CHAPTER III

The Pharmaceutical Industry

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EXECUTIVE SUMMARY

The health and life sciences industry in the United Kingdom (UK) is viewed as one of the most dynamic in Europe. Investors appreciate the fairness of the UK's regulatory environment, which has benefited from collaborative government-industry relationships. The wider impact of Brexit can be understood by looking at the industry's component parts.

Before considering the argument, key facts underpin the negotiations:

- Pharmaceuticals is one of the largest industries in the UK and the most research intensive component of the economy.
    - It employs <70,000 people.
    - It is responsible for 25% of commercial UK research.
    - £4 billion was invested in Research and Development (R&D) in the life sciences in 2014, more than any other sector.

- The UK pharmaceutical industry is currently very well funded.
    - The EU funded ~€8.8 billion between 2007 and 2013 through its Framework Programmes (FPs), >€3 billion more than contributed by the UK to this fund.
    - Private investment matches government spending 70p to each £1.

- The UK is a pioneer in worldwide drug manufacture.
    - The UK produced 25 of the top 100 most used drugs worldwide.
    - 20% of publications in pharmaceuticals are from UK scientists.
    - The UK controls 10% of the expanding genomic research sector.

- The industry is remarkably robust.
    - Pharmaceuticals have experienced consistent growth in output, productivity and employment over the last decade.
    - Growth rates of 4-10% per annum were forecast.
    - The sector continued to grow during 2008's financial crisis.

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INTRODUCTION

A glance at the stock market would suggest that the UK's pharmaceutical sector has emerged largely unscathed from Brexit, performing comparatively much more strongly than other industries in the immediate economic uncertainty that followed the referendum result last June. As industries such as banking and insurance grappled with the pound falling to its lowest level in thirty year,[68] the pharmaceutical sector appeared to buoy calmly above the chaos and volatility. The British pharmaceutical company, GlaxoSmithKline (GSK), which is headquartered in Brentford, UK, even saw its share price rise in the immediate aftermath of the vote, highlighting the robustness of the industry.[69] These results panned out promisingly, flouting widespread speculation that the sector would be one of the worst hit. Some in the industry, whilst acknowledging the potential negative impacts of Brexit, even hailed independence from the European Union (EU) as an opportunity for the UK to leverage its life science sector.[70]

Such short-term observations would make an optimistic evaluation of the impact of Brexit on the industry a seemingly straightforward one to write. However, it would likely prove short-sighted. As negotiations for a post-Brexit world take shape, the UK's pharmaceutical industry, one of the country's most reputable sectors, has perhaps more at stake than any other industry owing to the complex nature of its current regulatory, funding and research structures. The industry's fate relies on much more than selling drugs and market share.

The gravity of the potential disruption to the industry is reflected in the fact that the UK government has outlined science and innovation as one of the twelve 'negotiating priorities' of Brexit.[71] This is matched by the insistence of industry leaders that a solution be reached swiftly in order to prevent financial damage to the sector and possible risks to all those who depend on the research, products and services it delivers. For example, Steve Bates, CEO of the BioIndustry Association, has called for an early agreement on issues such as regulation of medicines and the ability of non-UK nationals to work in the UK life science ecosystem, whilst the European Federation of Pharmaceutical Industries and Associations has warned that 'any disruption could lead to delays in medicines reaching patients'.[72] The pharmaceutical industry is being afforded attention and a sense of immediacy in these early stages of negotiation, yet the details that will determine its future post-Brexit remain unclear.
This report aims to inform on the possible options available to the UK pharmaceutical sector now that its relationship with the EU faces potentially drastic changes. It is

