



Brexit:

The Road Ahead

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Introduction

The anticipated crowd of 100,000 protestors never materialised outside Britain's Supreme Court on December 5th for the hearing of the government's appeal. A small group, including a man bearing a sign claiming that Nigel Farage had been sent by God, did little to busy a large contingent from the London Metropolitan Police.

Seven months on and Brexit is becoming an ignominious problem for the British authorities. Every day we are treated to tales of near calamitous gaffes by Cabinet Ministers and their charges while the Prime Minister has taken to talking of a red, white and blue Brexit rather than offering anything of substance on the subject.

It must be stated that the British government has attempted to mitigate the effects of EU departure by announcing a new £2billion R&D fund, by minting special arrangements with manufacturers such as Nissan in Sunderland and promising to cut corporation tax to 15%. Nevertheless, the to-ing and fro-ing has done little to genuinely placate those of us in the life sciences sector seeking to help British life sciences firms to grow internationally.

As political decisions go, David Cameron's agreement to hold a referendum on the UK's continued membership of the EU must now go down in history as one of the most foolhardy of this generation. It is fair to say that in attempting to appease the Eurosceptic wing of his own party and to hunt the UKIP fox, he has caused decades of damage to the British economy.

The ABPI, the representative body of the British pharmaceutical industry, wants to continue its relationship with the European Medicines Agency rather than starting to build a new structure. We analyse the ABPI recommendations in this document.

We return to the issue of the European Medicines Agency in this document. Much has changed since our last whitepaper just three months ago. Political uncertainty in a number of EU countries has impacted on the chances of many cities that are hoping to host the agency.

Now that the Prime Minister has spoken and outlined a roadmap for Britain's departure from the European Union we, as a life sciences community, can start to plan. The triggering of Article 50 will set off a chain of events that will impact on us all.

As always, I welcome your insights and opinions on this issue.

**Gemma Robinson,
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Key Points from the Lancaster House Speech

Here is what British Prime Minister Theresa May MP said about the UK's plan for Brexit and how it might impact on the life sciences sector

Theresa May made her much anticipated speech about the UK's departure from the European Union at Lancaster House in London on January 17th 2017. In that wide ranging speech, she covered the 12 key principles that she said will be used to guide her in the UK's negotiations with the EU.

There was much coverage in the run up to the speech regarding the issue of migration. The Prime Minister touched on the issue during her speech and acknowledged that the topic had played a role in the UK's decision to leave the European Union.

Here are the key points of note in relation to the life sciences sector globally:

1 - The UK, she said, had no interest in driving Britain off a 'cliff-edge' in its quest to depart the Union. Neither is it interested in a never-ending transitional arrangement that sees the UK never really leaving the EU. Instead she is keen that the UK will enter into many transitional arrangements following the negotiation of the UK's exit. This will be done to allow businesses the time to plan for post-Brexit life. Furthermore, it will enable Britain the time to create and implement a workable immigration system.

2 - As part of the transitional arrangement, the UK will look at a period of transition for regulatory authorities. While, the Prime Minister referenced financial regulatory authorities in her speech, there is no doubt that the UK's relationship with the European Medicines Agency will need to be resolved.

3 - On the issue of immigration for skilled and highly sought after skillsets, the Prime Minister said that the UK would not be closing its door to the 'brightest and the best' but that it will need time to develop and implement a system that enables those with sought after skills to enter the UK while preventing the levels of immigration that proved to be so incendiary during the 2016 referendum campaign.

4 - Britain, she said, will continue to play a leading role in European science and innovation. The departure of the UK will preclude it from accessing funds such as Horizon 2020. Furthermore, there was a reference to, and much commentary on, the UK's future ability to innovate with global collaboration networks.

5 - While the UK is leaving the single market, the Prime Minister is keen to remain in the customs union: "We do want to have a customs agreement with the EU and we have an open mind on how to achieve this end" said the Prime Minister. The likelihood of Britain achieving this is one that will be pored over by trade experts for some time. If Britain secures such an arrangement without a common external tariff it may fuel further anti-EU sentiment from countries seeking to leave the Union.

