

Assessing the impact of Brexit on your healthcare business

United Kingdom voters' decision to exit the European Union (EU), known as Brexit, will likely mean changes for the NHS (National Health Service), pharmaceutical companies and the drug approval process, medical device makers, researchers, and others. Although the extent of the upheaval remains an open question, the effects of the vote may span several years - or even a decade - to play out.

The UK will first have to negotiate its exit terms with the EU's remaining 27 member states, which might take until 2018/2019. Separately, the UK will need to negotiate its future trading relationship with the EU. The EU will likely also undergo significant change in the coming months and years. Undoubtedly, the life sciences and healthcare industry will be affected by Brexit and the vote was a disappointment to the sector.

The life sciences industry contributes approximately 10% to the UK's GDP. Several major pharmaceutical companies, including AstraZeneca and GlaxoSmithKlein, are based in the UK and both depend on the EU-UK for at least a quarter of their revenue.

GlaxoSmithKline CEO, Andrew Witty, said in a letter to **The Guardian** that the UK remaining in the EU "would enable the sector to continue to operate within an established and harmonised regulatory approval system, ensuring that UK patients benefit from medicines more quickly, and that medicines researched and manufactured in the UK are available across the EU sooner." The letter, signed by over 90 life science stakeholders, added that "leaving the EU would bring added complexity and uncertainty, which is bad for business and research."

We are about to find out if they were right. But in the face of uncertainty, it is important to stay calm, review contingency plans and assess the possible implications for your organisation, including the risks and opportunities this creates.

At Grant Thornton we see our role as helping you navigate and shape this environment. Our international advisers are well placed to help you achieve your business objectives and we have outlined some considerations in this viewpoint. We will be sharing further insights over the coming months as the UK's path to exit from the EU and its implications become clearer.

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Assessing the impact

Regulatory upheaval

The EU's drug approval agency, The European Medicines Agency (EMA), is based in the UK and plays an important role in the healthcare sector. In fact, 20% of the EMA's activity comes from the UK. However, when Brexit takes effect the EMA is likely to relocate from London, and the UK could lose its 'seat at the EMA table'. It will no longer be part of the EU's centralised regulatory and market authorisation process and its influence will be reduced.

The role of the UK's drug regulator, the Medicines & Healthcare products Regulatory Agency (MHRA), also looks set to change. The MHRA currently conducts about a third of the regulatory work for EMA reviews and new arrangements will be required for this. This, in turn, could delay drug approvals.

In addition, as the UK regulatory process separates from the EU, the compliance burden on the industry may increase. This could both delay the UK's access to innovative medicines, and make it harder for UK firms to innovate. In fact, with the EMA and US Food and Drug Administration aligning policies to simplify market access, UK firms could be at a competitive disadvantage.

Finally, Brexit may impact on pharmaceutical companies involved in 'inversions'. These deals see US firms combining with EU businesses to obtain better tax rates. But with tax laws, treaties and trading relationships facing upheaval, this strategy may not be as favourable as in the past and previous inversions may need to be reevaluated.

Research funding

R&D is likely to suffer as the industry rethinks requirements after the Brexit vote. **About 16%** of the funds that UK life science companies spend annually on research come from EU grants. This is a particular problem for UK life science firms, who may lose their EU grants and funding from the European Research Council over time.

The UK also receives more funding from the European Research Council than any other EU country supporting university based research. One government minister told Parliament's Science and Technology Committee that Brexit could threaten as much as \$8 billion in EU funding for UK science over the next four years.

The National Health Service (NHS)

"When the British economy sneezes, the NHS catches a cold," Simon Stevens, the NHS England CEO, told the

BBC on 22 May, adding that "this would be a terrible moment for this to happen." A few days after this comment, survey results were released reporting that three-quarters of NHS chief executives felt that leaving the EU would have a negative impact on the NHS as a whole. They were worried about research funding and talent recruitment, but had economic concerns too. The NHS has already been under increasing budget pressure over the past several years and additional cuts could begin to affect quality, access, and timeliness of care.