[68] Roger Blitz and Leo Lewis. "Pound Tumbles to 30-Year Low as Britain Votes Brexit." *Financial Times*, 2016. https://www.ft.com/content/8d8a100e-38c2-11e6-a780-b48ed7b6126f
[69] Ana Nicholls. "SmartViews: Brexit - What's next for Pharma?," 2016. http://www.pharmatimes.com/magazine/2016/july_2016/smartviews_brexit_-_whats_next_for_pharma
[70] "Surviving Brexit," 2016. http://www.pmlive.com/pharma_news/surviving_brexit_1136772
[71] "The Government's Negotiating Objectives for Exiting the EU: PM Speech." *GOV.UK*, 2017. https://www.gov.uk/government/speeches/the-governments-negotiating-objectives-for-exiting-the-eu-pm-speech
[72] "UK Pharma Strikes Optimistic Note as Brexit Process Begins," 2017. https://www.pmlive.com/pharma_news/uk_pharma_strikes_optimistic_note_as_brexit_process_begins_1190435

impossible to predict whether this new affiliation will be one of continuing partnership, lukewarm cohabitation or absolute divorce in terms of the deals reached on regulation, clinical trials, and the movement of persons and drugs (amongst other factors). It is possible, however, to shed light on the intricacies of any one these options, drawing knowledge from the EU's current relationships with non-EU states. In this context, it is also possible to make objective suggestions in relation to the most appropriate course of action for the pharmaceutical industry as the UK negotiates a new position with its European neighbours.

This report will therefore begin by outlining the current state of the sector, covering pharmaceutical manufacturers and distributors, clinical trials, research in medicine, science and innovation, and the broader health and life sciences industry. This will make it possible to contextualise any possible post-Brexit impacts and solutions within the existing frameworks and organisations that comprise and support the sector at present. The report will then turn to areas most likely to be impacted by Brexit, namely innovation, trade, regulation and talent. It will detail how these potential risks and disruptions may be mitigated, and what this presents by way of challenges and opportunities for change within the industry.

The report will then consider three post-Brexit models: European Economic Area (EEA), European Free Trade Association (EFTA) and World Trade Organisation (WTO), frameworks that are already in existence. This will involve clarifying how nations such as Norway, Switzerland and Canada have forged favourable trade agreements with the EU whilst remaining independent. The report will also consider the possibility of the UK adopting 'associated country' status. However, it will not speculate as to whether the UK will be able to replicate any one of the options discussed. Instead, it will seek to make suggestions as to where negotiators and key players in the pharmaceutical industry may seek guidance and inspiration as they endeavour to build a workable UK-EU trade deal. This section will also detail potential ramifications for funding, focusing specifically on how Brexit is likely to impact research, science and pharmaceuticals.

Lastly, the report will open up the wider debate on the difficulties faced by the UK as it seeks to balance delivering the demands of the majority of voters who backed the leave campaign with the realistic and sensible policymaking required to reach a workable and accepted solution for all parties involved. Throughout, the report will provide a comprehensive and objective account of the current climate, how it impends on the pharmaceutical industry, and what this spells for the future trajectory of the sector now that negotiations for the UK's departure from the EU have been set in motion. The report comments on the wider implications of the current situation but with specific attention on the pharmaceutical industry.

1.0 PRE-BREXIT FIGURES

The pharmaceutical industry constitutes an important component of the UK economy. The UK life sciences sector contributed £30.4 billion in UK GDP, supported 482,000 jobs and contributed £8.6 billion in taxes in 2015,[73] a significant portion (over half) due to the pharmaceutical industry[74]. Two of the world's largest pharmaceutical companies, AstraZeneca and GSK, are headquartered in the UK, and almost all notable multinational pharmaceutical companies maintain a presence in the UK.

The UK's broader health and life sciences industry is viewed as one of the most dynamic in Europe and has received substantial foreign investment over the last ten years[75]. Investors appreciate the fairness and transparency of the UK's regulatory environment, having benefited from a collaborative government-industry relationship. It is important to evaluate the current climate of the pharmaceutical industry in order to understand the potential impact and implications of any legislative or commercial change brought forth by Brexit.

[73] Mike Thompson, Doris-Ann Williams, Peter Ellingworth and Steve Bates. "The Economic Contribution of the UK Life Sciences Industry," 2017
[74] Lilian Anekwe. "Pharma Contributes £32 Billion to UK Economy." *Pharmafile*, 2015
[75] Andrew Ward. "UK Life Sciences Hit 7-Year High." *Financial Times*, October 6, 2014. https://www.ft.com/content/6d0c13d6-4d55-11e4-bf60-00144feab7de

1.1 Industry Overview

The pharmaceutical sector employs approximately 70,000 people in the UK[76] and forms part of the broader health and life sciences industry, which employs more than 170,000. The pharmaceutical sector provides jobs in a number of areas: manufacturing, distribution, clinical trials and R&D.

