Brexit Industry Insights
Life Sciences

With the UK’s default to leave the EU without a deal, there are a number of steps businesses in the life sciences sector should take to prepare. Many companies in the sector are faced with simultaneously navigating an increasingly complex regulatory environment while trying to mitigate as much as possible the significant impact of Brexit – including the effects of weak drug development pipelines, access to talent, supply chain disruption and potentially reduced research and development (R&D) funding.

Detailed guidance on planning for no deal has been issued by the UK government and the Medicines and Healthcare products Regulatory Agency (MHRA). Many businesses have already taken significant steps to prepare for Brexit; the winners over the longer term will be those prepared to adapt, to face the change and the opportunities the post-Brexit trade and regulatory landscape will bring.

Focus on medtech
Medical Technology (medtech) companies face the challenges and uncertainties of Brexit coupled with the regulatory burden of complying with the incoming EU Medical Device Regulation (MDR), enforceable by May 2020. In a no-deal scenario, UK companies will be considered a third party under the new regulation, and therefore additional considerations are necessary when implementing MDR into business processes.

To ensure continued ability to place medical devices on the EU and UK markets, an EU-authorised representative and UK Responsible Person must be appointed in order to register the devices. Currently authorised representatives based in the UK are recognised as an EU-authorised representative and are able to authorise medical devices for the EU market. However, post Brexit this may no longer be the case. To ensure continued ability to place medical devices on the EU market, UK-based manufacturers will need to establish an authorised representative within the EU/EEA, and vice versa. Manufacturers of medical devices outside the EU with an Authorised Representative within the UK will need to designate an Authorised Person in the EU market. An update to the quality management system is also required following any change of Authorised Representative.

At present, there is only one recognised notified body in the UK British Standard Institution (BSI) in respect of MDR. Whilst the MHRA have stated in a no-deal scenario it will recognise EU issued CE marks in the short-term for products placed on the UK market, the EU will not reciprocate this for UK-issued CE marks. Post Brexit, UK CE marks are expected to be replaced by the UK Conformity Assessed (UKCA) mark.

Brexit and the Life Sciences sector
The UK has one of the strongest and most productive life sciences industries in the world, generating approximately £20.7 billion turnover (2015) with 90,000 jobs (2016)\(^2\). The industry relies heavily on integrated European supply chains which often involves inter- and intra-company cross-border process, goods and value flows. This streamlined movement is currently facilitated by the harmonised regulatory environment and lack of border controls\(^3\). Life sciences is a heavily regulated industry with a comprehensive EU-derived legislative framework governing the testing, approval, production, and distribution of pharmaceutical and other products. As such, life science businesses face a range of Brexit related issues, particularly in relation to supply chain, regulation, movement of people and cross-border data flows. Whilst the extent of these impacts depend on the facts and circumstances of each organisation, many of the key issues are common across the subsectors of pharmaceuticals, medical technology (medtech) and biotechnology (biotech).

What does this mean for business?
Some of the key implications for businesses operating in the sector are:

**Regulatory**
There are a number of regulatory issues businesses in the sector need to manage in order to ensure continuity of supply. Key considerations are summarised below.

**Marketing authorisation** - By law, before a medicinal product can be placed on the market, it must be given a marketing authorisation (in essence a product licence) by a medicines regulator. The UK regulator is the MHRA. After Brexit, the MHRA will naturally not be recognised as an EEA Regulator, and marketing authorisations held by UK companies may not be valid for EU sales. Companies relying on UK authorisations are looking to transfer their ownership and/or regulator to an EU member state, which may require additional permissions and risk triggering a tax charge on exit.

**Transfer of analytical methods, batch testing & release** – According to European Directive 2001/82/EC, medicinal products imported into the EU have to undergo quality control testing (batch testing) in the EU/EEA\(^4\). Currently this includes batch testing undertaken within the UK. Post Brexit, products batch-tested in the UK will no longer be accepted for release to the EU market. Organisations should therefore plan for the post-Brexit transfer of testing and release from the UK to the EU, of equipment, materials and people. This will require the transfer of knowledge and know-how through the training of new staff members. If a contract manufacturing organisation is used then communication of increase or decrease of services will be required. Potential third party capacity shortages should be expected. Post-Brexit the UK will accept testing performed on EU/EEA soil and third countries where the EU has a Mutual Recognition Agreement (MRA), for at least two years.

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\(^3\) UK EU Life Sciences Transition Programme Report, for the UK EU Life Sciences Steering Committee, 6 September 2016

Pharmacovigilance – or drug safety, includes all activities relating to detection, assessment, understanding and prevention of adverse effects with drugs or pharmaceutical products. Currently a UK ‘Qualified Person’ is able to deliver the relevant pharmacovigilance across the EU. Once the UK has left the EU, the Qualified Person for Pharmacovigilance (QPPV) will no longer be able to operate on UK soil. Similarly, the Pharmacovigilance System Master File (PSMF) will no longer be able to be stored in the UK. Organisations must therefore prepare to relocate QPPV to the EU and make provisions for storing PSMF in the EU as well. Conversely, the UK QPPV must be based in the UK by the end of 2020 to continue in the UK market.

