

# *Brexit Monitor*

## The impact on Pharma & Life Sciences





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In 2014, the pharmaceutical market value (in retail prices) in Europe was approximately €267 billion. More than 700,000 people are employed in the European pharmaceutical industry, of which 10% are in the UK. According to the International Trade Council, UK pharma exports to the other EU countries were valued at around £15 billion in 2015. Pharmaceutical products were in the top 5 of products most imported and exported from the UK to the EU and vice versa. In 2014, the pharmaceutical industry invested an estimated record €30 billion in R&D in Europe, although the R&D expenditure in emerging economies is growing even faster.

## Top 10 pharmaceutical production in European countries

	€ million
1 Switzerland	33,010
2 Germany	29,010
3 Italy	27,461
4 France	20,507
5 Ireland	18,896
6 UK	18,183
7 Spain	14,486
8 Denmark	8,725
9 Belgium	8,034
10 Sweden	6,677

Source: EFPIA

The pharma and life sciences industry is subject to more EU derived legislation than most other industries. Hence, the impacts will be large once the UK leaves the EU.

## What's in store for pharma and life sciences?

As pointed out in earlier Monitors, the main immediate effect of the UK's vote to leave the EU is heightened uncertainty for a period of at least two years. Depending on which exit scenario will materialise – EEA member, Free Trade Agreement, bilateral agreement or WTO scenario –, the pharma and life sciences industry may be affected in a broad range of areas from product development to market approval to the shipping of medicines and medical devices. In the UK, the pharma industry will want to manage the impact carefully to prevent some of the negative aspects. However, uncertainty will impact pharmaceutical and life sciences companies in other European countries as well.

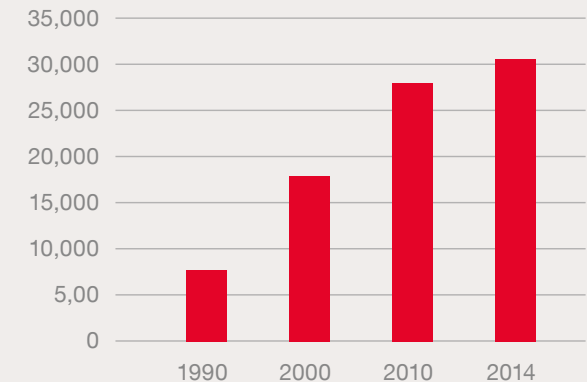
## Top 5 pharmaceutical R&D carried out in European countries

	€ million
1 Germany	6,063
2 Switzerland	5,048
3 UK	4,807
4 France	4,789
5 Belgium	2,493

Source: EFPIA

The main areas impacted will be:

## Pharmaceutical R&D expenditure in Europe (€ mln)



Source: EFPIA

## • Uncertainty about R&D funding

In any of the Brexit scenarios the UK pharma companies would no longer have automatic access to the EU's Research and Innovation programmes, such as Horizon 2020. Under an EEA or bilateral 'Swiss style' scenario, the UK could become an associated country or a third country to Horizon 2020 in order to continue to be eligible for funding. However, this comes with the condition that the UK would still contribute to the programme, and its share of funding may well fall. As negotiating the status of the UK in Horizon 2020 may take time, UK based multinationals might transfer key research



Pharma &  
Life Sciences

projects outside the UK to ensure that they can continue to participate in international research programs. Other European pharmaceutical companies may prefer to put their research teams in other EU countries in the lead. On the other hand, the UK would no longer be bound to strict tax regulation. This means that the UK would have the flexibility to enhance a favourable tax regime for innovative activities to attract new investments without running into illegal state aid risks. This could be a competitive risk for Europe.

On the fiscal side, a UK exit from the European Union – and especially under a FTA or WTO scenario – would mean decreased contribution to the EU budget, including to research funds. Any framework programs put in place after 2020 may therefore be impacted by a lower EU budget, and in the medium-term, continental pharma and life sciences companies would have to compete for a smaller amount of research and innovation funds.

- **Clinical trials may become more costly**

According to the Association of the British Pharmaceutical Industry, the UK is the EU's most popular location for phase I trials. It also ranks second, after Germany, for phase II trials and third, behind Germany and Spain, for phase III studies. As and when the UK exits the EU, the UK clinical trials industry may see a drop in the number of trials run out of the UK. Pharmaceutical companies and medical technology suppliers may favour running trials in EU member states, as it will give them access to a larger market.

Additionally, as of 2018, the new EU Clinical Trials Regulation will apply, aiming to facilitate pan-European clinical trials. If the UK would no longer be part of the EU regulatory system, UK involvement in these trials will become more difficult and costly. Pharmaceutical companies may need to set up separate trials for the UK, leading to higher costs and more time consuming processes.