**BREAKING NEWS****PRIME MINISTER THERESA MAY SAYS SHE WANTS TO REMAIN PART OF A CUSTOMS AGREEMENT WITH THE REMAINING 27 EU STATES****skynews.com** THERESA MAY HAS ANNOUNCED THE FINAL BREXIT DEAL REACHED BETWEEN THE UK AND EU WILL BE PUT TO A

The speech framed the UK Prime Minister's '12 Point Plan' for exiting the European Union. The 12 points are:

- 1 - Certainty
- 2 - Control of laws
- 3 - Strengthen the Union
- 4 - Maintain the Common Travel Area with Ireland
- 5 - Control of Immigration
- 6 - Rights for EU nationals in Britain, and British nationals in the EU
- 7 - Protect workers' rights
- 8 - Free trade with European markets
- 9 - New trade agreements with other countries
- 10 - The best place for science and innovation
- 11 - Cooperation in the fight against crime and terrorism
- 12 - A smooth, orderly Brexit

The full text of the speech can be read [here](#).

The Future of the European Medicines Agency

It could be argued that the European Medicines Agency is a bell weather for the plight of the Brexit negotiations. The Canary Wharf based agency is at the centre of much wooing from EU member states while the UK does its best to hold on to the regulator. If the agency does continue to reside in London after the UK departs from the European Union then its presence will give heart to Brexiteers wishing to ‘have their cake and eat it’.

In reality, the agency will be leaving 30 Churchill Place before too long. Negotiators, led by Michel Barnier, will be reluctant to allow other countries that are questioning their membership of the European Union to believe that exiting is without pain. The highly sought after agency, with its 885 staff, is indeed the bell weather of the EU's strength and it will not be allowed to remain in London.

In our second Brexit whitepaper we outlined the ‘runners and riders’ in the race to host the agency. Just three months on from writing that piece there is now a frenzy of competition from cities seeking to welcome the EMA. Denmark, Sweden, Finland and Germany now see themselves as the most likely venues for the EMA. Many people believe that the political uncertainty that has deepened in Italy has done much to scupper Milan's claim to be the next location. Matteo Renzi's resignation as the 65th post war Prime Minister of Italy and the continuing growth of Beppe Grillo's Movimento 5 Stelle (Five Star Movement) have negatively impacted on Milan's hopes. In particular, Grillo's self proclaimed leadership of the group and its vociferous Eurosceptic policies would do little to assure those deciding on the EMA's fate that Italy has a long term future as a member of the EU.

Dublin's capacity to play host must also be in some doubt based on the comments by EMA Director Guido Rasi that “wherever the agency goes next, it must be near an airport and hotels that can provide 350 rooms per night, five days per week”. Dublin already has a much publicised housing shortage. It also has a hotel room shortage with industry estimates that Dublin needs an additional 3,000 to 5,000 extra rooms to meet anticipated demands.

As a result of current demand, **Dublin has one of the highest hotel occupancy rates** of any European city. Added to that, the transport infrastructure linking Dublin airport to the city centre lags behind European counterparts. This must place Ireland's capital at a significant disadvantage in the competition.

Stockholm is regarded by many as now being the most likely location for the agency.

One of the arguments put forth most frequently by pro-Brexit supporters seeking to maintain the EMA in the UK capital is that such a move would cause serious disruption to the largely British workforce at the European Medicines Agency. However, that argument seems to be moot based upon information uncovered by current affairs magazine Private Eye.

60 Seconds on the future of The European Medicines Agency

Watch our 60 Seconds on the future of the European Medicines Agency video online by clicking above.

“Local staff tend to be heavily over represented in EU agencies...but at the EMA, Brits are under-represented with about 65 posts, significantly less than the French, Italian and Spanish contingents” (Private Eye, November 25th 2016, p5).

Guido Rasi, speaking to The New York Times in December 2016, highlighted the potential impact that moving the agency might have on public health:

The uncertainty has left the agency’s executive director, Guido Rasi, “very worried” as experts start to quit and others are recruited away.

“...the consequence, and the direct impact on the public health, is my main concern,” Mr. Rasi said, in a room overlooking London’s old docks.....Imagine if we are late in reaction for some crisis, something going wrong, something unexpected, some quality issue,” he added. “If we are not in a position to intervene fast and efficiently,” he added, “that is a serious threat to public health.” (New York Times, December 25th 2016)

It is almost inevitable that the EMA will be moving, but to where? It will be gifted to an upstanding member of the (European) community. In an era where populist politicians decry the European Union and other states loosely interpret community taxation laws the number of prospective recipients is ever shrinking.

