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Impact of Brexit on life sciences and healthcare

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How might the following processes be affected when the UK exits the EU in 2018+?

Business as usual
The exit from the EU will not happen for at least 2 years and potentially longer. In the meantime, the UK remains a member of the EU and all the EU obligations and benefits remain in place. In the short term therefore, it is business as usual in the UK up to at least autumn 2018.

After Brexit (2018+) the impact upon the life sciences and healthcare sector largely depends upon what model the UK adopts for its relationship with the EU. If the UK remains in the European Economic Area (EEA), then the changes may be minimal. If the UK joins the European Free Trade Association (EFTA) and negotiates sector specific access to the single market, then the landscape depends on the exact nature of that relationship. If the UK distances itself further from the EU, then the changes may be more extensive.

Whatever the relationship ultimately is, the UK has a strong track record in the life sciences and healthcare sector with tax incentives, investment and funding, R&D and other key drivers high on its agenda. We would expect that to continue. The UK accounts for approximately 25% of the EU market and will remain a key market. Switzerland (which is not in the EU) is a prime example of how the sector can develop effectively outside of the EU.

In terms of specific key areas, the precise changes remain to be seen. However, the below are some of the possible issues. We will keep you updated as matters develop.

Clinical Trials

The current clinical trial regime in the EU is due to be overhauled by the new EU Clinical Trials Regulation (No 536/2014) which is expected to be in force by October 2018. The new Regulation will modernise the current framework for clinical trials and ensure a greater level of harmonisation within the EU. The new Regulation, which provides for a single application for clinical trials across the EU via a single portal with an associated EU wide database, is designed to significantly reduce administrative burdens on applicants and allows for a simplified process where the investigational medical product poses less risk.

If the UK is not within this system, then this could pose extra administrative burdens on companies wishing to conduct multi-centre clinical trials in the EU and the UK. Separate centralised and national clinical trial authorisation procedures need to be followed. However, mutual recognition arrangements may be arranged to minimise any such inefficiencies brought about by Brexit.

Regulation of quality assurance of medicinal products
Regulation is managed at a national level. In order to ensure that high quality standards are maintained in respect of medicinal products for consumption in the UK, they must be manufactured in accordance with UK laws based upon EU Directives which lay down the principles of good manufacturing practice (GMP). This requires all manufacturers and importers of medicines located in the EEA to hold a manufacturing authorisation. The medicines regulatory authorities in each EU member state carry out periodic checks to ensure that GMP is being complied with. The current UK/EU GMP are similar to those within other developed countries such as the USA.

Even if Brexit resulted in the UK being outside the EEA, manufacturers in the UK would be able to continue exporting medicines to the EU and vice versa so long as the UK and EU regulatory frameworks remain equivalent. The UK is likely to maintain the GMP standard in order to facilitate mutual recognition agreements with the EU and other trading partners and aid imports into those areas. The cost of imports into the EU from the UK may, however, increase if additional checks would be required for non-EU imports.

Obtaining marketing authorisations
All medicines must be authorised before they can be marketed and made available to patients in the EEA. There are two main routes for authorising medicines: a centralised route and national routes. Via the centralised route a single application is submitted to the European Medicines Agency (EMA) and a single marketing authorisation is obtained. Once granted a centralised marketing authorisation is valid in all EU Member States as well as in the EEA. The authorisation holder has to be situated in an EEA state.

Following Brexit, if the UK is outside the EEA then a separate national authorisation would need be obtained for the UK. There could be an increased administrative burden of separate applications in the EU and UK. However, EU marketing authorisations could be taken into account (as they are in Switzerland) and the systems are likely to stay aligned. The European regulator, the EMA, is situated in London and it is expected to relocate to the EU.

Pharmacovigilance

EU legislation which governs the procedures for pharmacovigilance throughout the EU is comprehensive, calling for prompt collection of data, adverse reaction reporting, risk management, and transparency on marketing authorisation holders, national competent authorities and the EMA. The EU pharmacovigilance system is coordinated by the EMA which ensures effective and coordinated analysis, evaluation of risk, information sharing and periodic checks on market-authorisation holders throughout the EU.

Following Brexit, the UK competent authority would have smaller data sets than those in the EU, and the EU would be deprived of data from the UK. If Brexit results in less co-operation and sharing of expertise and information, the resulting pharmacovigilance would be less efficient and more costly. However, whether that transpires is debatable. These are issues directly relevant to public safety, the benefits of co-operation are clear and the EMA is a close partner of its UK equivalent.

