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

Get your free prior consultation @ EMA@twobirds.com
Bird & Bird is an international legal practice comprising Bird & Bird LLP and its affiliated and associated businesses. Bird & Bird LLP is a limited liability partnership, registered in England and Wales with registered number OC340318 and is authorised and regulated by the Solicitors Regulation Authority. Its registered office and principal place of business is at 12 New Fetter Lane, London EC4A 1JP. A list of members of Bird & Bird LLP and of any non-members who are designated as partners, and of their respective professional qualifications, is open to inspection at that address.

Sally Shorthose
Partner
Tel: +442079826540
sally.shorthose@twobirds.com

Wouter Pors
Partner
Tel: +31703338823
wouter.pors@twobirds.com

Eleanor Root
Partner
Tel: +442079056376
eleanor.root@twobirds.com

Sarah Faircliffe
Legal Director
Tel: +442079826521
sarah.faircliffe@twobirds.com

Eduardo Monopoli
Partner - Baseline
Tel: +44 (0) 7745 628 818
eduardo.monopoli@twobirds.com

Iris Olivier
Regulatory Counsel
Tel: +31 (0)70 353 8859
iris.olivier@twobirds.com