

Sector briefing

Life & health sciences



Sector Briefing : Life & Health Sciences

The UK is a global leader in Life Sciences, with 25 per cent of the world's top 100 prescription medicines discovered and developed in the UK. (BMI Research, "United Kingdom Pharmaceuticals & Healthcare Report, Q1 2016", p. 61).

There are over 5,600 life sciences companies operating in the UK, generating a turnover of over 60 billion GBP and more than 30 billion GBP in exports. These companies span the life sciences product development, supply and services chain, and employ more than 220,000 people.

Northern Ireland has a thriving and innovative Life Sciences sector with expertise in precision medicine, clinical trials and digital health. It is a major contributor to the NI economy with over 170 companies exporting almost £1b annually.

The success of the sector in the UK will depend on four key areas being addressed

- Medicines Regulatory Environment (including data protection)
- Trade
- Funding of research
- Access to talent

Regulation

The European Life Sciences sector has a highly sophisticated regulatory system developed over the past 50 years, overseen by the EU regulator, the European Medicines Agency (EMA).

UK membership of the European Union (EU) provides much of the scientific, regulatory and trade infrastructure for the sector in the UK. The decision of the UK not to be part of the European Economic Area (EEA) post-Brexit, could have a significant impact on the Life Sciences companies and post Brexit, and future agreements regarding regulation will be critical to the working of the sector.

The UK regulatory system is underpinned by a series of EU directive and regulations. Directives have been implemented into UK national law and will therefore remain in place (subject to amendment). Regulations, in contrast, are directly applicable in the UK without the need for being implemented through UK law and therefore, in theory, when the UK leaves the EU, regulations will no longer continue to apply.

The [Great Repeal Bill](#) will convert all EU law into United Kingdom law. While the Bill will replicate EU law at a domestic level. It cannot, itself, guarantee that rights granted under new UK rules will continue to be recognised by other EU member states.

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Any new UK regulatory system may increase administration for life sciences companies. Regulatory requirements, for example clinical trial authorisations and marketing authorisation applications, will need to be obtained under a new and separate legal framework from the UK regulator.

Ultimately the future relationship between the respective regulatory frameworks is all subject to negotiation. The EMA cooperates with regulatory bodies from around the world with specific agreements in place, so these provide precedents which the UK and EU could seek to build on. The UK Government has publically stated it is committed to continue to work closely with EMA and other international partners in areas such as inspections, safety of medicines and exchange of information.

The UK Government has also stated that, should we not achieve our desired relationship with the EU, it will set up a regulatory system that protects the best interests of patients and supports the UK Life Sciences industry.

Data protection

Data is becoming an ever increasing feature in healthcare provision and clinical trials, where it is an essential component in the development of new products. Many NI LS companies trade on global basis, which often requires them to process and share personal or clinical data across international borders.

Data protection is currently controlled by the EU Data Protection Directive and forthcoming General Data Protection Regulations (GDPR) which will apply from 25 May 2018. Even if the UK opts to adopt GDPR, as it currently stands once the UK leaves the EU, it will no longer be part of the EU 'safe zone' for personal data or an EU commission-approved white-listed country. All of these issues are subject to negotiation and will require agreement with EU.

Trade

On leaving the EU, depending on any future agreement, trade between the UK and EU countries could be subject to customs duties, i.e. import VAT. Until the details around trade are clear concerns have been raised that import/export declarations and inspections could cause disruption and cost.

Developing a solution that ensures UK access to medicines and medical technologies and provides an attractive environment for the continued manufacture of products for export in the UK will be crucial.

R&D and Funding

The strength of the UK Life and Health Sciences research is widely recognised throughout the world. Northern Ireland has globally recognised strengths in

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precision medicine, diagnostics and digital health research, which is underpinned by research strengths in both local universities.

The UK has been a major net beneficiary of EU funding for research, through programmes such as Horizon 2020, with Northern Ireland business benefiting significantly from European Regional Development Funding (ERDF) for research and innovation.

The UK Government has guaranteed funding for projects initiated under the Horizon 2020 initiative while the UK remains a member of the EU, but a long-term solution still needs to be agreed. The government has indicated it will seek to establish bilateral and/or multilateral agreements with the EU and other nations/entities in order to access or extend funding/collaboration options.

One possibility being proposed is that access to EU R&D funding could be retained, through the UK gaining “*associate member*” status for Horizon 2020 and its successor (as achieved by Switzerland and Israel). This would also allow UK-based academics to lead and participate in EU-wide collaborations.

Movement of People

The success of the UK Life Sciences sector is closely linked to its ability to recruit and train the best possible workforce with the variety of skills required to service a diverse sector. It relies on a steady influx of international scientists, with around 26 per cent of academic staff in UK universities being non-UK nationals. Northern Ireland companies and universities are equally reliant on attracting talent from across the globe.

The government has made clear that, although freedom of movement will cease to apply in the UK, the UK will continue to welcome the brightest and best, and as such, migration between the UK and the EU will continue after the UK leaves the EU.

Conclusion

The [Association of the British Pharmaceutical Industry \(ABPI\)](#) produced a [report](#) which sets out the sector’s preferred outcomes in each of these key areas for the UK to address as it negotiates exit from the EU.