Brexit: Implications for Pharma and Life Sciences companies

Brexit

Pharma and Life Sciences Sector

February 2018





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With negotiations in full swing we now see a clearer path to the UK's exit from the EU

November 2016 High court rules Parliament must vote on the triggering of Article 50 February 2017 The UK government publishes a white paper setting out the strategy for existing the **March 2017 European Union** UK government triggers Article 50 and publishes the Great Repeal paper **June 2017** 1st round of negotiations begin **European Medicines Agency (EMA)** announces decision to relocate July 2017 PM rules out freedom of movement UK government publishes position papers on nuclear materials, judicial procedures and privileges August 2017 2nd and 3rd rounds of negotiations begin UK government publishes position papers stating preference for an interim customs union September 2017 Brexit Secretary suggests prioritisation of 4th round of negotiations begin isotopes supply (Euratom) UK government publishes position paper on science and innovation October 2017 **UK Prime Minister delivers her Florence speech** 5th round of negotiations begin UK government publishes position papers on *November 2017* trade and customs arrangements EMA announces relocation to Amsterdam Autumn Budget 2017 is announced **Winter 2017** UK government announces its Industrial Strategy Terms of Withdrawal Bill agreed with sector deals to be announced early December European Council meeting on Brexit Spring 2018 UK Life Sciences sector deal announced Potential start of negotiations on future trade Autumn 2018 **European Council meeting** Agricultural Bill published Withdrawal and Implementation **Bill published**

UK exit from the EU (with or without a transition period)

May 2019

European Union parliament elections

March 2019

Ten things we now know about leaving the EU



Current thinking is that the outcome of UK-EU negotiations will be in part a bespoke exit deal

Prime Minister Theresa May has stated that the UK government will seek 'a model which suits the UK and the EU' rather than using an 'off the shelf' model already agreed by other countries.

This will mean a bespoke scenario unlike any existing models. Any scenario will need to consider and balance the major pieces of the Brexit puzzle...



Potential Brexit scenarios which could emerge

No deal / WTO rules
'No deal' – the UK moves to a default WTO trading relationship with the EU, with no overall trade agreement or bilateral deals – e.g. on aviation, financial services or data.
While an extreme form of 'no deal' (e.g. no agreement on aviation) ought to be avoided, in trade terms this outcome would mean very significant change
 The recently announced UK Life Sciences Strategy has drawn substantial investment into the sector, confirming that the UK is still seen as an attractive destination for pharma companies to conduct research and manufacturing: GSK is planning to invest more than £140m in UK production for their respiratory and HIV medicines between 2017-2020. This is in addition to the £275m manufacturing investment announced last year MSD have announced plans to plans to establish a UK Discovery Centre and potential new EU HQ in London Qiagen have announced a partnership with Health Innovation Manchester to develop a genomics and diagnostics campus Novo Nordisk have unveiled a plan to invest £115m in a new research centre in the UK

The impact of leaving the EU on the Life Sciences sector



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The impact on the Pharmaceutical and Life Sciences industries

With the UK's decision to leave the EU, you will no doubt be considering the impact of issues ranging from Life Sciences regulations and funding to migration and trade. We have now reached a critical point in the negotiations where leaders need to make decisions and act on their Brexit strategies. The outcome of Brexit will have an impact across industries, but it can be hard to access the facts. Here we set out some of the issues relevant to the pharmaceutical and Life Sciences sector to help you make informed decisions about your strategic choices.

Throughout the life cycle of a medicine, medical device or medical digital technology, European regulations govern processes, including following their launch.

For example, clinical trials in the EU must comply with the Clinical Trials Directive, soon to be replaced by the Clinical Trials Regulation. This new regulation will apply from 2018 and aims to more easily facilitate large pan-European trials. However, should the UK no longer be governed by the Clinical Trials Regulation, UK involvement in these trials may become more difficult and costly. Ultimately this could result in companies choosing not to include the UK in trial design, or to include UK at a later stage only.

The Medicines and Healthcare Regulatory Agency (MHRA) is responsible for UK regulation – implementing many European Regulations and Directives. The MHRA and other UK bodies currently have significant influence in shaping European regulations, setting the European and even global standard. The level of this influence will be impacted by the type of deal UK and EU reach. for European regulation of medicines. This includes the centralised authorisation procedure for licensing medicines. This grants a single marketing authorisation for all EU and EEA countries.

