BREXIT IMPACT ON UK LIFE SCIENCES: PREPARATIONS AND PRACTICAL GUIDANCE

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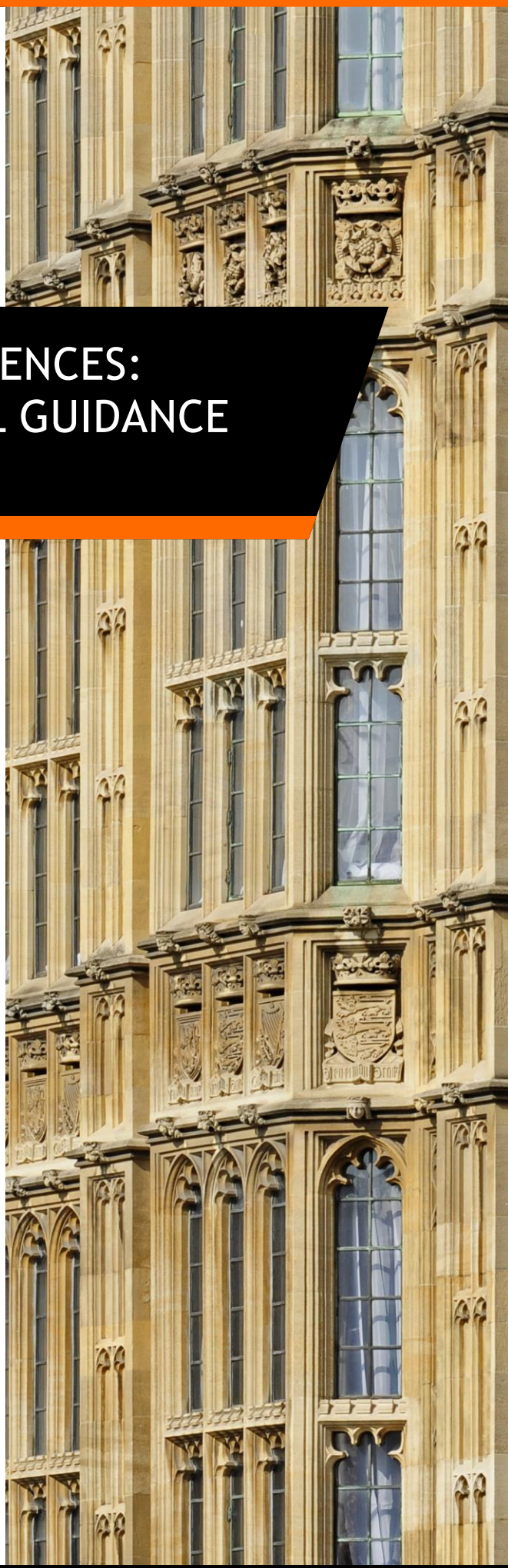

With the current Article 50 extension deadline of 31 October 2019 looming against a complex and uncertain political backdrop, and talks between the UK and EU continuing without any clear sign of a definitive outcome, the possibility of a no-deal Brexit remains at an all-time high.

This report highlights the specific risk implications of a no-deal Brexit scenario, the preparations undertaken thus far to protect industry stakeholders and the commitment and investment made by the government to ensure that the UK retains its status as a world leader in science, innovation and healthcare.

EU LAW IN THE UK POST-BREXIT

Life sciences is one of the most highly regulated industry sectors, predominantly underpinned by EU legislation. EU directives that have been adopted into UK law by domestic legislation will remain binding post-Brexit. EU regulations have immediate direct effect in the UK and there is no need for implementation by way of domestic legislation. This means that upon the UK's departure from the EU, without additional legislation, existing EU regulations will no longer have effect but directives will.

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To prevent a legal black hole, the European Union (Withdrawal) Act 2018, which provides for the repeal of the European Communities Act 1972 with effect from a specific exit date (currently 31 October 2019 at 23.00), will effectively "copy and paste" those current EU laws, which until now have been directly effective in the UK, into domestic law.