Funding can also impact the NHS specifically as a purchaser. The NHS may have less money to spend with private suppliers and may look for better value per pound it spends.

Talent

Talent recruitment and retention is an on-going challenge for the NHS. A recent '**NHS Workforce Statistics report**' stated that approximately 56,000 EU nationals work in the NHS as of February 2016 - with more in the long term care sector. Brexit may reduce the NHS's ability to access this talent pool and salaries could therefore increase, impacting on costs, access to care and quality of care. Talent is also an issue for UK pharmaceuticals. But their concerns relate to funding cuts and the regulatory fallout from Brexit, which may see scientists emigrate to find more conducive conditions elsewhere.

Private healthcare

It is possible that NHS funding cuts could boost the UK private healthcare market. With the industry's regulators in turmoil, some experts predict that competition could actually increase access and potentially improve quality in the UK healthcare model.

What's next?

In summary, there are more questions than answers to the Brexit vote and its ultimate impact on the industry. The financial markets do not like uncertainty, and neither do many of the industries that rely on capital funding from those markets. No one was quite prepared for a 'leave' vote, and the ramifications around the world are still not clear. As EU cohesion and European and UK financial instability progress, trade agreements and other contractual relationships are all at risk. Many experts suggest a 'wait and see' approach, but it is wise to think through the possible risks and opportunities to your business so that appropriate strategies can be considered to weather this uncertain storm.

Considerations

To keep moving forward in the post-Brexit environment, companies must anticipate the changes it will bring and adapt to meet them. In looking at the threats and opportunities Brexit poses for your business, and in planning how you can create and protect value, you should consider:

People and talent

Short term:

- Assess how many of your UK employees are of EU or non-EU origin
- Consider what to communicate to them and what reassurance you can give
- Assess the impact of exchange rate fluctuation on global talent.

Medium term:

- Review employment contracts and take steps to protect your non-UK talent
- Assess the impact on any outsourcing or teams in other EU jurisdictions.

Long term:

- Consider your current location. Where is the best place to operate from?
- Plan for the longer term impact on talent recruitment, development and pensions.

Strategic ambitions

Short term:

- Consider what to communicate to stakeholders
- Review your existing strategy and immediate impacts.

Medium term:

- Review M&A transactions and due diligence
- Identify transitional market and customer opportunities.

Long term:

- Identify new markets and commercial opportunities
- Assess the opportunities for organic growth, joint ventures and acquisitions.

Finance growth

Short term:

- Consider what to communicate to investors
- Assess the impact on any immediate refinancing

Medium term:

- Review the impact on sources of capital
- Assess the opportunities and risks around re-financing.

Long term:

- Assess the funding requirements for future strategy
- Identify future capital markets and investors.

Master risk

Short term:

- Assess the funding requirements for future strategy
- Identify future capital markets and investors.

Medium term:

- Assess the impact on business risks including issues such as working capital management and financial reporting.

Legal:

- Assess the impact on existing legal contracts and mandates, and cross border data management
- Identify what documentation will need to be changed.

Long term:

- Assess the longer term plans for business risks including tax structure and pension structures
- Review your strategies for mitigating fraud, bribery and corruption risks.

Optimise operations

Short term:

- Consider what to communicate to customers and suppliers
- Identify your current and future exposure to interest rate and foreign currency exchange rate fluctuation.

Medium term:

- Assess the impact on processes and control
- Future regulatory compliance
 - Identify which regulations critically impact your business
 - Consider the likely timescale for any change in these business critical regulations.

Long term:

- Review your operational effectiveness and efficiency including back office and manufacturing/cost base
- Identify opportunities for developing supply chain value in different trading relationships.

Contact us

As you face a more uncertain environment we can help you work through the implications and develop the best plans for your organisation.

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