Should the UK government decide not to join the EEA upon leaving the EU, the UK will no longer be a part of this process. The MHRA will then need to perform the same task, requiring companies to submit a separate UK marketing authorisation application.

However, this increased demand on the MHRA could result in a slower authorisation procedure, and as a result, slower UK market access. Furthermore, the MHRA currently undertakes an estimated 30% of EMA casework. Without the capacity and expertise of the MHRA, the European regulatory system may also experience delays and disruption.

On leaving the EU, if the UK is not covered by the Unitary Patent, they would be denied access to Europe's Unified Patent Court (UPC), which could result in potentially lengthier and more costly patent disputes for companies. The UPC for Life Sciences is currently planned to open in London, but this location decision may now be revisited.

The European Medicines Agency (EMA), which is to relocate to Amsterdam following Brexit, is responsible



The pharmaceutical and Life Sciences industries directly employ 220,000 people in the UK, approximately 7% of whom are non-British EU citizens¹. Were the UK to remain an EEA member, provisions for freedom of labor would mean there would be little impact on this workforce. However, should the government choose to fully exit the single market, free movement would end and could cause a short term decline in productivity, with a longer term question over the UK's attractiveness for investment due to the ability to attract and retain top talent. For example, academics who frequently move around Europe could find crosscountry collaboration harder, ultimately impeding the UK's participation in research.

UK Life Sciences has access to a wealth of funding initiatives in Europe, including Horizon 2020 and the European Investment Fund. In fact, as of 2011, the UK was the beneficiary of 16% of the funding from one such initiative², compared with the UK's contribution to the EU of 11.5%. HM Treasury has agreed to underwrite funding for Horizon 2020 projects even when specific projects continue beyond UK's departure from the EU. In the UK government's latest Industrial Strategy it has committed to increasing R&D spend to 2.4% of GDP across all sectors by 2027. In addition to this, it has also reinstated the Biomedical catalyst and launched a set of Challenge Funds to further support UK businesses and research. However, UK access to EU funding beyond Horizon 2020 is still unknown. To ensure the UK remains a dynamic market for innovation, significant investment will need to be maintained.

Currently, pharmaceutical companies invest 16% of their European R&D spend in the UK, compared with only 9% market share by sales. Foreign investment in UK Life Sciences, from the US and Japan for example, has often been with a view to accessing a wider European market. A recent European Federation of Pharmaceutical Industries and Associations (EFPIA) survey³ revealed there are currently 2,400 centrally authorised MAs that will need to be transferred before March 2019. In addition there are over 1,500 clinical trials underway in the UK for a number of EU member states. Depending on the type of trade and regulatory arrangements that emerge from the vote to leave the EU, there may be implications for the UK's attractiveness as a platform through which to access Europe. Furthermore, current uncertainty around the form of exit the UK will take, may result in delayed internal and external investment decisions.

These are just some of the issues, and while these changes will occur over a period of time, it is critical to consider the potential scenarios and their impact now, in order to plan how to mitigate negative impacts and identify potential opportunities.



¹⁾ The economic contribution of the UK Life Sciences industry, PwC, 2017

^{2) 7}th Framework Programme (FP7)

³⁾ Brexit EFPIA survey results (08/11/2017)

Key implications for the sector are around regulation, investment, talent and trade

Regulation

- UK may have to adhere to European regulations without having a say in their development
- Loss of single marketing authorization through the EMA could slow access to the UK market
- The MHRA's influence and global reputation may diminish as EMA offices move out of the UK
- If the UK adopts alternative clinical trial regulations, management of trials may become too complex to develop future medicines to sell in Europe

Commercial & Trade

- UK would seek to negotiate a variation to the 'EU-Canada' deal, which would provide for reciprocal duty-free treatment of goods
- Added costs and cashflow impacts could arise if trade with the EU became subject to duties (for component parts and other goods outside finished pharmaceuticals), import VAT or border controls
- UK may lose access to FTAs negotiated by the EU such as those with Israel, South Africa and South Korea

Supply Chain & Operations

- Companies that use the UK and their European manufacturing or import hub may face increases in lead times due to customs checks
- Regulatory changes will impact supply chains and companies should hold sufficient stock to cover a Brexit transition period i.e. MA transfers

Investment / Funding

- The UK may lose access to EU funds including the EIB and EIF, ultimately reducing funding access and venture capital investments
- This would have a knock-on impact on the UK's research reputation and talent pool
- The UK may become less useful as a platform from which to access Europe, impacting European investment decisions made by international companies