Pharmaceutical manufacturing is one of the few components of the UK's manufacturing sector to have experienced fairly consistent growth in output, productivity and employment over the last decade. Looking ahead, growth rates of 4-10% per annum had been forecast for the sector.[77] The pharmaceuticals industry is also the most research intensive component of the UK economy and is responsible for around 25% of all commercial R&D conducted in the UK.[78]

1.2 Pharmaceutical Manufacturing

The UK's reliable legal system and strong protection of intellectual property has helped establish the country as a major centre for the manufacture of medical devices and pharmaceutical products. It is estimated that there are over 500 pharmaceutical manufacturers in the UK.[79] Products produced in the UK can either be sold there, exported within the EEA or exported to the rest of the world.

The UK's domestic market for pharmaceutical products is currently valued at round £30 billion[80] and demand for pharmaceutical products is expected to grow substantially in the future due to the pressures of an ageing population. Weak economic growth could reduce growth projections for the sector but, in general, demand for healthcare products has been resilient to economic downturns in the UK with growth of the sector remaining positive even during the 2008 financial crisis.

The UK government has been focusing on cost reduction measures in recent years and this has included emphasising the use of generic drugs. Spending on generic drugs as a portion of total healthcare spending is expected to rise over the next decade.

Biosimilar drugs are non-branded near-equivalents of branded biopharmaceutical products. It is possible that the government will also seek to encourage the use of

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[76] The Association of British Pharmaceutical Industry. "Did You Know? Facts and Figures about the Pharmaceutical Industry in the UK," 2011. http://www.abpi.org.uk/our-work/library/industry/documents/did you know_jan11.pdf

[77] Department for Business Innovation & Skill. "Growth Dashboard." *Growth Dashboard*. Vol. 22, 2015. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/396740/bis-15-4-growth-dashboard.pdf

[78] Ben Hirschler. "Brexit Spells Upheaval for EU and UK Drug Regulation." *Reuters*, June 24, 2016. http://www.reuters.com/article/us-britain-eu-corporates-pharmaceuticals-idUSKCN0ZA26J

[79] Business Monitor International. "Pharmaceuticals & Healthcare Q416 Round-Up," 2016. http://store.bmiresearch.com/pharmaceuticals-healthcare-q416-round-up.html?ito=638&itq=bf6559e0-3ad7-495c-8cbd-223a6d16a0ae&itx%5Bidio%5D=4118473

[80] Simon Hammett, "2015 Life Sciences Outlook: United Kingdom," 2014. https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015-life-sciences-report-united-kingdom.pdf

biosimilars over the same period, although these drugs do not offer the same cost savings as generic drugs.

Drug pricing and reimbursement is an exclusive competency of member states in the EU. Consequently, third parties can purchase branded pharmaceuticals in bulk in EEA member states with lower prices and then resell them in other EU member states.[81] This process is known as parallel importation. Parallel imports of pharmaceutical products were prohibited in Sweden until it joined the EU in 1995; evidence suggests that, since then, parallel imports have reduced pharmaceutical prices[82].

The EU remains the largest single export market for UK pharmaceutical companies. Exports to the EU have grown by around 30% over the last 10 years and further growth is expected. Germany is a crucial market due to its large and wealthy yet rapidly ageing population.[12] However, due to the European debt crisis, EU countries such as Italy, Portugal and Greece are expecting very harsh austerity measures over the next decade and beyond. This could impact their ability to afford some of the innovative drugs that the UK specialises in producing.[83] The EU now represents less than half of total UK pharmaceutical exports. Exports to outside the EU more than doubled over the last ten years. Key growth markets are Asia (especially China) and the United States (US).[12]

1.3 Clinical Trials

The UK's National Institute for Healthcare Research (NIHR) is the largest funder of clinical trial research in the EU.[84] Clinical trials provide important information for academics and R&D departments, and the UK's status as a major location for clinical trials enhances its desirability as a location for pharmaceutical development.

