

Bird & Bird

Life Sciences & Brexit



Brexit & Life Sciences

On 29 March 2019 the UK will leave the EU, whether there will be a transitional period until 31 December 2020 remains uncertain despite the desire for a deal. In any event, the general direction of travel continues towards the EU and the UK becoming separate jurisdictions for all regulatory issues, such as marketing authorisations for medicines, pharmacovigilance, clinical trials and medical devices.

Consequences for your business

From a UK based perspective, current EMA authorisations and running procedures may become invalid without appropriate action. From a continental based perspective, separate marketing authorisations will be required to access that market. Clinical trials for EU and UK marketing authorisations will be subject to separate regimes. For pharmacovigilance, qualified persons will need to be appointed in both jurisdictions, as will authorised representatives for medical devices.

Just in time delivery of active ingredients, medicinal products and medical devices across the new UK-EU border will require adapted logistics.

Brexit clock is ticking

Time is of the essence to be prepared for business in the post-Brexit environment, particularly for the scenario of a No Deal (where there is now finally more clarity as to the UK's approach).

Your Brexit Strategy & Bird & Bird

Bird & Bird is the number one firm for organisations being changed by technology and the digital world. We have one of the largest and most respected Life Sciences teams in Europe and APAC covering all practices from IP, Regulatory and Data Protection to Corporate, Employment and Finance. We assist companies of all sizes and provide advice at each stage of the life-cycle of medicinal products, biotech and medical devices.

We have teams in all relevant EU locations and our one firm culture allows for a cohesive and collegiate relationship between lawyers in different countries, offering a seamless service.

Our professionals will guide you every step of the way. Tailored to your individual needs our services may include:

- a Analysis of your portfolio
- b Strategic Solutions advice
- c Regulatory assistance
- d Incorporation of legal entities
- e IP Rights audit
- f Medical Devices audit
- g Package deal – selection of the above

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