People

- Visa processes and costs could be burdensome
- Rights after Brexit for EU nationals living in the UK and visa-versa have now been settled, however there is still little clarity around the registration criteria
- Clarity needed on the recognition of professional qualifications from other EU countries as part of the Visa/access rules

R&D

- The level of UK participation in future EU research and development programmes is still unclear given EU funding requirements
- The UK may not be covered by Unitary Patent and might be denied access to the EU Unified Patent Court (UPC), leading to lengthier and more costly patent disputes

Depending on the scenario and agreement reached on the UK's exit from the EU, these are some of the critical implications for the sector



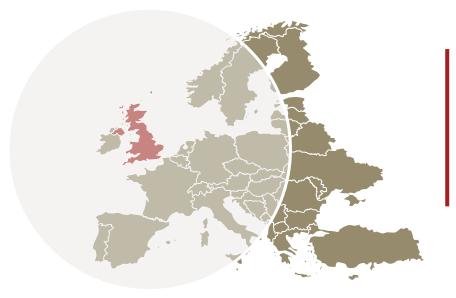
How does Brexit impact the role of the UK in your European strategy?

The United Kingdom has so far been a prime European hub for Life Sciences

- Four of the world's top six universities for research in and study of clinical, pre-clinical and health topics (Cambridge, Imperial College, Oxford and UCL) are based in the UK.
- Companies benefit from sophisticated regulatory and IP protection systems.
- The UK is a leader on global public health issues such as dementia and anti-microbial resistance, and new technologies such as genomics.
- Biotech company clusters and partnerships are found across the country (e.g. MedCity in the South East, NHSA in the North of England and IBioIC in Scotland), making up the largest biotech pipeline in Europe.
- The UK government is fully aware of the sector's importance, as stated by PM Theresa May: "It is hard to think of an industry of greater strategic importance to Britain than its pharmaceuticals industry."

- For companies based outside of Europe, the UK offers several comparative advantages vs. other European countries:
 - Talent is easier to find, hire, and retain and employment laws are generally more flexible.
 - A strong and diverse Life Sciences ecosystem.
 - Good IP and legal frameworks.
 - Having English as the main language makes the country more desirable as a relocation destination.
 - A vibrant and internationally recognised media, arts and culture scene, with London recently ranked 1st for both entertainment and attractions, and relocation attractiveness.
 - London's transport hub boasts convenient flight connections around the world.

As a result, the **UK plays an essential role in the European strategy** of many US and European multinationals. Indeed, many companies have chosen to locate their regional headquarters, R&D and/or manufacturing facilities in the UK, as well as taking advantage of the country's EEA membership to supply other EU markets.



Companies now need to assess how Brexit may impact their operations in the UK. While the country's talent and scientific base will take years to evolve, other areas such as regulation, IP, trade tariffs or taxation could change in the short term after the UK exits the European Union.



Global Life Sciences companies broadly fall into three types of players

Businesses with key operational presence in the UK

Companies that have located their regional headquarters, R&D and/or manufacturing sites in the UK. These operations support not only the UK business but also other subsidiaries across Europe or even globally.

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• Typical companies in this group include medium to large multinational pharma and biotech companies with a strong presence in European markets. Businesses without key operations in the UK but selling its products there

- Companies with an existing commercial presence in the UK (including, but not necessarily, local offices) but with no key operations (e.g. regional HQ, R&D or manufacturing) in the country.
- Companies in this group vary significantly, ranging from small enterprises starting to grow internationally, to wellestablished multinationals with a long history in European markets.

Businesses considering entering the UK market

- Companies considering the potential of the UK market (for either a full entry or just to market some of their products), its suitability for locating operations there and/ or the UK's potential as a gateway to other European markets.
- Typical companies in this group include fast-growing biotech and small to medium enterprises looking to expand into Europe, as well as companies adjacent to Pharma and Life Sciences that are looking to expand into the sector.



While all companies will be looking to manage the risks arising from Brexit, each type of company should focus on different areas

While the current level of uncertainty around Brexit negotiations outcomes may prevent companies from making major strategic decisions, each company type will have a different set of priorities and actions to consider now.

