The reverberations of the United Kingdom’s (UK) decision to opt for Brexit are still being felt one week on. Its aftermath has left a trail of political resignations, volatile markets and unrest in European capitals and beyond. This should come as no surprise; such a momentous decision is without parallel in peacetime politics. While immediate discussions focus on if and when the UK will invoke Article 50 and formally begin the process of exiting the European Union (EU), thoughts are also turning to the impact of the decision on the EU’s far-reaching policy and regulatory agenda.

EU institutions have not ground to a halt following the vote; the EU will continue to regulate and formulate new policies in areas that impact business and affect investment decisions not only within the EU, but globally. With 73 Members of the European Parliament, an active and effective diplomatic network, and crucially 29 votes in the Council of Ministers (the same number of votes as Germany, France and Italy), it is clear the effects are beginning to be felt already. As well as the wider political implications of the UK’s exit, FTI Consulting is taking a detailed look in this series of snapshots into what Brexit means for some of the EU’s policies of most relevance to business.

The EU healthcare sector

Health and life sciences are heavily regulated sectors, which directly employ a significant proportion of the workforce across health and care delivery, pharmaceuticals, research and development, education, animal health and the many other issues covered by the sector. The sector drives a significant percentage of trade inside and outside the EU market and healthcare consumes, on average, 10 per cent of national budgets across the EU.
As with all other sectors, the real impact of Brexit on the health and life sciences sectors will not be known until the timeline and form of Brexit has been established. Current indications are that the UK will not invoke Article 50 – the relevant article of the Treaty on EU that enables withdrawal – until a new Prime Minister is in place.

In the short term, therefore, the main impact of Brexit is one of uncertainty as businesses and individuals try to work out how to plan within a vacuum.

In this snapshot, we highlight the areas of EU legislation and policy that impact health and life sciences, focusing on the three key areas of market access and trade; research and innovation; and patient care and patient mobility.

**Market Access and Trade**

European Medicines Agency and central marketing authorisation

London hosts the European Medicines Agency (EMA), the EU’s one-stop shop for a centralised marketing authorisation (MA), which allows medicinal products to enter all EU and European Economic Area (EEA) and European Free Trade Association (EFTA) states (Iceland, Liechtenstein and Norway).

The centralised procedure is compulsory for all human and veterinary medicines derived from biotechnology and other high-tech processes. It is also open to products that bring a significant therapeutic, scientific or technical innovation. As a result, the majority of genuinely novel medicines are authorised through the EMA.

The EMA is very unlikely to stay in London; interest to host the agency has already been shown by Germany, Italy, France, Sweden and Denmark. The move is likely to be reasonably swift and may raise the following issues:

- **EMA Staffing:** UK scientists may have to leave the EMA following the withdrawal process; others may be unwilling to relocate in another EU country.
- **Legal:** Internal rules and polices of the EMA currently refer to the law of England and Wales, and will need to be changed depending on where the EMA is relocated.
- **Workload:** 15 per cent of all applications via the centralised procedure are currently handled by the UK Medicines and Healthcare Product Regulatory Agency (MHRA), the UK notified body. These would have to be redistributed amongst the remaining notified bodies. Moreover, the UK will not be eligible to supply rapporteurs or committee members participating in the EMA’s decision-making.

These issues are likely to cause a general slowdown in the agency’s work, including market authorisations.

It remains to be clarified how EMA market authorisation will impact on sales into the UK market by non-UK companies seeking market access based on EMA authorisation, and how domestic sales will be regulated.

The slowdown could result in increased costs (direct or indirect) for companies seeking access to European markets and lead international companies to prefer the US Food and Drug Administration rather than the EMA for first authorisation of their products, thus impacting access to EU market and citizens.

EMA internal organisational and licensing arrangements are restricted to EU and EEA members. If the UK government is not an EEA member, it may want to negotiate a Mutual Recognition Agreement with the EMA for mutual recognition of decisions with the UK MHRA. Such agreements already exist between the EMA and Switzerland, Canada and Australia.

**Clinical Trials Regulation and Medical Devices and In Vitro Diagnostic (IVDs) Regulation**

Clinical trials and health technology assessment in the EU are governed by the Clinical Trials Regulation and Medical Devices and IVDs Regulations, which were recently agreed upon. Brexit is unlikely to affect the functioning of these regulations significantly, but will raise issues for the UK.

The EU Clinical Trials Regulation (EU) No. 536/2014 will fully enter into force between 2017 and 2018, with a new EU clinical trial portal and database. However, considering that the UK’s withdrawal procedure would still be under way, it is unclear whether UK-based companies will have access to the trial portal and database. The impact on trials already underway in the UK – and future trials – will have to be assessed. In the future, it is likely that the UK will need to reach separate agreements with pharma companies to conduct clinical trials, leading to increased paperwork.
The Medical Device Regulation sets the standards for the European Conformity Mark (CE Mark), which all medical devices require to enter the European market. If the UK does not join the EEA, the UK and the EU may try to agree on a specific mutual recognition agreement for medical devices, where CE Marked devices can enter the UK. Regardless of the future set-up, however, the impact for the UK medical device industry looks negative.

