# BREXIT AND ITS IMPACT ON THE LIFE SCIENCE INDUSTRY

The countdown has started. The UK will leave the European Union in less than a year. Companies need to get ready for the post-Brexit era. The transition period until the end of 2020, which EU leaders have now signed off on, is a gain in time but does not provide respite. This is especially true for companies with a business model depending on the regulatory framework created for the EU Single Market.

The life science industry is subject to more EU-derived legislation than most other industries, which is why the withdrawal of the UK will have significant implications for pharmaceutical and medical device industries across Europe.

Pharmaceuticals are amongst the top five most traded products between the UK and the EU. Some 45 mio patient packs are supplied to the EU every month, and 37 mio packs are shipped the other way. Alignment and mutual recognition between the UK and the EU regarding authorisation, testing and surveillance of medicines have therefore always been crucial, and should remain so in future. Whether this will be negotiable is yet to be seen.

In the guidelines on the framework for post-Brexit relations with the UK (EUCO XT 20001/18), adopted on 23 March 2018, the European Council has clearly stated that no sector-by-sector approach to participation in the Single Market will be acceptable.

Political uncertainty is forcing companies to put in place business continuity plans that include the "No Deal" worst-case-scenario of a future relationship governed solely by WTO free trade rules. Even if the EU and the UK start to negotiate a free trade agreement it is unlikely to be settled by the end of the transition period.

That which needs to be considered in detail by a given company depends on its particular portfolio and business locations. Some examples of areas that must be considered are:

- The replacement of UK-based Marketing Authorisation Holders for approved products. Possibly the need to establish a new entity for this purpose in Germany or another EU member state.
- The transfer of functions if the UK acts as Reference Member State for products approved via Mutual Recognition or Decentralised Procedure.
- Assessment of the need to renegotiate customer and supplier contracts.
- The relocation of UK-based sponsors for clinical trials conducted in the EU27 (New EU-GCP-Regulation).

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- The Qualified Person Responsible for Pharmacovigilance must be from an EU member State.

These few examples already demonstrate the broad range of comprehensive legal issues that companies need to address. An in-depth assessment of all processes along the value chain will be necessary.

The same applies to the medical device sector in which companies have to meet the requirements of the new Medical Device Regulation (MDR). Companies are already concerned that the number of Notified Bodies (NBs) will decrease. Thus far, UK NBs are still used for a large amount of CE marking activity. It is therefore important that existing and valid CE marking certificates issued by UK NBs remain recognised until their expiration date. As the problem is not yet solved, companies have to consider this.

Digitalisation is progressing rapidly in the life science sector. Experts throughout Europe are exploring the benefits of digital healthcare, big data management of health data and genomics – with major contributions, however, from UK-based institutes and stakeholders. Due to their sensitivity, health data must be protected in accordance with the General Data Protection Regulation (GDPR) and other sector-specific European provisions. On 25 May 2018, the GDPR has become effective in the UK. Yet, withdrawal will mean that the UK will be classified as a "third country" and will have to demonstrate that an adequate level of protection is guaranteed. Companies conducting clinical studies in multiple EU member states and the UK, as well as businesses offering E-Health products, will have to consider this.

As the processes and procedures in the life science sector are complex, clarity about the future regulatory framework for the trade and supply of medicines and medical devices needs to be provided as soon as possible. This will be crucial for the life science industry but also for patients and their access to life-saving drugs and medical technologies.

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