Businesses with key operational presence in the UK

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- UK-EU negotiations and influencing industrial policy: While companies in this group face the highest level of exposure to Brexit, they are also best positioned to influence policy outcomes via industry associations and the joint government-industry Life Sciences Steering Group.
- **Supply Chain risk:** Companies with a supply chain footprint in the UK may carry out scenariobased contingency planning around supplier contracts, manufacturing operations and trade.
- Talent management: Companies in this group will likely have employees with key expertise and skills located in the UK, and may benefit from planning for staff support and retention as well as proactively engaging staff early in the process. Plans to attract and retain talent will need to be considered.

Businesses without key operations in the UK but selling its products there

- Regulation monitoring: Closely monitoring development in the regulatory area and understanding their impact on business costs and operations, such as clinical trials, data protection and market authorisation and SPCs.
- **Potential impacts to trade:** Companies with UK subsidiaries will have to assess the potential Brexit scenarios and their impact on trade costs (e.g. tariffs, import VAT) and operations (e.g. border inspections).
- Talent management: While companies in this group may not have key expertise and skills located in the UK, they will need to assess potential impacts for EU nationals and ensure adequate workforce engagement and support.

Businesses considering to enter the UK market



- Scenario-based assessment of business growth plans: While companies in this group are the least exposed to Brexit, a review of international growth plans is in order. Companies may benefit from assessing potential post-EU scenarios and the strategic choices the may face under each of them.
- Monitoring of overall political and sector-specific developments: Companies will have to follow Brexit developments and assess what level of certainty around negotiation outcomes they require to update their growth and investment plans.



How should you plan for the implications of Brexit on your business?

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To what extent does Brexit impact your business?

You will need to understand the impacts across your operating model ...

of registered rights / IP

rights in the UK?

- Strategy مرق
- Do you use the UK as a gateway to Europe/EMEA region?

Person (QP) for batch

release and Quality

Control (QC) testing

implications for you

running a separate

located?

What are the

- To what extent do you want to continue leveraging the UK's strengths in Pharma and Lifesciences?
- Have you assessed the challenges, opportunities and inherent risks your business is facing from Brexit?

There you assessed the chances so, opportunities and interest these your business is hearing from Dreater			
Regulation	R&D	Supply Chain & Operations	Commercial & Trade
 Do you hold Marketing Authorisations (MAs) in the UK? Where are your EU Qualified Person Pharmacovigilance (QPPV) and Pharmacovigilance System Master File (PSMF) located? Do you import products into EEA? If yes, where are your Qualified Person (OP) for batch 	 How much of your R&D talent and facilities are UK-based? Are you partnering with UK academic institutions? Do you conduct clinical trials in the UK? If yes, is the duration of any of them extending past March 2019? Do you hold a portfolio 	 Do you have a manufacturing footprint or HQ in the UK? How reliant is your supply chain on the UK? Do you import into EEA? If yes, what is your point of entry / import HUB? Are some activities in your supply chain licensed to contract manufactures (CMOs)? 	 Do you have centralised Marketing/Sales functions in the UK? Do you have any commercial distribution agreements in the UK? What is the current balance of your trade flows in and out of the UK – both within and outside the EEA?

If yes, have you assessed

Do you hold sufficient

transition period, while

stock / inventory to

cover the Brexit

their Brexit

preparedness?

How is your legal structure set up in terms of entity(s) that takes title (revenue /profit registration)?

regulatory process ir UK?	n the potential UK held MAs are being transferred?
People	 How important are UK / EU nationals for your talent pool and workforce skills? Have you assessed which employees will need to apply for working permits / Visas? Have you communicated Brexit's impact on the business to internal / external stakeholders
Investment () Funding	 How much do you rely on UK investors and sources of funding? Have you considered how to secure future R&D spend if current funding channels are not available to the same extend?
M&A	 Could you become vulnerable to a hostile bid due to falls in share price? Alternatively, could you acquire other companies by using Brexit as a catalyst to expand footprint in UK / EEA?

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Understand the "no regret" actions to be taken irrespective of the Brexit timeline and negotiations

We set out a number of considerations to initiate your efforts in navigating this uncertain period



Identify risk and quantify cost of risk mitigation strategies

Timing and responsibility	Resources needed and teaming – internal and external
Governance – Oversight, decision rights, decision processes and risk management	Internal and external stakeholder communication



PwC contacts and credentials

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We have a deep understanding of Brexit and its implications for the pharma industry

Supporting UK Life Sciences understand Brexit priority issues and opportunities and present a case to the UK government

The ABPI and BIA wanted to develop a position paper that voiced the priority issues and preferred future steps for the UK Life Sciences (pharma, biotech, med-devices and animal health). In summer 2016 we:

