ARTHUR COX

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Brexit and the Irish Life Sciences Industry

As the largest net exporter of pharmaceuticals in the EU and one of the largest in the world and given that most of the world's largest pharmaceutical and medical device companies have substantial operations in Ireland, it is clear that the industry will be significantly impacted by Brexit.

At a recent meeting hosted by the Irish Health Products Regulatory Authority (**HPRA**), Ireland's Competent Authority, representatives from industry, government and the regulator discussed the potential effects of Brexit on the sector.

Overall, the general message was pragmatism and preparation. The HPRA reaffirmed that it is open for business and will assist the industry through their Brexit planning. However, stark warnings were issued to companies to approach them early to discuss their plans, and avoid a backlog of applications on the eve of Brexit, currently set to be March 2019. A key concern and driver behind these messages is to ensure continued supply of medicines post-Brexit.

Some of the other key issues identified at the HPRA meeting and which life sciences businesses should be working on right now are outlined below.

1. PRODUCT AUTHORISATIONS

To market medicinal products in the EU it is a requirement to have a marketing authorisation (**MA**), which may only be held by entities established in the European Economic Area (**EEA**). MAs can be granted by the European Commission or the national authorities.

Centralised MAs granted by the European Commission allow companies to market products throughout the EU under that single MA which, at the moment, includes the UK. When the UK leaves the EU, UK companies can no longer hold these MAs as they will no longer be an entity established in the EEA. To continue to market the product throughout the EU, the MA must be transferred to an entity established in the EEA.

When the UK leaves the EU, products may no longer be placed on the UK market on the basis of MAs granted via the current EU regulatory framework. Conversely, the national MAs granted by the UK competent authority, the MHRA, may not be recognised by other EU Member States for the purposes of placing products on their markets as part of mutual recognition or decentralised procedures.

The HPRA confirmed that it is happy to take over the role of Reference Member State (**RMS**), at no additional cost, for products where the UK MHRA is currently the RMS and the HPRA is a Concerned Member State.

While the EU and the UK may adopt some form of mutual recognition procedure as negotiations progress, the message for industry now is to prepare for a hard Brexit (as the EU regulatory network are). It is critical that businesses conduct a mapping exercise of MAs currently held by its various entities, the market in which those MAs are operating and engage early with the HPRA to discuss plans for MA and RMS transfers arising out of this exercise.

2. UK WILL BE A "THIRD COUNTRY"

As the UK will no longer be part of the EEA after Brexit, medicinal products manufactured in the UK will require an import authorisation before they can be placed on the EEA market. Products must also undergo batch control and testing at a site in the EEA to ensure they have been manufactured in accordance with EU Good Manufacturing Practices. Therefore, companies will need to identify batch release locations within the EEA.

Aside from the resulting regulatory and operational burdens, associated costs and delays will need to be considered.

3. PARALLEL IMPORTATION

Products that are parallel imported into Ireland from the UK may also be affected due to the UK's status as a third country. Many products in Ireland are imported from the UK and registered under the Dual Pack import Registration scheme and parallel product authorisation. The HPRA also recognises that joint packaging is a critical issue and one on which they will take a pragmatic approach by assessing these products on a case by case basis depending on the level of divergence.

4. QPPV AND PSMF MUST BE BASED IN THE EEA

The HPRA reaffirmed the guidance issued by the EMA earlier this year in relation to the Qualified Person responsible for Pharmacovigilance (**QPPV**). After Brexit, QPPVs can no longer be based in the UK and companies will need to appoint EEA based QPPVs.

Similarly, the Pharmacovigilance System Master File must also be located within the EEA, and will need to be transferred if currently held in the UK.

5. SUPPLY CHAIN

The UK is one of Ireland's largest export markets for medical and pharmaceutical products. Relationships between Irish and UK suppliers, finishing plants, distribution hubs and third party customers are inextricably linked. These relationships will need to be re-examined as transactions between the UK, a country that will no longer be in the customs territory of the EU, and Ireland, may have customs duty and VAT implications.

Territorial rights and potential exchange rate, customs and import duty implications will also need to be examined.

6. UK NOTIFIED BODIES

The most obvious regulatory impact in the medical device sector is whether the CE Certificates of Conformity granted by the UK notified bodies (a necessary prerequisite for placing certain devices on the EEA market) will continue to be recognised for marketing purposes in the EU. Companies that hold certificates from UK notified bodies will need to consider alternative options should these certificates no longer be effective for EU marketing purposes.

7. AUTHORISED REPRESENTATIVES

Another area of impact involves Authorised Representatives (**ARs**). ARs are established in an EU Member State and allow non-EU medical device manufactures access to the EU market. Following Brexit, UK ARs will no longer be able to represent non-EU manufacturers thus forcing those companies to seek ARs elsewhere in the EU or, alternatively, establish a presence within the EU.

OTHER CONSIDERATIONS

1. THE EMA

A key issue in the sector will be the relocation of the European Medicines Agency (**EMA**) from London. The EMA plays a vital role in the evaluation of the safety, efficacy and quality of new products, whose assessment the European Commission rarely fails to follow when approving a medicinal product for use in the EU. 19 Member States, including Ireland, have expressed an interest in attracting the EMA and their submissions have been published on the website of the Council of the European Union.

Relocation of the EMA, an agency employing 890 staff and hosting valuable scientific expertise, to Ireland would have immediate positive impacts for the industry in Ireland. There would be much to gain from shared expertise between the EMA and the HPRA, a highly respected agency in the EU network. An English speaking educated population, a dynamic manufacturing and development cluster, a well-respected competent authority and proximity to London gives Ireland a number of advantages in the decision on the relocation of the EMA.

2. FUTURE REGULATORY DIVERGENCE

Finally, there is also uncertainty over the UK's transposition of the new EU Medical Device Regulations and Clinical Trials Regulation.

The EU Medical Device Regulations will apply in 2020 for medical devices and 2022 for IVDS. The UK played a key role in drafting these Regulations.

The Clinical Trials Regulation, designed to streamline the conduct of clinical trials within the EU, provides a single application procedure for multi-site trials conducted across the EU. It was adopted in 2014, but is due to come into effect during 2019.

It is hoped that both of these Regulations will be captured within the Great Repeal Act in the UK and automatically apply as UK law. However, the status of the Regulations in a post Brexit landscape remains unclear.

KEY CONTACTS

COLIN KAVANAGH
PARTNER
+353 1 920 1196
colin.kavanagh@arthurcox.com

CIARA FARRELL
SENIOR ASSOCIATE
+353 1 920 1427
ciara.farrell@arthurcox.com