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## Brexit – legal consequences for commercial parties

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The EU legislative framework is the cornerstone of many laws, regulations, procedures, and guidance governing the day-to-day activities of life sciences companies operating in the EU – we assess the likely impact of a Brexit

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### Issue in focus

This paper focuses on those life sciences companies most likely to be impacted by a Brexit, namely pharmaceutical and biotechnology firms. It is particularly aimed at innovative firms engaged in research and development activities covered by regulation and focused on the protection and exploitation of intellectual property and other rights. It is important to note upfront, however, that the true impact of a Brexit will be felt by a much broader set of stakeholders. These range from regulatory agencies, national health bodies and institutions, scientists, pricing and reimbursement authorities, government payers, economic operators such as pharmaceutical wholesalers and retail pharmacies, and healthcare professionals to perhaps the most important of all, patients.

*“The implications of a Brexit are wide-ranging and complex on a number of levels. The uncertainty surrounding exactly how the UK would exit the Union means life sciences firms could be faced with an uncertain and complex operating environment for years to come. Brexit is a serious topic, legally and otherwise, because it could set an unwelcome precedent for other EU Member States regardless of the outcome of the UK*

*referendum and potentially de-stabilise the harmonisation process that touches so many critical areas from a life sciences regulatory standpoint.”*

Alexandre Rudoni, Partner and head of Allen & Overy’s life sciences regulatory group.

### Analysis

2015 marked the 50th anniversary of pharmaceutical legislation in the EU, which all started with Council Directive 65/65 in 1965 in the wake of the Thalidomide disaster in the early 1960s, when thousands of babies were born with deformities when their mothers took the drug during pregnancy. The directive reinforced the basic tenet of pharmaceutical law as we know it today, that no medicinal product may be placed on the market in a Member State unless a marketing authorisation has been issued by the competent authority of that Member State.

Since the introduction of Council Directive 65/65, a sophisticated, integrated framework of EU law has evolved for medicinal and other products for human use that safeguards public health as well as promoting the development of the life sciences industry and trade in medicinal products. The result is that life sciences firms organised or operating in the UK follow EU legislative

measures and jurisprudence that set minimum harmonised standards and procedures in all aspects of scientific, regulatory and commercial activity within the sector. In light of the depth and breadth of EU regulation governing life sciences firms, a Brexit could be a catalyst for a wide range of unintended consequences. We, therefore, consider below some of the key issues that life sciences firms globally may need to grapple with in the areas of regulation, intellectual property and commercial transactions.

## How would a Brexit affect industry regulation?

There has been much commentary about the regulatory implications of a Brexit for the life sciences sector, particularly the increased regulatory burden that would likely follow. For example, the centralised procedure that is compulsory for obtaining market authorisation for medicines to treat more serious diseases such as cancer and diabetes would no longer apply in the UK. The question, therefore, arises as to how the UK would address the consequences arising from a Brexit of the potential invalidity of existing market authorisations for centrally-approved products. If firms continued to market products with an invalidated authorisation they would risk off-label promotion, which can carry civil and criminal liability. If, on the other hand, firms chose to cease supply of a centrally-approved product because of invalidity, that could compromise patient access to important medicines. Practical questions would also arise in relation to how the UK would handle variations of marketing authorisations approved under the mutual recognition and decentralised procedures.

It is unlikely that the UK would allow such a gap to arise. UK regulators and the industry association would almost certainly put in place a sensible transitional agreement or protocol to facilitate a smooth transition to a Brexit that minimised the impact on business continuity and did not compromise patient safety. An example of this would be the grandfathering of existing centrally-authorized products under any transitional or new regulatory framework. The full impact of a Brexit on life sciences regulation will, however, ultimately depend on what basis the UK exits the Union and the legislative form of regulation in question. The UK, for

example, would need to pass new legislation to plug the gap created by current EU Regulations, which are directly effective in the UK and need no implementing national legislation (except for sanction for breach).

A bigger headache for the life sciences sector is the risk of interruption to the many important EU harmonisation initiatives that benefit EU citizens. The European Directive on cross-border health, for example, provides citizens with a fundamental right to purchase healthcare services across the EU and to apply for reimbursement from their home system. Other important initiatives involve efforts to provide patients with greater access to more consistent product safety information; or regulators prioritising the development of new medicines to address unmet medical needs through the PRIME initiative. A Brexit could also cut off important channels of funding for emergency health situations such as the current global emergency declared by the WHO regarding the Zika virus and where a number of UK life sciences firms are actively researching potential treatments.

