COVINGTON

# Impact of Brexit on Pharmaceutical Regulations and Structures

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Life Sciences

Last week, the UK voted in an advisory referendum to leave the European Union. The next steps are not yet clear, but the referendum may have significant implications for the pharmaceutical industry in the UK and for international companies operating in the UK. Its impact will very much depend on the form a post-Brexit UK will take, the relationship that the UK chooses to have with the EU, and indeed the relationship that the EU is willing to accept. That will not become clear for some time as it will likely take at least two years for the UK to negotiate an exit from the EU from the point when the UK notifies the EU of its intention to leave, which will not be until October 2016 at the earliest.

There is a fundamental tension between a desire to participate in the EU's internal market and a conflicting desire to limit immigration, which was one of the key drivers behind the vote to leave. In return for any participation in the EU internal market, the EU is likely to insist on free movement of persons. In other words, the UK will not benefit from free movement of goods and services to and from the EU without accepting immigration from the EU. The price of a free trade agreement with the EU may well also include acceptance of some EU social and employment regulation. If the UK is not prepared to accept this, it may ultimately force the UK out of the internal market.

There are generally thought to be three types of relationship that could emerge:

- ***The "EEA model"*** -- The UK would need to sign the European Economic Area (EEA) Agreement, joining Norway, Iceland and Liechtenstein as EEA member states. The EEA Agreement would allow the UK to participate in the EU's internal market, but it would require the UK to implement into its national laws the bulk of EU legislation designed to facilitate free movement of goods, services, capital and persons, and without having a formal ability to influence that legislation in the future. This includes all EU pharmaceutical legislation and, as discussed below, the effects for companies under this model would be modest. However as EEA member states must accept free movement of EU citizens, that is likely to be difficult to accept for many in the UK.

- ***The "EFTA model"*** -- The UK could join Switzerland in the European Free Trade Association (EFTA). It would then enter into free trade relations with the EEA and EU by negotiating bilateral agreements on a case-by-case basis. It would not be obliged to implement EU laws, although the EU has in the past voiced concerns over Swiss "cherry-picking" of EU policies. There would be some pressure to allow for some free movement of workers, but the UK would have greater ability to control its own borders.

- ***The "WTO model"*** -- The final option would mean that the UK is independent of any existing free trade arrangements with the EU. It would need to seek a tailor-made bilateral free trade agreement with the EU. Since the 1960s, the EU has negotiated bilateral free trade agreements with neighbouring countries and beyond. The first

example is the EU-Turkey agreement, which has resulted in a customs union for industrial goods, but not services, since 2000. The more recent free trade agreements include the EU-Canada Comprehensive Economic and Trade Agreement (CETA) which accepts some degree of regulatory convergence. The other option would be to trade with the EU on the same basis as other countries, such as China, including accepting applicable import duties.

**The Impact of Brexit**

Each of these options will differ significantly in terms of their impact on the existing pharmaceutical regulatory scheme. Before discussing each of these options in turn, it is worth making some general comments.

Whatever the outcome of Brexit, the UK would lose much, if not all, of the influence it has in the EU legislative, policy and regulatory procedures. Rather than being able to influence and participate actively, it would simply need to implement legislation that the EU Commission, Parliament and Council adopt and accept guidelines and policy decisions by the European Medicines Agency (EMA).

The UK is also likely to lose the EMA, which is currently located in London. It is very unlikely that the EU would accept that the EMA should remain in a country that is not an EU member state, even if the UK joins the EEA. A number of the other EU member states have already expressed an interest in hosting the Agency post-Brexit.

The prestige and influence of the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) would also diminish. The UK Agency is currently an active and influential participant in many EMA activities, procedures and committees. The best it can hope for post-Brexit is to have observer status within the EMA's committees, such as the CHMP, COMP, PDCO and CAT.

Life sciences in the UK will also lose a significant amount of EU funding for research. The EU is very active in funding research and development programs. Companies (particularly SMEs) and researchers benefit from EU research programs like FP7 and Horizon 2020. There is also a wide range of EU public/private partnerships, such as the Innovative Medicines Initiative, which supports collaborative research projects and helps build up networks of industry and academic experts to boost pharmaceutical innovation in the EU. Brexit could reduce the amount of funding available for research in the UK.

One area in which little will change is the pricing and reimbursement of medicines in the UK. The EU does not have competency to regulate the manner in which Member States structure their health services and determine the products that are available under them. EU law requires only that reimbursement decisions are based on objective and justifiable criteria and that pricing and reimbursement decisions are made efficiently and on a non-discriminatory basis. We expect that the NHS and the UK's healthcare systems will remain largely unchanged.