- **Slower authorisation of new medication and medical devices**

Medical devices need to be assessed and should meet the quality standards of the European Medical Devices Directive. When approved, they get a CE mark. In all Brexit scenarios the CE mark will no longer automatically grant access to the UK market. In the EEA scenario, the UK would be able to continue manufacturing, importing and exporting medical devices with a CE mark, although these devices would have to be nationally authorised in the UK by national administrative measures or by measures automatically ratifying EU authorisation decisions. In the Swiss scenario, the UK would need to approve medicines and medical devices separately from the EU. Within such a bilateral agreement however, there would be some scope for recognition of the quality of pharmaceuticals manufactured in the EU and vice versa. Separate assessments and quality control testing would thus not be necessary.

In the other Brexit scenarios, the UK would need to create a similar medical device authorisation process to the EU in order to smooth the pathway to market for new devices.

If Single Market authorisation from the European Commission would no longer apply for the UK, the UK's Medicines and Healthcare products Regulatory Agency, MHRA, may be equipped with the task of authorising medicines for the UK market – either by duplicating the European Medicines Agency's (EMA) assessment or by setting up a new process for recognising EU approvals. In either case, extra pressure on the MHRA might slow the authorisation process of new medicines. Pharma and life sciences companies may be faced with having to make two applications for the same product – for the EU and UK markets. This would lead to significant costs increases.

- **Uncertainty regarding IP rights and increased administrative burden**

The pharmaceutical and life sciences industry relies heavily on intellectual property (IP) rights, in particular patent rights, to allow and protect the exploitation of medication and medical devices. Brexit causes considerable uncertainty regarding the geographical validity of patents. Will national UK patents automatically be enforceable in the EU and will European Patents automatically be enforceable in the UK? This will depend on the form that Brexit will take and on the changes to IP legislation that the UK and the (member states of the) EU will make.

Also, with respect to patents, the EU is close to creating a 'Unitary Patent' (UP) and a 'Unitary Patent Court' (UPC) which offers patent protection across the EU. The UK has been committed to



Pharma &  
Life Sciences

implementing the UPC agreement, but with a Brexit approaching it is likely that the UPC system will proceed without the UK.

Pharmaceutical and life sciences companies should review their IP portfolio, with a particular focus on the geographical validity/enforceability of their IP rights. Depending on the form that Brexit will take, there may be a need to apply for separate UK national IP registrations and/or for separate EU IP registrations. This would mean an increased administrative burden. IP licence agreements should also be reviewed for their geographical cover and whether the Brexit could trigger 'material adverse change' type clauses.

### ***Mainland Europe more attractive as place for market entrance***

In the past, American and Asian pharma and life sciences companies have invested in the UK as a foothold to enter a wider European market. Depending on the negotiation outcome, the UK could become a less suitable platform for accessing Europe. Which country could fill this void? Germany, Belgium, the Netherlands, Switzerland and France are potential alternatives, given their skilled workforce, nearly native English speakers, favourable climate for expats and good tax incentives for innovative activities. The list of countries speaks for itself and if the UK would manage to obtain a status similar to that of Switzerland in its exit negotiations with the EU, the UK may still provide this foothold.

### ***Trade***

The current EU system grants free movement of goods. This means that a UK manufactured product – pending market authorisation – can be shipped directly to the rest of the EU and vice versa. In all but the EEA scenario, trade would be impacted and a UK based manufacturer would likely need an import licence, as well as mutual recognition of manufacturing standards and safety regulations.

### ***Labour market***

The UK based pharmaceutical industry directly employs around 73,000 people, of which 10,000 work in research and development (R&D). Multinational pharma companies with their base in the UK typically employ international teams. The pharmaceutical and life sciences industries in the UK employ approximately 5,000 non-British EU citizens.

Should the UK change its migration policy and restrict freedom of labour as part of its exit deal with the EU, this may impact both established companies and the core research base in the UK. Companies may consider relocating to other EU countries as this would facilitate the employment of EU nationals. On the other hand, relocating to the EU could mean that UK employees would then face burdensome visa processes and costs. Other EU countries may benefit from a change in immigration regulations. As working for an UK based company might become less attractive for highly educated foreign employees, these employees may turn to companies in the EU.

### ***Relocating EMA and Life Science Patent Court***

In addition, at an EU level, there are also two very practical implications to consider. The European Medicines Agency (EMA) which regulates the access of medicines to EU member states, is currently based in London and would need to be relocated. In all but the EEA scenario, the UK would no longer be covered by the EMA based system. The country would need to devise a framework to ensure authorisations for existing products are maintained for both new and existing products. Besides the EMA, there is also the Unified Patent Court for Life Sciences. In early 2017, the Unified Patent Court (UPC) will start operating in the EU. One of its branches, on chemicals and pharma, is currently planned to open in London. This location decision would now be revisited.