A Brexit could also impact efforts to protect patients from illegal trade in falsified medicines through the Falsified Medicines Directive, which will guarantee medicine authenticity for the benefit of patients and businesses, and strengthen the security of the medicine supply chain. There is also the imminent new Clinical Trials Regulation that will simplify the application process for the conduct of trials in the EU. It will create a single database of information relating to trials and also strengthen the disclosure of clinical trial data, which is seen as critical for industry transparency and innovation.

## What of patents and regulatory data exclusivity?

Currently, originator life sciences companies in the UK can benefit from a range of EU incentives such as market exclusivity for products that treat rare diseases that qualify for orphan designation under the EU Orphan Drug Regulation and supplementary protection certificates.

The proposed Unified Patent Court (UPC) system and the corresponding Unitary Patent will also offer life

sciences firms the opportunity to obtain a single patent valid in 25 participating EU Member States and to enforce their patent rights on a pan-European basis. The UK has been a major driving force behind the UPC, which offers a simpler, more efficient and cost-effective mechanism for obtaining, exploiting, and protecting patent rights across Europe. In summary, a Brexit would put an end to the UK's involvement in the UPC and the associated benefits. The full implications of a Brexit on the future European patent system are examined in more detail in one of a series of specialist papers on Brexit available by visiting [www.allenoverly.com/brexit](http://www.allenoverly.com/brexit).

Regulatory data exclusivity in Europe is separate from a product's patent position and contemplates additional periods of market exclusivity depending on the date a product is first approved, the type of product, and whether any new indications have been approved during the original period of data exclusivity. A Brexit would likely trigger a need for innovative life sciences companies to reconsider their market exclusivity strategies alongside their wider regulatory and patent strategies, as they may not be able to rely automatically on the provisions currently built into EU law relating to additional data exclusivity periods. This could, therefore, lead to increased uncertainty, both commercially and legally, for life sciences companies considering registering and launching new technologies in the UK, which in turn could have potential implications for access to new medicines.

## What are the implications of a Brexit for English governing law and jurisdictions clauses for transactions undertaken by life sciences companies?

Much of the Brexit debate in a life sciences context has rightly focussed on the sector implications. In common with other industries, however, life sciences firms routinely enter into a wide range of commercial contracts with an equally wide range of public and

private counterparties relating to virtually every aspect of the operations of the firm. It is, therefore, advisable for life sciences firms that conduct activities in or from the UK directly, or via third parties located anywhere, to consider reviewing their contract-drafting procedures. They may need to adjust the form in which they contract post-Brexit, for example, because they use standard form agreements that reference European legislation or define the territorial scope of the agreement or a particular provision (such as a non-compete) as the European Union including the UK. It is also possible that, for certain material contracts or strategic transactions, life sciences companies expressly wish to provide for the possibility of a Brexit itself, such as for the purposes of a material adverse change clause. The full implications of a Brexit on English governing law and jurisdictions clauses are examined in more detail in two of a series of specialist papers on Brexit available by visiting [www.allenoverly.com/brexit](http://www.allenoverly.com/brexit).

## So what are the likely Brexit options from a life sciences perspective?

The UK could join the ranks of the current European Economic Area along with Norway, Iceland, and Lichtenstein and relinquish membership of the EU in favour of the EEA contingent on continuing to follow the EU regulatory regime. This would largely preserve the status quo from a legislative framework perspective (though the UK would be less able to shape the content of future legislation and have no access to the EU decision-making institutions. It could also mean that the UK is able to preserve its leadership position in the life sciences sector as home to the European Medicines Agency and the life sciences branch of the forthcoming Unified Patents Court. There is no guarantee, however, that the remaining EU members would be content for this to happen. Negotiating an entry into the EEA, therefore, appears at odds with the UK's desire to be a driving force in the EU and global life sciences sector.