**Trade**

According to the Confederation of British Industry (CBI), the EU accounts for 56 per cent of UK pharma exports, which total around €64 billion. The impact of not being able to export as part of the EU will be significant for the UK pharma industry. The negotiations will have to clarify how the UK will continue to trade within and outside the EU.

Beyond pharma trade, there is also a certain amount of cross-border healthcare trade between EU countries in which both public and private healthcare providers buy planned interventions and surgery from partners in other countries to relieve load and waiting times on healthcare providers in their own countries. This will also be affected.

The impact in trade will also stretch into the health technology sector – notably health IT – where the UK has several large players. In theory, even though the UK would no longer be legally required to comply with EU regulations in this area – such as data protection and information and IT security – it is unlikely that they would be able to abandon their requirements if they wish to continue to trade in public healthcare markets, as well as some private markets.

- UK pharma export is likely to decrease. The Economist Intelligence Unit estimates that UK-based pharma could lose up to 10 per cent of sales as a result of Brexit.
- The inclination of major international pharma companies to locate regional headquarters in the UK may be reduced if the UK no longer hosts the EMA and is no longer part of the EMA authorisation system.
- The UK could not easily take part in planned cross-border care trading; health IT trade is also likely to be impacted.

**Research and Development**

The EU currently runs the world’s biggest research and development (R&D) public/private partnership programme, The Innovative Medicines Initiative and Horizon 2020 provide public funding to attract investment in developing new medicines and products. These collaborations are not only about providing finance but also encourage the sharing of knowledge and expertise between industry, academia and government to boost pharmaceutical innovation within the EU. The EU research budget invests heavily in UK healthcare and life sciences research, and benefits from the active engagement of UK university and industrial laboratories taking part in research - both collaboratively with other EU entities and individually.

- The primary negative Brexit impact is likely to be on the UK, which received approximately €7 billion, or 15.5 per cent of total Horizon 2020 funding, second only to Germany. As the UK leaves the EU, there will be a lengthy period of uncertainty in relation to R&D funding as the UK negotiates its exit and new regulations and legislation are decided.
- The impact on research staff, both British and European, could also be significant as some seek to move out of the country, creating a ‘brain drain’.

There is a risk of disinvestment from the EU even before Article 50 is triggered, resulting in reduced R&D funds being made available to UK academic and research institutions.

**Patient Care, Patient and Professional Mobility**

Fundamental EU freedoms include mobility of services and people, which in the health sector extends not only to the mobility of researchers as noted above, but also of patients and healthcare professionals.

Since 2011, the European Patient Rights Directive has codified the processes of access and reimbursement when a European citizen seeks healthcare in a country other than his or her country of residence.

- British citizens may not be able to access planned or emergency care in the EU at present – new insurance products may have to be created.
- The UK National Health Service (NHS) currently treats many European visitors; new billing systems to cope with this care would need to be established.
- The NHS Confederation has noted there are currently 130,000 EU health and care workers in the UK, including 10 per cent of doctors and 5 per cent of nurses.
- In a post-Brexit scenario it is unclear whether these staff could or would want to remain in the NHS. New recruitment from Europe could also be much more difficult; both issues could cause significant staffing shortages in the NHS.
The organisation has already warned that doctors and nurses from Europe may be put off accepting jobs after the referendum. There are signs this had already started happening, with reports that an EU recruitment drive in West Yorkshire had already run into difficulties.

The UK is heavily involved in the current initiative to create European Rare Disease Networks (ERNs). The UK has a leadership role in more than half of the ERNs earmarked for the first round of funding, which will now have to be reconsidered. In this context, the UK would not be able to share its rare diseases expertise in the way planned under the new ERNs and UK patients may not be able to benefit from them.

Conclusions
Brexit will have profound consequences on the healthcare and life science sector both in the EU and in the UK. Those who had previously relied on UK governmental support to make their case in Brussels are now likely to require help from elsewhere, given questions about the UK’s continued influence in Brussels.

The pharmaceutical industry, patients, researchers, advocates and employees in the sector, will all be affected from the existing uncertainty and the re-negotiation of the UK’s position vis-à-vis the EU. A number of different potential scenarios are currently under consideration by European and British experts. Being prepared to quickly react to the potential policy and legal consequences of these has become the priority. At the same time, the resulting uncertainty requires immediate action within organisations, particularly related to preparing management and offering reassurances and guidance to employees.

The EU has far-reaching and subtle effects on the health sector beyond purely economic considerations, raising many questions about what the prospect of leaving it could mean for the NHS. What is clear, though, is that health service and medical research face an unprecedented situation and it is difficult to predict the level of impact that Brexit will have on the NHS. It is also clear, however, the sector will not grind to a halt. Patients will continue to need care, trials already in process will continue, and disease prevention strategies will continue to be implemented as far as possible. It should also be noted that not only the EU, but also the World Health Organisation and other UN bodies have a role to play in driving national and international healthcare and life sciences policy.