

Get ahead of Brexit's pharma issues

Strategic advice and market access for medicinal products and medical devices

Your experienced partner

Diapharm is a leading global service provider and consulting firm. We are dedicated to supporting the consumer healthcare and pharmaceutical industry with over 30 years of market experience, passion and OTC expertise.

We support our clients with multidisciplinary experience when it comes to regulatory affairs, scientific and medical affairs, quality management and pharmaceutical consulting. Our staff of over 100 specialists are committed to our clients' projects worldwide, always keep the big picture in mind and help ensure that everything goes smoothly. With offices in Germany, Austria, Benelux and China, Diapharm operates worldwide.

Contact us:

We would be happy to help you decide which model is the right fit for your Brexit needs. Contact us!

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Legal certainty in any Brexit outcome

Diapharm helps pharmaceutical companies from the United Kingdom retain easy market access to the European Union even after Brexit.

Following Brexit, the United Kingdom and the EU27 will be separate legal jurisdictions. For British manufacturers and distributors of medicinal products and medical devices, this means that the UK will be a third country for the EU27. This third-country status will apply under all Brexit scenarios at some point, even under what is known as the “Norway-plus” model.

Diapharm offers a pragmatic, long-term solution that provides legal certainty and compliance for British manufacturers who want to market their medicinal products and medical devices in the EU27 after Brexit.

EU27 market access for medicinal products

To market medicinal products in the EU a legal and sales organisation in a European jurisdiction is required.

For more than a decade, Diapharm has been successfully helping manufacturers from third states to market medicinal products in full compliance with EU Directive 2001/83/EC.

Depending on your requirements we can take on:

- Responsibility as the marketing authorisation holder (MAH) with a registered office in the EU or EEA
- The role of qualified person (QP)
- GMP- and GDP-compliant supply chain restructuring (e.g. wholesale distribution licence)
- EU import authorisation for medicinal products from third countries
- Analytical batch testing in the EU or EEA, including required method transfers and more
- EU market release (batch release) of all batches of medicinal products destined for the EU or EEA
- The role of qualified person for pharmacovigilance (QPPV) including pharmacovigilance system master file (PSMF) located in the EU or EEA
- and much more

EU27 market access for medical devices

Manufacturers and distributors of medical devices or IVDs who do not have a registered office in the EU need to appoint an EC representative (EC REP).

The representative acts as a contact for the authorities and holds third-party liability for the use of these products.

Diapharm can take on this responsibility on your behalf.

We offer a wide range of additional services:

- Conformity assessment involving a notified body for (substance-based) class II and class III medical devices
- ISO 13485-certified quality management, mandatory for CE marking
- Providing QM and safety officers and the person for regulatory compliance under the MDR
- EU market release (batch release) of products for the EU or EEA
- (Product-related) responsibility as manufacturer or as authorised representative (EC REP)
- and much more