A second option would be for the UK to follow the Swiss model of membership of the European Free Trade Association (EFTA). Switzerland has a thriving life sciences industry and is home to some of the most successful healthcare companies globally, while being a member of neither the EU nor the EEA. On paper at least it seems that the UK may be able to have the best of both worlds. Or can it? Being a member of EFTA, much like the EEA, would mean adopting a position that requires the UK to take the “burden” of EU laws without any of the corresponding benefit of having a seat at the EU table to influence new, or changes to existing, legislation. Further, the relationship between Switzerland and the EU is characterised by a framework of multiple, complex bilateral treaties that some commentators argue the EU is unlikely to want to replicate for the UK as it will simply create a new bureaucracy. Unlike the UK, however, Switzerland has never been an EU Member State and so striving to exit the EU only to then seek to recast the UK’s relationship with it along the lines of the Swiss model may seem an unattractive compromise for the life sciences sector. Being part of an integrated, harmonised legal framework arguably offers more advantages than not and is more in keeping with the UK’s desire to be a leading contributor to, and beneficiary of, pan-European life sciences initiatives than with the subordinate nature that inevitably characterises membership of the EEA or EFTA.

A third way would be for the UK to disengage from the EU lock, stock and barrel. One reason for doing so might be to strategically try to reduce the amount of regulation to which the UK life sciences sector is subject or possibly increase the number or types of financial and other incentives on offer. (Examples of this are the UK Patent Box, Bolar Exemptions, and government grants permitted under state aid rules, which are all seen as enhancing UK competitiveness). This could help to make the UK a more attractive place to do business but seems an unlikely strategy in an industry where safety and quality are paramount. There is also the prospect of having to navigate a separate, even if substantially EU-aligned, regulatory framework that could, although not difficult to put in place, lead to an increase in the regulatory compliance burden in an industry that is very global in nature such that the competitiveness of the UK in that global marketplace is adversely affected. Many non-UK companies choose to base their regional and sometimes global manufacturing and distribution facilities in the UK. Even if the UK retained national

legislation implementing the various EU Directives governing these commercial activities, significant uncertainty would still exist as to how national legislation would evolve and be interpreted, particularly as regards references in such legislation to EU law.

If the UK left the EU single market, life sciences firms operating in the UK would no longer be subject to the free movement of goods principle enshrined in EU law. This raises an interesting question as to whether a Brexit would lead to patent owners seeking to assert national rights to reduce the incidence of parallel importation of medicines by traders. Such traders typically exploit price disparities for the same product between different Member States arising from the different pricing and reimbursement laws and regulations of each Member State, which often comprise controls on a combination of prices charged by manufacturers, their profits, and the level of reimbursement by the government. Parallel importation has long been a thorny issue in the life sciences sector owing to tension between enforcement of intellectual property rights and EU competition law. It is, therefore, conceivable that a Brexit could result in increased scrutiny by the UK competition authority of strategies to thwart parallel trade, at a time when the pharmaceutical sector is already under intense scrutiny by the UK competition authority.

UK-based life sciences businesses currently benefitting from state aid and other incentives from other EU Member States, for example manufacturing and R&D investment grants or low corporation tax in jurisdictions such as Ireland, may find it more difficult to obtain preferential treatment from the remaining EU governments for projects, or existing grants, loans, and other financial incentives may become subject to review or change in the event of a Brexit. The full implications of a Brexit on competition law enforcement are examined in more detail in one of a series of specialist papers on Brexit available by visiting [www.allenoverly.com/brexit](http://www.allenoverly.com/brexit).

## What should you be doing now?

It is clear that a Brexit will have profound implications not just for commercial parties but for the life sciences sector as a whole.

The precise impact of a Brexit will depend very much on a company's own corporate and operational structure. With the UK being a key market in the global pharmaceutical and biotechnology sector, many life sciences businesses in the EU, U.S. and Asia, have some degree of UK involvement or nexus that will have a bearing on how concerned they are going to be about the fall out from a Brexit. It is, therefore, important that firms encourage cross-functional internal teams to start mapping how their structure and operations are, or may be, influenced by the UK, and what potential considerations flow from that.

While we have endeavoured to identify possible issues and scenarios in this paper, it is, at least for the time being, difficult to address every conceivable permutation and many unknowns remain. We will be keeping the situation under review and would be pleased to discuss any specific concerns or questions on an individual basis.

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