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Law Brexit brief

Brexit and Life Sciences — the perfect storm

While it has been business as usual for the life sciences sector after the service of the Article 50¹ notice by the UK, come 29 March 2019, it is likely that this sector will be one of those most affected by Brexit; particularly in the UK, which has a strong track record in the life sciences. The time to act is now.



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Why is that?

On one hand, the life sciences sector is highly regulated, on the other, it is highly harmonized by the EU directives and regulations.

Pharmaceutical companies and, to a lesser extent, medical devices companies, need to anticipate the regulatory steps that will be carried out as a consequence of Brexit so that they can continue to operate and supply the UK and EEA markets smoothly.

Marketing authorization holders

For pharmaceutical companies there is likely to be a requirement for the authorizations, operations and systems to be moved from the UK

to an EEA location so that they can continue to trade in the EEA market after Brexit.

PharmaCos'² EU Marketing Authorizations (MA) will need to be transferred from the UK to an EEA-based company or UK companies holding EU MA will have to transfer their place of establishment, e.g. their head office, to an EEA Member State.

Similarly, UK holders of orphan medicinal designations will need to transfer those designations to EEA based companies or to transfer their place of establishment to an EEA Member State.

¹ Article 50 of the Lisbon Treaty sets out how a member state may withdraw from the EU

² See in particular the Notice to marketing authorization holders of centrally authorized medicinal products for human and veterinary use (2 May 2017) and the Q&A related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the centralised procedure" (31 May 2017) published by the EU and the European Medicines Agency.

Some pharmaceutical operations and Systems need to be performed in the EEA, meaning that:

- The Qualified Person for Pharmacovigilance (QPPV) must be located in the EEA.
- The Pharmacovigilance System Master File (PSMF) must be located in the EEA.
- Sites of batch control and batch release must be located in the EEA for medicinal products manufactured or imported into the EEA.

The same should apply to scientific information services (including to the contact person).

Some of these activities may be outsourced (provided that the service providers are in the EEA). This should be analyzed on a case-by-case basis, keeping in mind that the marketing authorization holder, when relocated in the EEA, will need to show adequate regulatory substance.

Movement of pharma goods

Similar changes will need to be implemented with respect to the physical movement of pharmaceutical goods between the UK and the EEA.

Physical movement of medicinal products (in their finished form) from the UK to the EEA, and reciprocally, will likely be deemed as imports, meaning that an importer holding a manufacturing and import authorization, (MIA) will need to release these products in the EEA. The nature of the release controls will depend on whether a mutual recognition agreement is signed with the UK at the separation date.

Physical movements of active substances from the UK to the EEA, and reciprocally will likely be deemed as imports too, meaning that the MHRA may need to certify that they comply with the EU Good Manufacturing Practices (GMP) standards. While this should not be an issue at the separation date, subsequent divergence in regulation may make this something to be dealt with at a later stage.

Buy and sell operations between the UK and the EEA (even though there are no border movements at all) might be deemed as imports (depending, in particular, on Annex 21 to the GMP relating to “virtual import”). This might raise some complex issues in supply chain organizations where a UK company holds the title of ownership of medicinal products

which are manufactured or packaged and then sold in the EEA.

Market access strategy

Finally, if products manufactured in the UK are mainly for the EEA, one may wonder whether the manufacturing sites should not be transferred to one of the “big four” EEA markets (Germany, France, Italy or Spain), in particular, when these countries take into account the number of jobs provided by the pharmaceutical company when setting the price of the medicinal products.

Medical devices

For medical devices companies, it is likely that manufacturers based in the UK may need to appoint a legal representative based in the EEA, and that EEA operators buying from UK manufacturers will be deemed as importers.

Manufacturers might need to change their notified bodies if their current UK notified body does not relocate to the EEA which may be, however, quite hypothetical.

R&D

Whether R&D centers should be moved to the EEA is to be analyzed on a case-by-case basis, depending, in particular, on the level

Brexit: key regulatory questions



of EEA grants received, as well as on the market access strategy. Here, again, it is key to keep in mind that some countries may take into account R&D activities carried out domestically when they set the price of a medicinal product.

So what should be done?

In these conditions, life sciences companies need to anticipate the possible consequences of Brexit and work on a contingency plan for their regulatory strategy, supply chain, and regulatory organization, as well as all third-party and intercompany contract network, e.g. quality agreements.

It is all the more important that EMA has already warned about a possible disruption in its operations and that we have heard that the regulatory authorities of possible

countries of choice to relocate regulatory activities in the EEA are already struggling to handle new filings triggered by Brexit.

Where to move?

Among the key regulatory criteria to take into account when assessing the country of choice, we can list:

- Whether there are intra-group companies that already have the right authorization, e.g., MIA, which will allow them to host the new operations, to be relocated in the EEA
- The responsiveness of local authorities and their interpretation of the notion of “virtual import” and the possibility for a company to hold the “title of ownership” of medicinal products
- The ease of access to the right regulatory resources, e.g., QPPV
- The ease of access to the right service providers, e.g., for logistics and testing.

To prepare this contingency plan, there are other key criteria which need to be taken into account, among them, tax and employment law aspects.

Future regulation

In addition, there are many other regulations that will come into force in the sector within the next few years, the consequences of which need to be anticipated too, e.g.,

- Clinical Trials Regulation
- Annex 21 to the EU GMP
- Medical Devices Regulation

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EYG no: 06424-172GBL

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