Novasecta

INSIGHTS

What Pharma Can Do About Brexit

Though most companies are watching and waiting, those that are at a point of considering new or increased long-term investment in European R&D or manufacturing footprint are less enamoured by the UK now that its relationship with the EU has become so uncertain.

The business uncertainty that was created by the UK's referendum vote on 23rd June 2016 will be felt for many years to come. The result of the vote was certainly an unwelcome surprise to the pharmaceutical industry. Novasecta privately interviewed 20 top executives from leading European pharmaceutical companies to ask how they are dealing with it. Their perspectives do not make cheerful reading for the industry. With the exception of short-term currency gains for some, the executives did not cite any clear benefits for their companies. And though most companies are watching and waiting, those that are at a point of considering new or increased long-term investment in European R&D or manufacturing footprint are less enamoured by the UK now that its relationship with the EU has become so uncertain.

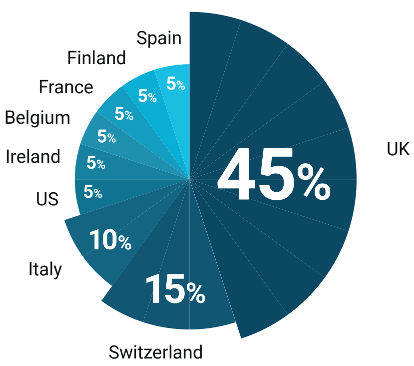
Novasecta systematically researched the implications of the Brexit vote over the three-month period since the UK referendum vote on 23rd June 2016. In this paper we share the insights from our research and suggest what can be practically done about it.

We carried out 20 in-depth private individual interviews with top executives from the European pharmaceutical industry. The 20 companies that we covered all have pan-European and global interests. 75% of the interviewees were members of the corporate management team ("C-suite") of their companies. Half were from companies headquartered in the UK, half were from companies headquartered in other European countries.

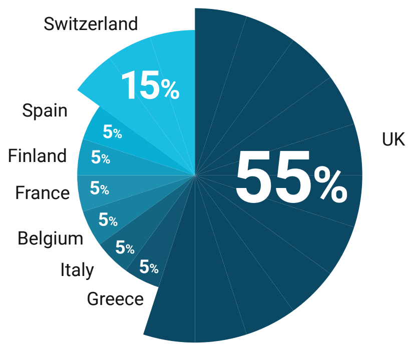
All of our interviews were carried out on the basis that none of the comments made would be attributed to any individual or company. This approach has yielded a unique insight into what is actually being discussed and decided upon in the top management teams of leading pharmaceutical companies across Europe.

We interviewed a diverse set of top European pharmaceutical executives

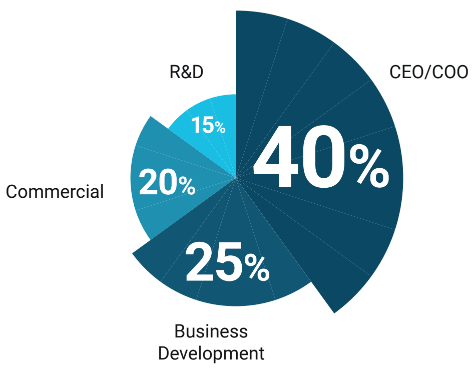
Company HQ Location



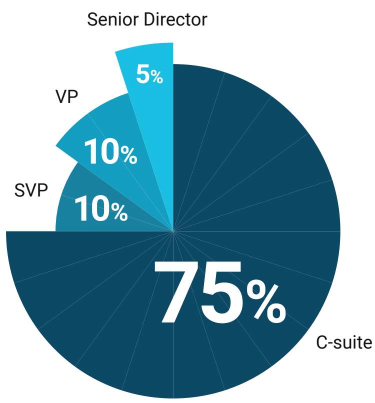
Respondent Location



Functional Area



Respondent Title



An unwelcome surprise

Pharmaceuticals is a long-term business. The executives we interviewed were therefore universally reluctant to make immediate decisions to reverse any prior commitments that were made to the UK when it was firmly part of the EU.