## The Options

The impact of Brexit will depend largely on the extent to which the UK disengages and whether it remains part of the EEA, joins the EFTA or disengages even further.

## The "EEA Model"

If the UK becomes an EEA member state without being a full EU member, as in the case of Norway, Iceland and Liechtenstein, it would have full access to the EU single market.

The EEA Agreement requires that EEA member states implement most EU legislation relevant to the free movement of most goods and services, whether they be pharmaceuticals, medical devices, cosmetics, food, electrical equipment, *etc*. That means that the UK's implementation of the existing EU pharmaceutical laws would remain valid, and the country could continue to implement future laws.

UK companies would continue to be able to participate in EU regulatory procedures, including the centralized, decentralized and mutual recognition procedures. The new Clinical Trials Regulation, due to take effect sometime in late 2017 or early 2018, will introduce a single portal for submitting applications to begin trials in the EU, together with an EU-wide trials database and UK companies would also be able to participate in this process. They would also be able to apply for and hold marketing authorizations, clinical trial authorizations - not only for the UK, but also for other EEA member states - and act as sponsor of orphan designations. Individuals, such as the qualified person for pharmacovigilance (QPPV), could remain in the UK.

Similar considerations would apply to the pharmaceutical supply chain. Authorized manufacturers, importers and distributors in the UK would be able to continue importing and manufacturing products for release on to the EEA market and distributing products throughout the EEA.

One change associated with EEA membership would be that existing or future centrally authorized medicinal products will have to be nationally authorized in the UK after the Commission has approved the product in the EU. This happens by administrative measure in Norway and Iceland, or the UK may wish to enact legislation which gives automatic effect to EU marketing authorization decisions, as is the case for Liechtenstein.

A downside is that the UK would lose much of the influence it currently has in the EU institutions and will become a less significant participant in EU regulatory procedures. EEA member states often only have "observer" status.

**The "EFTA Model"**

If the UK decided to follow the Swiss route and opt for EFTA membership outside of the EEA, the UK would need to approve medicines and grant clinical trial authorizations, *etc*. separately from the EU (and EEA). Companies in the UK would not be able to hold EU marketing and clinical trial authorizations and the UK would play no role in the regulation of products in the EEA. Key individuals, such as the QPPV, would need to be located in the EEA.

There would, however, be some scope for the UK to agree bilateral treaties with the EU. For example, Switzerland currently recognizes the quality of pharmaceuticals manufactured in the EU and *vice versa*. That means that a manufacturer or importer of products in the EEA may import products from a Swiss manufacturer and rely on that manufacturer's confirmation that the product has been manufactured in accordance with good manufacturing practices (GMP), without the need to carry out a separate assessment and perform quality control testing. Switzerland also recognizes CE marking or medical devices and allows devices sold in the EEA to also be sold in Switzerland.

**The "WTO Model"**

The last option would presume a total separation of the UK systems for pharmaceutical regulation from the EU. There would, for example, be little difference between the situation in the UK and that in the United States. The MHRA would approve products for the UK in accordance with standards that the UK would adopt and the MHRA would regulate the pharmaceutical supply chain in the UK and for the UK alone. There may, however, be scope to agree mutual recognition of GMP inspections and certifications, such as is the case for the EU and Canada. That said, the standards to which companies develop and manufacture pharmaceuticals have in substantial part been harmonized, *e.g.* through initiatives such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). There are numerous areas in which we will see little change.

**Summary**

The UK's loss of the EMA and the diminishing influence of the MHRA would make the UK a less attractive environment for the pharma industry post-Brexit. The full effects of Brexit will, however, remain unclear until the UK's new relationship, whatever that may be, is established with the EU. In the meantime, companies will undoubtedly wish to begin planning for Brexit. At a minimum, they should undertake a mapping exercise to ensure that they understand:

- For which products is a UK company a marketing authorisation holder or an applicant for authorisation?
- For which trials is a UK company a sponsor or applicant?
- For which orphan medicines is a UK company a sponsor or applicant?
- To what extent are UK companies important elements of a company's pharmaceutical supply chain?

They may also want to start establishing greater links with, or a presence in, countries within the EU to influence EU laws and procedures.

**Webinar: the implications of Brexit**

Covington will host a webinar, led by partner Grant Castle, discussing the implications of the Brexit vote on the pharmaceutical industry in the UK.

The webinar will run on Thursday 30 June at:

- 12pm EST
- 5pm BST
- 6pm CET

Please click here register for the webinar.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Life Sciences practice:


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