UK national licences – According to guidance published by the MHRA in March 2019 there will be automatic grandfathering of Market Authorisations (MAs) for existing Centrally Authorised Products (CAPs) to UK national licences. There will be a requirement for organisations to submit product data to the MHRA for all licenses they wish to maintain post-Brexit in the UK. Marketing Authorisation Holders (MAHs) will have a period of one year starting on exit day to make these submissions. Organisations should assess portfolios with considerations to licences held in the UK that are referenced to other markets.

Change to EU legal representation for clinical trial authorisation – According to the Association of the British Pharmaceutical Industry (APBI), the UK is the EU’s number one location for phase I clinical trials. Currently an EU registered Qualified Person is required to provide clinical trial authorisation. At present Qualified Persons within the UK are recognised as an EU-Qualified Person. However after the UK departs the EU this will no longer be the case and an EU Legal Representative will be required to authorise any future clinical trials.

Labelling - Changes to Authorised Representative for medtech and market authorisation for medicinal products will impact labelling as the new address of the relevant representative must be added. Other updates to product characteristics, artwork and package information leaflets may also be required to reflect new addresses and roles. The lead times for these updates can be significant and may be required for both new and existing stock.

The UK government has indicated it would like to maintain a close working partnership in respect of medicines and highlighted three key principles: patients should not be disadvantaged; innovators should be able to access the UK market as quickly and simply as possible; and we will continue to play a leading role in both Europe and the world in promoting public health. The European Council guidelines for the Brexit negotiations also seek a close partnership in this area.

Case study
A global pharmaceutical business approached Deloitte to validate its Brexit readiness planning, asking for a ‘crisis management’ workshop in which its preparations were comprehensively tested. Using a series of interactive scenarios, each encompassing more territories and/or product lines than the last, we helped the group understand areas where strengthened planning of its mitigation strategy could be of benefit.

Our modular approach provided robust readiness for a no-deal outcome, and meant the business had increased confidence of ensuring continuity of patient supply and conduct of clinical trials.

Research and Development
The UK has key strengths in life sciences R&D. In 2013, the UK spent around US$2.6 billion of government funding on health R&D, ranking second only to the US. Firms may also rely on EU Funding, such as Horizon 2020 or the European Research Council (ERC) to support R&D activities. Sources of EU funding may no longer be available or become less readily available to UK operations post-Brexit if the UK loses access to EU programmes and research funds. However, there is a commitment from the UK government to continue R&D investment post Brexit rising to 2.4% of GDP by 2027. Companies should explore ways to access these new sources of UK funding.

People
Under a no deal, free movement of people will end once the UK leaves the EU. EU/EEA citizens resident in the UK before 31 October 2019 will retain their rights to settlement and access to services, and they will need to apply under the EU settlement scheme by 31 December 2020. EU/EEA citizens moving to the UK after 31 October 2019 will for a transitional period be able to move to the UK to live and work as they do now. But those wishing to stay beyond December 2020 will either need to apply for European Temporary Leave to Remain by 31 December 2020 or leave the UK. The UK is expected to introduce a new immigration regime from January 2021 for all EU nationals arriving in the UK after this date.

Multinational life sciences companies often have a highly mobile international workforce and are reliant on the efficient deployment of individuals around the world including within the EU. Post-Brexit changes will need to be factored into existing processes to avoid delays in putting feet on the ground and/or increased costs. For example, immigration requirements for UK nationals planning to work in the EU will need to be confirmed on a country-by-country basis including expected timelines for completion of the immigration process. Dual social security liabilities could arise for employers and mobile employees if member states do not agree to reciprocal arrangements with the UK.

Supply Chain
The life sciences industry has streamlined and integrated European supply chains. These often involve inter and intra-company cross-border processes, goods and value flows, currently facilitated by the harmonised regulatory environment and lack of border controls. Organisations should analyse impacts of the loss of this harmonised environment and potential introduction of border controls for current products and products in development. Product plans may need to be adapted, and product portfolios prioritised. Import/export licences will also be required for the cross-border movement of drug precursors. Understanding the impact of a reduced harmonisation is also important such as with the new EU Falsified Medicines Directive, where the UK is expected to lose access to the European Medicines Verification System.