> **“The Board and Executive Team didn’t believe we’d leave”**

The stages of dealing with the vote are familiar to dealing with any political/economic shock. Since none of our sample expected the UK to vote as it did, once the vote had occurred they moved swiftly to consider the implications more deeply. Almost all had assigned responsibility to a senior executive or team to report out to the top management and sometimes Board of their companies on the implications of the vote and what to do about it. In some cases, executives were assigned to assess implications before the vote, and almost all did post-vote.

> **“We can waste a lot of time speculating on all the aspects”**

Three months in, executives are getting used to the new uncertainty. For some this is down to straight pragmatism:
From a commercial perspective, when compared to other countries in the world the UK has always been a tough market for pharmaceutical companies with its relatively difficult pricing environment and small size in terms of GDP compared to more attractive and larger markets such as the USA. This is unlikely to change much as a result of Brexit, so our executives are typically taking a more or less “business as usual” philosophy to their UK commercial operations.

However the R&D and Manufacturing implications are potentially more profound. The UK has traditionally been one of the strongest companies in the EU from the point of view of science base, clinical/regulatory ecosystem and funding environment. While no hasty actions are being taken by the companies in this area, those that are making decisions on R&D or manufacturing footprint are already factoring Brexit-related uncertainty into their decision-making.

People have been the biggest immediate impact so far

Clearly there have been some exchange rate benefits or losses so far depending on the company’s individual footprint, but these were not considered to be strategically significant or warrant any specific response. Executives have had to deal with global exchange rate fluctuations for many years and will do so for many years to come.

The only effect that has already been felt, and to be clear only by some in our sample, is on people and talent. Executives have had to deal with current non-UK employees of their companies who are now located in the UK, and of those that are or were considering moving themselves and their families to work with their companies in the UK.

> **“Companies are people, and our people are pretty rattled”**

The effect on people is not something that can be measured in a business case of profit and loss account, but it is not welcome in an industry that has traditionally been highly international and globally minded. The innovation that is required for success in pharmaceuticals ultimately comes from motivated people. Executives expressed concern about both their employees in the UK and the potentially contagious effects of xenophobia and isolationism across Europe that may have been triggered by the UK’s vote.

For current employees located in the UK, a perceived atmosphere outside of work of “non-UK citizens not welcome here” that has been stirred up by the vote itself, and by much of the political and media noise around it, is already taking its toll according to the executives that employ a significant body of non-UK EU citizens in the UK.

> **“A potential senior hire from outside the UK had second thoughts, saying it is too difficult to take a big decision [to move to the UK] based on the uncertainty”**

The negative impact for recruiting into the UK has also started. More than one executive gave an example of a senior-level potential hire who would have moved to the UK to join their companies but withdrew his or her application having heard of the vote result. Others reported that they knew other companies that had experienced the same. While such examples are not universal, after all the industry has traditionally been international with executives locating seamlessly between many EU and non-EU countries, they are real.

Rationally choosing where to work on the basis of whether UK ends up in the EU or not may not make logical sense compared to choosing on the basis of the nature of the work and people in the company itself. But emotions can trump rational decision-making. The toxic effect of Brexit on people living in the UK will sadly be felt for many years to come.

Fiscal effects will require careful management

Pharmaceutical companies typically have complex supply chains in Europe for both their on-market products and for their clinical trial supplies. The fiscal rules on tax treatment of profits, tax relief on activities such as clinical trials, and the tax treatment of royalties on Intellectual Property (IP) in the various non-EU and EU European countries will likely change. Similarly companies are considering the effect on their supply chains and the potential extra costs of transferring goods between their various European locations, even if such supply chains are with contract manufacturing organisations. Detailed issues such as transfer of goods, packaging and registering need to be considered by every company with a pan-European footprint.

While our sample of executives were not considering changing anything immediately on the basis of fiscal effects as a result of the vote, these issues were high on the agenda for one that happened to be already in a process of decision-making concerning its UK operations in the context of the company being headquartered in a non-UK EU country. No-one can predict how the tax, exchange rate and potential tariffs and regulations will evolve over the years, but the uncertainty and risk of the UK as a potential non-EU county is adding a negative weighting to business cases that involve investing in it.