The 2018 Act also empowers UK legislators to amend EU legislation previously adopted by the UK in order to remedy any existing deficiencies. If a withdrawal agreement is indeed concluded, the current draft agreement states that the UK will continue to apply EU law for the duration of the proposed transitional period. If the UK leaves without a deal, the secondary legislation required to amend any deficiencies will need to be in place by exit day.

EU regulations and directives that come into force after Brexit will not become UK law unless specific action is taken by Parliament. For example, the new Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), which came into force on 25 May 2017 and will fully apply in EU member states from May 2020 and 2022 respectively, will only be partly in force on 31 October.

To buffer the lapse in applicability of this important new regulatory framework the UK has confirmed its intention to transpose into domestic law all key elements of the MDR and IVDR post-Brexit.

Similarly, for EU-wide clinical trials, the new EU Clinical Trial Regulation (CTR) is expected to be implemented in 2020. Whilst the government aims to align UK law with parts of the CTR, it is now clear from the Medicines and Medical Devices Bill (as put forward in the Queen's Speech of 14 October 2019) that in some respects, it will also be seeking to act independently of it, as evidenced by the proposal to "remove unnecessary bureaucracy" for low risk clinical trials.

NO-DEAL BREXIT: WHAT TO EXPECT?

In the event of a no-deal Brexit, these are some of the key impacts on the life sciences sector:

Regulation of medical devices and medicinal products

The UK's participation in the EU's regulatory network would cease. The MHRA will take on responsibilities for the UK market that were previously performed by the European Medicines Agency such as registration of all medical devices and market surveillance. The Medicines and Medical Devices Bill also places further responsibility on the MHRA to develop innovative regulation to ensure early access to new technologies.

Clinical trials

UK clinical trial applications will continue to be authorised by the MHRA, and UK clinical trials data will still be admissible in the EU and globally. Although the UK will cease participating in the European regulatory network, it will be able to continue participating in multinational trials. For those wanting to carry out trials in the UK, clinical trial requirements will remain unchanged and the UK will continue to recognise existing clinical trial approvals. There would be no need to reapply.

However, the sponsor or legal representative of a clinical trial would need to be in the UK or alternatively in a country on an approved country list, which would initially include EU or EEA countries. As above, the Medicines and Medical Devices Bill also proposes to cut the red tape in respect of low risk clinical trials with a view to making the UK an attractive place for companies to trial their products as well as enabling speedy access to medicines.

Increased administrative burden and potential delays in bringing products to market

Companies will need to comply with new requirements relating to the registration and importation of medical devices, e.g. non-recognition of devices previously certified by UK-based notified bodies will require reauthorisation by an EU notified body in order to place devices on the EU market. New devices that require a notified body to carry out a conformity assessment will require assessment by an EU notified body based in order to CE mark the device and place it on the UK or EU market.

Information sharing

Post-Brexit, the MHRA will have oversight of all pharmacovigilance activities in the UK. However, the sharing of common systems and formal exchange and recognition of data submitted between the UK and EU would cease placing the UK at risk of delayed awareness of serious adverse events.

Potential medicine shortages

In January 2019, the Department of Health and Social Care issued new reporting requirements on manufacturers to provide information about the availability of health service medicines,

discontinuations or anticipated supply shortages. As a result, Marketing Authorisation Holders are expected to be fully accountable for their supply chain to the UK market and are required to understand the potential impact on UK patients in the event supplies of their produces become unavailable.

In anticipation of counterfeit medicines entering supply chains arising from potential shortages and patients turning to the black market, the Medicines and Medical Devices Bill offers comfort to manufacturers, suppliers and patients by proposing the implementation of a scheme to combat this as well as a registration scheme for online sellers.

End to free movement of people

There are 175,000 EU nationals currently in the UK sciences and research sector who will need to apply for settled status by the end of 2020 if they wish to remain. Anticipated arduous immigration processes may dissuade top talent from wanting to work and live in the UK.

