical devices, underpinned by science and research." Now that Theresa May has taken up office as the new Prime Minister, the approach that the UK will take with regulation of the life sciences sector should become clearer and we will monitor these developments closely as MHRA takes this work forward.

How We Can Help

Our firm offers the strongest combination of legal, regulatory and government advocacy expertise to most effectively advise and assist entities affected by the complex issues associated with Brexit. We are globally renowned for our expertise in representing clients on matters involving the intersection of business, law and government, and for representing both public and private entities in negotiations with government agencies. We offer insights gleaned from our extensive knowledge of, and direct experience in, international political and regulatory climates.

Additional Information

Please check our Brexit Legal blog: http://www.brexitlegal.com

We are setting up a series of client briefings to discuss the consequences of Brexit in more detail and will communicate relevant dates and details shortly. In the meantime, if you have specific concerns arising from the Brexit vote or otherwise, please contact your usual Squire Patton Boggs contact or any of the contacts below.

Contacts

Aline Doussin
T +44 207 655 1146
E aline.doussin@squirepb.com

Adrian Spooner
T +44 207 655 1067
E adrian.spooner@squirepb.com

Sarah H. Stec
T +1 202 457 6304
E sarah.stec@squirepb.com