Increased regulatory complexity, costs, and delays

The Brexit topic that inevitably comes high on the list for pharma companies in Europe is that of the European Medicines Agency (EMA). Based in London, this institution has been responsible for making the registration and regulation of drugs in the European Union much more straightforward for pharma companies than having to register individually in each European country. However the institution is currently located in London, and if the UK is not part of the EU, the pharmaceutical executives we interviewed found it hard to envisage this most European of institutions residing in a non-EU country.

> **"EMA is a fundamentally EU institution: it cannot remain in the UK"**

Related to the EMA issue is the future of the UK's Medicines & Healthcare products

Regulatory Agency (MHRA). MHRA prides itself on being one of the most influential country regulatory bodies in EMA, indeed in terms of the number of Committee for Medicinal Products for Human Use (CHMP) rapporteurships/co-rapporteurships, the UK was the largest country contributor in 2015 with 40 compared to next largest Sweden (34), Germany (27) and the Netherlands (22), according the EMA's 2015 annual report. If the EMA moves out of London (Sweden, Italy and Denmark have already made no secret of their desire house the EMA) the MHRA is highly unlikely to disappear entirely, but its reach will be diminished and it is hard to see its influence in Europe increasing.

Our research revealed the two fundamental issues for the industry regarding EMA. First the prospect of more complexity in European registrations: yet another body to get approval from in addition to the Swiss and other non-EU countries. Inevitably companies expect additional cost and potential delay in getting their medicines approved in the UK. Delays are bad for the companies in terms of revenue and bad for patients in terms of access to medicines.

The second issue relating to EMA is the clinical/regulatory ecosystem that has evolved around the EMA and MHRA in London. European and non-European companies that have located in the UK admit to one of the main reasons for having done so being the proximity to this ecosystem and network. The risk long-term is that the UK clinical/regulatory ecosystem may wither if EMA moves to another country and consequently talent and business migrates to where the EMA is.

"We have subsidiaries in other countries, at a certain point we could move [our clinical and regulatory capability] from the UK to the country where EMA is"

New inward investment to the UK will be delayed or not made

It is the convenience of the UK as an EU country that is now in question for non-UK companies wishing to locate R&D footprint in the UK. Those in our sample that already have R&D footprint are committed to staying: it typically takes years to set up all of the relationships and talent required to be successful, and one vote does not remove that.

"We are riding the wave of good relationships developed in the UK over 25 years, but once the rest of the world catches up we could be very limited"

"Many Big Pharmas have left the UK already [before the vote]"

The issue is therefore longer term. The new investment commitments to the UK and increases in commitments to the UK are being questioned much harder than they used to be: yes, the international English language and London as an attractive global city will remain, but the whole talent pool and system of MHRA, EMA, and clinical trials in the UK requires a strong network, close relationships and a hub location. Our research revealed that executives do not see this as favourably as they used to.
When it comes to investing in any European country, almost all the executives are pursuing a "watch and wait" approach. Those that are questioning the value of the UK as an R&D and/or manufacturing destination are limited to those that were in a corporate decision cycle for such matters anyway. The conclusion from our research is that we will not likely see any immediate effects like companies exiting the UK as an R&D or manufacturing (or commercial) location.

> **"Will Brexit stop us [investing in] the UK in the future? Absolutely not, but now Europe is hard to predict, and the UK is harder"**

While watch and wait does not create immediate downside for companies, corporate decision cycles do have a habit of coming round. Over the next three to five years companies will inevitably be confronted with decisions regarding European footprint. At that point, if the current uncertainty persists on what the relationship between the UK and Europe is at a practical level (i.e. trading, regulatory, fiscal arrangements), the UK will inevitably be at a disadvantage compared to other EU countries, particularly if EMA is known to be moving. Our sample of executives were resigned to persistent uncertainty, and none had confidence that the UK's relationship with the rest of Europe will be resolved completely for many years yet.