PRACTICAL GUIDANCE

Until early 2018 there had been very little by way of published practical guidance. A wave of communications followed, including:

- The EC's 'Notice to Stakeholders' highlighting the legal and practical implications of a 'no deal scenario' for certain products, to include the placement of medical devices on the European market.
- Specific industry guidance published by the MHRA and the Department of Health in respect of the proposed transition period were a deal to be reached with the EU and a series of publications relating to a no-deal Brexit, to include guidance on the regulation, of medicines, medical devices and clinical trials.
- A series of 106 Technical Notices published by the government including notices on the submission of regulatory information on medical products and batch testing of medicines.
- Advice from the Department of Health setting out the steps to be taken to ensure the continuation of the supply of medicines and medical products in the event of a no-deal Brexit, including in relation to controlled stockpiling. Further, the government is reported to have recently signed freight contracts worth £87 million with four ferry companies to transport vital medicines to the UK in the event of a no-deal Brexit.

Whilst many in the sector may say that preparations were underway soon after the UK voted to leave the EU in 2016, these publications have offered some clarity on what needs to be done to prepare for a hard or no deal Brexit.

COMMITMENT TO UK LIFE SCIENCES

Evidence of the government's ongoing commitment to the life sciences sector include:

- Professor Sir John Bell's 2017 Industrial Strategy report provided recommendations to the government on the long-term success of the UK's life sciences sector, to include industry growth, increasing productivity, improving the use of data, the development of new medical technology the critical role of the NHS and maintaining access to talent.
- The government's deals with the life sciences sector including close to £500 million of government support for major new research programmes and over £1 billion of new industry investment.
- The proposed establishment of the Health Advanced Research Programme which is backed by a £210 million Industrial Strategy Challenge Fund through which industries, charities and the NHS can collaborate on ambitious and long-term UK-based projects to transform healthcare and take advantage of the medical trends of the next 20 years.
- The government's pledge to increase R&D investment of £2.3 billion in 2021/22, raising total public investment in R&D to £12.5 billion and to boost spending on R&D to 2.4% of GDP by 2027.

Most recently, Boris Johnson announced plans to develop a new fast-track visa route to attract elite researchers and scientists to the UK as well as a pledge to invest £200 million into the sector to help companies raise capital and develop manufacturing capabilities. He has stated, "*it is part of my vision to have a vibrant post-Brexit economy fuelled by science and technology. The life sciences is a key component of this and we must continue to implement the life sciences industrial strategy*".

The Medicines and Medical Devices Bill builds upon this continuing commitment and investment, as set out here.

The government's firm commitment to the sector has encouraged continued investment in the UK by some of the world's well-known manufacturing and pharmaceutical companies. For example, Amgen, AstraZeneca, GlaxoSmithKline and Johnson &

Johnson have contributed £100 million to the UK Research and Innovation's £200 million "Whole Genomic Sequencing" project designed to research, treat and prevent life changing diseases such as cancer.

COMMENT

Notwithstanding the sector's ongoing doubt and uncertainty as to what lies ahead, stakeholders should be encouraged by the pragmatic approach taken by the UK to prepare for and safeguard the industry from the impact of a no-deal Brexit.

Furthermore, these no-deal preparations mean that the UK is likely to be well placed in respect of any deal that may be reached, bearing in mind that terms are unlikely to be agreed for some time. In these circumstances, the proposed transition period will act as a buffer, allowing time for companies to prepare for life post-Brexit.

In respect of a no-deal scenario:

- Companies can expect to continue trialling and selling products in the UK in the event of a no-deal Brexit.
- Whilst the UK would be treated as a "third country", UK-based manufacturers will still be able to continue selling products across Europe, providing that their products are aligned with EU safety standards and that relevant authorisations are obtained.
- Contingency plans continue to be implemented to respond to any risks to the supply chain and shortages, in the event that they do happen.

Overall, the industry should be buoyed by the continued commitment shown by the government and global pharma companies to investing in the future of UK life sciences.

FURTHER INFORMATION

To find out more about our services and expertise, and key contacts, go to: **kennedyslaw.com/brexit**

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