- Conducted interviews with over 150 experts and facilitated 50 hours of workshops
- Identified four priority areas for the sector, detailing what is at stake and the industry's recommended way forward. Created a ministerial paper & Brexit playbook
- Highlighted opportunities to invigorate UK Life Sciences innovation as a key pillar

Supporting a global pharma company assess the regulatory and supply chain impact of Brexit

The client wanted to better understand the impact of Brexit on their European business and prioritise their risk mitigation activities. To help we:

- Mapped key timelines & overall Brexit implications on the UK pharma and life sciences industry
- Assessed where large pharma hold their MAs in the EU and how this could change with Brexit
- Supported the organisation develop a Brexit plan and corresponding business case for their UK affiliate

Strategic industry review for a top UK genomics & biodata research institute

Our client was looking to establish a 10 year strategic plan in the context of Brexit and the UK government's industrial strategy. To help we:

- Conducted interviews across the genomics industry to identify preferred technologies with the highest investment potential
- Assessed the client's strengths & capabilities within the prioritised genomics and biodata technologies
- Recommended strategic options and the most appropriate operations model for the future

Enabling a Japanese pharma company understand the implications of Brexit

The client wanted to learn how Brexit would impact their R&D, manufacturing and trade. To help we:

- Reviewed their Brexit MA transfer plan & developed a set of transfer options with associated strategic considerations
- Helped them better understand the benefits and disadvantages of different CMO arrangements
- Assessed the client's trade with non-EU countries to help them better understand any additional cost to service that may follow Brexit

Using our Brexit Impact Tool to help a UK company understand how Brexit would impact its supply chain costs

A UK company imported goods into the UK from 3rd party suppliers and sister manufacturing companies located in the EU and APAC. To help we:

- Used our Brexit Impact Assessment Tool to model :
 - Customs duties for supply either affected by loss of access to FTAs or on goods supplied from the EU
 - Increased cost of customs declarations across a new UK/EU customs border
- Showed that the supply chain was likely to be unfeasible post Brexit

Supported the UK government develop the Accelerated Access Review (AAR)

The client wanted support to develop an accelerated pathway for the development of drugs. To help we:

- Conducted desktop research and conducted 50+ interviews to assess current regulatory processes and pricing & reimbursement models
- Developed a new pathway for medicines and attained stakeholder approval
- Worked directly with industry, regulatory and HTA stakeholders to review the Early Access to Medicines Scheme (EAMS)



Pharmaceuticals and Life Sciences contacts



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Pharmaceutical and Life Sciences credentials

We are a global leader in providing professional	We provide services to 9 out of the 10 pharmaceutical companies in the Fortune 500 All 10 pharmaceutical companies listed in the Forbes Global 2000 are
services to the Pharmaceuticals and Life Sciences sector	PwC clients Globally, we have 6,400 consultants dedicated to
	Pharmaceuticals and Life Sciences
We offer a wide range of services to support our clients	Our Global Pharmaceuticals and Life Sciences Industry Group has experience working with companies on industry-specific strategic, operational, and financial issues. As well as assurance, tax and advisory services, we also have specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support
M/a hava	A Advanced Madical Tashnalogy Association A BioIndustry Association LIK (BIA)

We have established relationships with major industry associations across US, Japan, the UK and Europe

- Advanced Medical Technology Association, USA (AdvaMed)
- Pharmaceuticals Research and • Manufacturers of America (PhRMA)
- Japanese Pharmaceuticals Manufacturers . • Association (JPMA)
- Association of British Pharmaceuticals • Industry (ABPI)
- **BioIndustry Association, UK (BIA)**
- **European Medicines Agency (EMEA)**
- **European Centre for Pharmaceuticals** Medicine (ECPM)
- **European Federation of Pharmaceuticals** Industries and Associations (EFPIA)
- **International Federation of** Pharmaceuticals Associations (IFPMA)

We are thought leaders in Pharmaceutical and Life Sciences



2020: Building Strategic Coherence in the New Health Economy



21st Century Pharmaceutical Collaboration: The Value Convergence



The economic contribution of the UK Life Sciences industry



Supporting our pharmaceutical and life sciences team we have a dedicated Brexit task force

Our Brexit task force works closely with our pharma and life sciences specialists to support clients successfully navigate Brexit. Our task force covers areas that we believe are the most relevant areas when considering the implications of Brexit. If you would like further information please contact us directly or visit www.pwc.co.uk/the-eu-referendum.

Contacts



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