The UK's science base will remain strong

Of all the Brexit topics we explored, the one where we found our executives to be relatively sanguine was the UK's science base. This was in spite of significant concerns being raised by the smaller UK biotechs and academic communities involved in the earlier stages of research, who for example cite the prospect of reduced access to EU funding such as the Horizon 2020 programme and other grant/government funds.

By contrast the pharma companies (and indeed investors we have asked) are comfortable seeking out science from all over the world, and in that context consider any Brexit-related impact on the UK science base to be minimal. This is partly because there is plenty of good science around the world for them to choose from, and has the added reason that ultimately good science relies more on people, universities and science than the vagaries of grant funding.

Our conclusion is that for pharmaceutical companies the earlier preclinical stages of R&D will not be significantly affected by the Brexit vote, whereas the impact of later clinical and regulatory stages could be more profound, particularly if a relocation of EMA precipitates a brain drain away from the UK.

European contagion is a real risk

A final concern raised by the executives we interviewed was the potential contagious effect of the Brexit vote on the rest of Europe. Uncertainty is never welcome in any business, and the future political and economic context that the industry operates in has now become more uncertain, not just for the UK. A further concern raised by executives in our sample was that Europe will become weakened as a pharmaceutical hub compared to increasing strength of the US and Asia.

> **" The European project is absolutely a bigger worry"**

One of our executives explained that an Asian company he was in touch with had postponed their planned European entry because of the Brexit vote. For sure, from the outside Europe now looks more divided and less attractive than it did before the vote. We will not directly see the delayed and postponed decisions that companies like this are making until it is too late, or indeed see the decisions to not increase investment in Europe. As with the effect on talent, these relatively invisible but real delays and decisions not made will be the lasting legacy of the Brexit vote for many years to come.

Our conclusion: watch, wait, and factor the uncertainty into decision-making

The perspectives of the top executives that we interviewed do not make cheerful reading for the industry. They see the Brexit vote as an additional nuisance, complexity and cost to manage as they build their European businesses, as well as a contributor to further European uncertainty. But these executives and the pharma companies they represent are used to long-term thinking and uncertainty, so they are taking it in their stride.

> **"Nobody says it will be positive, it's more how to limit it and make sure we manage it"**

"We started hot and heavy, now we feel more secure"

The executives that sought out connections with the politicians and negotiators who are dealing with Brexit at a practical level report that they are now coming to terms with the vote. This may be because they are hoping that those that are responsible for converting the vote into practical decisions will come to the conclusion that the UK in the EU is preferable to a hard exit. The Swiss experience since a referendum vote in 2014 requesting more clampdowns on immigration is instructive here. As one executive explained "2 years later there is no political will to implement it". Or it may be that they realise that the real effects of Brexit are likely to take many years to appear, and there are plenty of other global uncertainties to deal with in the meantime.

Our conclusion for pharmaceutical companies is therefore to watch and wait. Of course some will in parallel wish to step up their lobbying efforts to governments to encourage the free trade and free movement between countries that has contributed to their success to date. In the case of UK companies they may also wish to ensure that the Life Sciences industry gets the priority it deserves as the UK government evolves its industrial strategy. But the Brexit vote in itself is not a credible reason to downscale or upscale UK pharmaceutical operations, or indeed operations in the rest of Europe. That said, the uncertainty caused by the vote in the UK and the whole of Europe is for sure a factor that should be carefully built in to any future decision-making regarding European footprint, particularly in clinical development, regulatory and manufacturing.

Over the next years the politicians and negotiators from the UK and the EU and the other European countries will continue to talk with each other and make general, and sometimes conflicting, statements to the media regarding what Brexit is and what it is not. The best response from pharmaceutical companies of all nationalities should be to keep their focus on developing and commercialising great medicines for patients. The Brexit vote was indeed an unwelcome surprise, but the business ramifications for the companies in the industry are manageable for those with an open mind to both Europe and the entire global pharmaceutical ecosystem.