### ***Healthcare Trilemma***

As pointed out before, depending on which exit scenario will materialise, the pharma and life sciences industry may be affected in a broad range of areas, from product development to market approval, to the shipping of medicines and medical devices. But what might be the consequences for the European consumer? If we look at the healthcare trilemma: accessibility, affordability and quality of care, higher costs for pharmaceuticals and medical devices companies, because of tariffs and/or non-tariff barriers, costs for relocating research teams, or slower market authorisation processes, may result in rising costs of medicines and medical devices. These increasing costs will in the end be





Pharma &  
Life Sciences

passed on to health insurers and consumers. The accessibility of new medicines and new medical devices may be threatened, as it will take time to establish and optimise new authorisation processes. The good news is that we do not think the UK leaving the EU will affect the quality of care in Europe or in the UK.

### **What can pharma and life sciences companies do to deal with these changing conditions?**

With the uncertainties and possible scenarios in mind, what should pharma and life sciences companies do to deal with these changing conditions?

- Begin to plan for uncertainty: consider the four main scenarios for Brexit in the key areas of regulatory, labour, investment and fiscal then identify risk mitigation strategies and ask yourself “are we prepared?”
- Assess how each future scenario may affect business.
- Apply familiar risk management tools, but do not focus only on risks, and keep an open mind to opportunities.
- Perform an immigration check to identify those key employees who could lose their right to remain in the UK, as well as the UK nationals who may need to relocate from the EU to the UK.
- Communicate with your staff to reassure them that they are valued. Consider sharing guidance on applying for permanent UK residency. Consider sharing guidance on applying for permanent residency for UK staff in the EU countries where you have any operations.

	<b>EEA member (Norwegian option)</b>	<b>Free Trade Agreement (FTA)</b>	<b>Bilateral Agreement (Swiss option)</b>	<b>No access agreement (WTO/ MFN)</b>
Situation	The UK remains part of the EEA and keeps the four freedoms of people, capital, goods and services	The UK negotiates a Free Trade Agreement (FTA) with the EU	The UK enters into a bilateral integration treaty with the EU	The UK does not establish any new trade agreements with the EU
Potential implications	The UK would need to contribute to the EU budget and comply with EU social, employment and product regulation	Tariff-free trade between the UK and the EU	The UK would have access to some areas of the Single Market, at the cost of adopting the relevant EU regulations	Only WTO terms apply – UK goods and services would be treated in the same ways as those of third countries
Impact on pharma companies	This scenario would allow the UK to retain access to the EU market and participate in trials. EU authorised medical products would have to be nationally authorised in the UK. Alternatively the UK may wish to enact legislation which gives automatic effect to EU marketing authorisation decisions.	Depending on what agreement is reached. The UK may want to negotiate as complete market access as possible. Depending on the concessions demanded by the EU, extensive market access may be feasible or not.	The UK would need to approve medicines and grant clinical trial authorisations etc., separately from the EU (and the EEA). The UK could recognise the quality of pharmaceuticals manufactured in the EU and vice versa, thus ensuring quicker market access.	This scenario presumes a complete separation of the UK systems for pharmaceutical regulation from that of the EU. Under a Most Favoured Nation (MFN) status, a 0% tariff would apply to the UK on pharmaceuticals. However, there could be tariff implications for component parts and broader goods used. There could be scope to agree mutual recognition of GMP inspections and certifications, subject to negotiations and the willingness of the EU.

These scenarios are the most likely, however a number of variations could be negotiated



Pharma &  
Life Sciences

- Be prepared to answer questions from your investors - how may existing funding be affected and do you have alternative funding in place?
- Review your regulatory and clinical trials strategies to determine if they will work under the different Brexit scenarios and timescales.
- Identify the products — both marketed and those in the pipeline — that would be directly affected, with red flags for those facing the highest uncertainty. ■

#### The view from an emerging market

Turkey, as an emerging market, will be impacted when the UK leaves the EU through trade conditions and currency fluctuations. More specifically, there is a direct relation between European pharmaceutical prices and the Turkish ones, as Turkish pharmaceutical prices are indexed to the euro. Any changes in the market value will directly impact the prices of pharmaceutical products.

On the other hand, Turkey uses a reference pricing system, in which the price of a pharmaceutical product is set at the lowest sale-to-warehouse price of (i) five EU reference countries (France, Spain, Italy, Portugal and Greece); (ii) the country where the product is manufactured; or (iii) the country from which the product is imported. Thus, it may have indirect effects on the pricing in Turkey when the five EU reference countries use pharmaceutical products that have been imported from the UK.

The authorisation process of medicines will be an even more important issue to Turkey. Turkey currently accepts medicines that are EMA approved. When the UK leaves the EU, in all but the EEA scenario, the UK would no longer be subject to the EMA approvals. Authorisation processes will take more time, unless specific new bilateral or (free) trade agreements are ratified.



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