Border delays: Brexit, and particularly a no-deal Brexit, will likely cause significant supply chain disruption. Revised UK government planning assumptions predict significantly reduced access across the short straits (i.e. Channel crossings between the south east and mainland Europe), for up to six months in a worst case scenario\(^4\). In the event of a no-deal Brexit the UK government have stated medicines will be given priority import access. However, there are uncertainties as to the operational reality of this. Businesses should explore contingencies to avoid chokepoints (in particular the Dover-Calais strait).

Stockpiling: As part of no-deal planning, the UK government has issued guidance to pharmaceutical companies that supply to the NHS from/via the EU/EEA to hold an additional six weeks of stock to help mitigate potential disruption to supply routes\(^5\). However, organisations must consider the challenges of cold chain and radioactive medicines with time-sensitive lifespans.

Trade and customs: Many pharmaceutical products are zero-rated on import into most countries, and we expect this to be the case for pharmaceutical products imported into the UK post-Brexit. However, there are also ancillary products associated with the production of pharmaceutical products which are liable to customs duty, e.g. packaging. Duty rates and market access arrangements between the UK and third countries could also change by virtue of the UK losing access to the benefits of Free Trade Agreements (FTAs) which it currently has because of its EU membership. UK negotiations with third countries are ongoing.

Export controls on dual-use items (items which can be used for both civil and military purposes, such as chemicals, toxins and equipment): Whilst the overall framework of controls will not change, the movement of controlled items intra-EU shall become subject to the respective export authorisation requirements. A UK export authorisation will be required for exports from the UK to the EU, and an EU export authorisation will be required for exports from the EU to the UK. An export authorisation issued by one of the EU27 will no longer be valid for export from the UK.

Tax
The tax implications of business changes will need to be considered. For example, this includes determining whether any activity being transitioned from the UK to the EU is a transfer of a business and the associated exit tax and valuation issues. The impact of EU VAT simplifications no longer applying, and the recovery of import VAT – particularly in toll manufacturing scenarios – will need to be assessed.

What can businesses do to prepare?
- Identify the suitable alternative member state for marketing authorisations, and register new Authorised Representative in the relevant Member States.
- Transfer or re-issue EC certificates by an EU-based notified body before the withdrawal date. Assess impacts to the rest of world where the market depends on UK-based EC Certificates.

13. UK EU Life Sciences Transition Programme Report, for the UK EU Life Sciences Steering Committee, 6th September 2016
• Select countries as sponsor of Clinical Trial Application currently held by the UK and transfer Clinical Trial Application registration by submitting required documents.

• If Qualified Person release sites are currently taking place in the UK then register new Qualified Person sites in the EU.

• Review your products to understand if export licences will be required for the cross-border movement of drug precursors.

• Review the tax implications of changes to business activity, particularly where assets and/or operations are moved cross-border.

• Continue to engage with and encourage your existing workforce to certify their residency status while also reviewing recruitment strategy for critical roles. Monitor information from countries in which you operate to ensure you understand local visa and work permit requirements.

• Assess impacts to post Brexit supply chains, including active pharmaceutical ingredients and bulk stock.

• Develop and maintain an appropriate stockpiling strategy, aligned to the UK government’s official guidance.

• Update stock keeping systems to ensure continuation of supply. In some cases this may require warehouse expansions, inward processing and customs comprehensive guarantees for all sites and development of a sample management strategy.

• Review any use of EU funding, particularly for R&D. Evaluate how funding sources may change once the UK has left the EU and identify potential new sources of funding and government incentives.

• Keep up to date on UK and EU government, European Commission and regulator announcements for news on policy changes. Develop a strategy for government engagement on the issues that matter most to the business in order to influence future policy.
How can Deloitte help?
Deloitte has been supporting multiple businesses across a range of industries to understand the implications of, and prepare for, the UK’s withdrawal from the EU. We have supported many clients with their Brexit planning. Our teams combine Brexit insights, industry knowledge and technical expertise to support our clients with their Brexit readiness planning – from risk assessment to applying the lessons learned to optimise for the future trading environment.

For further information please contact Deloitte Brexit Support brexitsupport@deloitte.co.uk

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Further reading
No-deal guidance for the pharmaceutical sector

UK No-deal Technical Notices:
• The life sciences sector and preparing for Brexit
• Regulating medical devices in the event of a no-deal Brexit
• Further guidance note on the regulation of medicines, medical devices and clinical trials in a no-deal Brexit
• Businesses supplying medicines and medical devices – what to expect on day one of a ‘no deal’ scenario
• Guidance on pharmacovigilance procedures in the event of a no-deal Brexit

UK Business Preparation Tool:
• Prepare your business or organisation for Brexit

European Commission
Brexit Preparedness:
• Clinical trials
• Medicinal products for human and veterinary use

Regulators
• MHRA Brexit guidance and publications
• European Medicines Agency Brexit guidance

This no-deal guidance is not exhaustive. Companies should routinely review the latest official updates and technical guidance as and when they are published by the UK, EU, and individual EU Member States.