Navigate the Maze

Let us help you minimise the impact of Brexit on your company

The UK's decision to leave the EU will impact on all business sectors. It could be argued that the life sciences sector will be one of the most impacted. There is much to consider when assessing the impact of Brexit on your business.

Right now, we are working with companies from all over the world who are considering their options in light of the Brexit decision.

We are offering a range of services to help companies navigate through this difficult period.

Expert Briefings

We can supply a team of regulatory affairs experts who will prepare and deliver a briefing on the impact of the EU referendum on your organisation. They will outline the latest information relating to the sector and how it impacts on your business.

Senior Management & Board Briefings

Our team can develop a customised presentation and strategy session, looking at your products and regulatory affairs structure to outline the impact of Brexit on your business.

Market Opportunity & Risk Assessment

We can carry out an off-site assessment of the issues related to Brexit that will impact on your organisation. The Market Opportunity & Risk Assessment report will outline steps to take to protect your business.

If you would like to talk to us about any of the options listed above, or any issue relating to Brexit, then please contact us on **00353 52 61 76706** or e-mail: info@acornregulatory.com

The ABPI Response

The Association of the British Pharmaceutical Industry (the ABPI), as the voice of the UK pharmaceutical sector, has been particularly visible in the Brexit debate since the referendum result became known. In the immediate aftermath of the result the organisation spoke of ‘dismay’. However, with the publication of its **UK EU Life Sciences Transition Programme Report in September 2016** it has sought to look at ensuring that the impact to the UK pharmaceutical sector is minimised.

The aforementioned highlights some of the key attributes of a sector that is vital to the overall UK economy. For example:

- The UK life sciences sector has a turnover of £60 billion annually.
- Two thirds of all jobs in the sector are based outside of the economic powerhouse that is London and the south-east.
- The largest pipeline of biotech products in Europe is in the UK.**

In recent years the UK life sciences sector has been a major beneficiary of the EU’s Horizon 2020 fund and the ABPI report posits the idea that the UK might continue to be a member of Horizon 2020, albeit in an associate membership just like Switzerland and Israel, in order to maintain access to funding. The announcement in recent months by Chancellor of the Exchequer, Philip Hammond, that the government would guarantee funding for Horizon 2020 projects was welcomed. However, the announcement did little to quell the jitters of those concerned about longer term funding of the sector.

The ABPI also referenced the issue of a potential skills shortage (an issue that we covered in our second Brexit whitepaper). They have called for an immigration system that “facilitates ease of movement for talented students and workers”.

The September 2016 report from the ABPI can be read **here**.

In January 2017 the ABPI commented further, particularly about the need for a transitional arrangement to be put in place with regulatory agencies. Speaking about the issue ABPI CEO Mike Thompson said:

“...Securing continued regulatory cooperation and alignment with the EU for medicines will be in the best interests of the UK government, EU member states and patients”.

The ABPI has, understandably, carried out some excellent work on the topic and their website can be found at www.abpi.org.uk

The Future for EU Authorised Representatives

The UK's impending departure from the EU will necessitate a change in designated EU Authorised Representatives for companies that are currently using a UK based representative at present. This will cause considerable upheaval and disruption to companies using such a service. The consensus view that Britain will seek to leave using a hard Brexit mechanism means that there is scant hope of companies being able to maintain representation through UK representatives.

We have surveyed a number of companies that are already making plans to move their representation to another more EU friendly jurisdiction. This, however, is not without its issues. Many companies over recent years have opted to use a distributor as their EU Authorised Representative. Making a change to a new English speaking EU territory could be particularly onerous as there will be a need to reprint all manuals and packaging. Significantly, the issue of dealing with product that has already been sold will also have to be considered. Issues exist also for those who have chosen a UK based EU authorised Representative who is not a distributor. These companies will have to manage many of the same issues as outlined above.



We also must factor in the possibility that companies will also need to source a UK based representative in the coming years to represent them in the United Kingdom.



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