Will Brexit mean the end to the free movement of goods between the UK and EU, and would this mean that intellectual property rights holders would be able to assert their rights over cheaper goods coming from the EU into the UK?

As territorial limits apply to intellectual property rights, a purchaser's freedom to deal with a protected product is typically limited to the territory in which the product is purchased. However, owing to the principle of free movement of goods, the relevant territory extends beyond the national territory to the EEA in order to preserve the free movement of goods within the single market.

The impact of parallel importation has always been acute for pharmaceutical companies particularly during the life of the patent because the pricing and reimbursement of medicines are not harmonised and falls under the exclusive competence of EU member states. This means that third parties are free to buy up branded medicines in an EU member state where the price is typically low, and gain significant profit by selling in a more expensive EU member state, by undercutting pharmaceutical companies' prices.

If Brexit results in the UK leaving the single market, pharmaceutical companies may be able to stop importation into the UK by asserting their intellectual property rights (typically patents or trade marks) against the parallel importers – subject to any other defences that may already apply to parallel imports from outside of the EU. However, this would not necessarily be the position. The UK could legislate so that the position remains the same, with the relevant territory being the EEA and the UK.

Will the UK continue to comply with EU product safety legislation and if not how would the UK position its product regulation?

The implementation of uniform product safety laws across the EU has allowed advanced standards of product safety for products both imported and exported into and out of the EU. This has allowed increased safety standards for consumers and a level playing field for enforcement within Europe.

For example, the General Product Safety Directive (2001/95/EC) provides a uniform standard for product safety where sector specific legislation may not apply. This provides a safety net for consumers and certainty for manufacturers/those in the supply chain.

Following Brexit, it is expected that the UK would continue to apply product safety standards in common with those in the EU or higher because failure to do so could affect the competitiveness of UK goods and suppliers given the global drive to higher standards. The UK could also lose the benefit of co-operation and information sharing with other EU member states including enforcement initiatives such as the RAPEX rapid alert system, which allows urgent notification of product safety issues between regulators in EU member states. These drivers may result in the UK continuing to mirror the EU product safety regime.

What will happen to IP in the UK?

Patents
The current system of national patent protection obtained through the UK Intellectual Property Office (UKIPO) or the European Patent Office (this is not an EU institution) remains unchanged.

However, an overhaul of the patent regime in EU was due to come into force in the second quarter of 2017, enabling proprietors of inventions to apply for a single, pan-EU Unitary Patent (UP) covering most of EU, and with a single Unified Patent Court (UPC) to hear and determine patent disputes on a pan-EU basis. Brexit will mean that the UP will not cover the UK. Although the UPC system can be implemented including the UK as planned until Brexit, it is likely that the UK will be excluded from the outset. In either case, the UPC start date is also likely to be delayed.

Businesses were already considering whether they wished to take part in the UP and UPC and these businesses will now need to consider additionally whether the UP and UPC (as opposed to the national routes) is a viable option for them without the UK. This is likely to continue to be decided on a case by case or patent by patent basis.

SPCs
Supplementary Protection Certificates (SPCs) are an additional right for patentees for medicinal, veterinary, and plant protection products which have obtained market authorisation in the EU. An SPC can extend the patent protection of a product by up to five years. Given the high investment, the (20 year) patent term and the long lead time to market, SPCs are valuable, protecting a patented product at the point when sales may be highest. Equivalent extensions to patent protection are available in other countries, for example Japan and the US.

The EU introduced the SPC via two EU Regulations which will no longer bind the UK upon Brexit. It is likely that equivalent regulations will be adopted but precisely what will happen to existing SPCs and the nature of an equivalent UK right is not yet known. Assuming that, driven by the economic importance of the SPC, the UK does legislate for SPCs, it would be free to amend and improve the system. A particular advantage could be the ability to take the best and leave the worst of the numerous European Court judgments on SPCs that we have seen in recent years and clarify the issues these judgments have thrown up.

Trade Secrets
Unlike much of the EU, the UK already has strong trade secret protection.

However, the level of protection of trade secrets currently varies between EU member states. The EU Trade Secrets Directive (Directive (EU) 2016/943) has come into force (5 July 2016), which to some extent addresses this issue by setting a minimum level of protection. The EU member states will have 2 years to implement it into national law. The idea is to raise the level of protection in those member states where is it lacking.

Given Brexit, the UK may not implement this Directive. But as said, the UK has a robust common law of confidentiality, and so a proprietor's right in the UK will continue in most cases to be stronger than in most member states of the EU.

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