Since 2004, the UK has been party to the EU Clinical Trials Directive (CTD), 2001/20/EC EUCTD, which has received criticism for adding red tape, whilst bringing few tangible benefits and perhaps encouraging clinical trials to take place outside the EU (to the detriment of the UK). Michael Rawlins, current chair of the Medicine and Healthcare Products Regulatory Agency (MHRA), referred to the original CTD as a 'catastrophe'.[85] Nonetheless, with substantial changes to this directive due to be implemented in 2018, there is little support amongst the research community for leaving the EU-wide clinical trials network.

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[81] Norton Rose Fulbright. "Impact of Brexit on Life Sciences and Healthcare," 2016. http://www.nortonrosefulbright.com/knowledge/publications/136982/impact-of-brexit-on-life-sciences-and-healthcare

[82] Mattias Ganslandt and Keith Maskus. "Parallel Imports of Pharmaceutical Products in the European Union." *Policy Research*, 2001. http://apps.who.int/medicinedocs/documents/s17518en/s17518en.pdf

[83] Business Monitor International. Western Europe Pharmaceuticals Industry Report January 2017. 2017.

[84] Sally C. Davies, Tom Walley, Stephen Smye, Lisa Cotterill, and Christopher J. M. Whitty. "The NIHR at 10: Transforming Clinical Research." *Clinical Medicine (London, England)* 16, no. 6 (December 2016): 501–2. doi:10.7861/clinmedicine.16-6-501

[85] Daniel Cressey. "Overhaul complete for EU clinical trials." *Nature*, June 2014. http://www.nature.com/doifinder/10.1038/nature.2014.15339

One key issue is the increased emphasis on rare diseases and genetic research. Both rare illnesses and specific genetic markers may occur highly infrequently, making it impossible to generate a sufficiently large sample in any particular EU country.[86] This necessitates international longitudinal studies and it is feared that the UK will be unable to participate in such studies once outside the framework of the European CTD. That said, the UK is home to The 100,000 Genomes Project, a national initiative aiming to sequence the DNA of 100,000 people. This is the largest project of its kind in the world.[87]

1.4 Genomics

Genomics refers to the study of the chemical and structural properties of DNA. Genomics provides the tools necessary to analyse an individual's DNA and, in the future, could allow specialised treatments and a better understanding of a given individual's predisposition towards various illnesses. Genomics research is a multi-stage process: first, DNA samples must be acquired, then they must be sequenced (decoded). After DNA has been sequenced, it can be analysed and perhaps used to create commercial products.

The majority of UK genomic companies are start-ups focused on DNA sequencing. The UK currently controls 10% of the world genomics market with Cambridge being the main location in the UK for genomic research. Oxford and London are also important. Switzerland and Ireland are the other two main locations for genomic research worldwide.[88]

1.5 Financing

The UK is the main location in Europe for venture financing of pharmaceutical companies, accounting for over a third of the total Venture capital (VC) raised in the pharmaceutical sector in Europe.[89] The London Stock Exchange, including its smaller sub-market, Alternative Investment Market (AIM), is an important source of funding for pharmaceutical companies, although it is not dominant within Europe.[90]

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[86] Science and Technologies Committee. "EU Regulation of the Life Sciences," 2016. https://www.publications.parliament.uk/pa/cm201617/cmselect/cmsctech/158/158.pdf
[87] Genomics England. "The 100,000 Genomes Project | Genomics England," 2017. https://www.genomicsengland.co.uk/the-100000-genomes-project/
[88] Mike Standing and Elizabeth Hampson. "Genomics in the UK: An Industry Study for the Office of Life Sciences," 2015. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/464088/BIS-15-543-genomics-in-the-UK.pdf
[89] Steve Bates. "UK Biotech Financing and Deals in 2015/16," 2016.
[90] Julia Bradshaw. "UK Biotech Is Surging but More Support Is Needed, Industry Warns." *Telegraph*, June 16, 2016. http://www.telegraph.co.uk/business/2016/06/15/uk-biotech-is-surging-but-more-support-is-needed-industry-warns/

1.6 Distribution

Pharmaceutical distribution is generally regulated by individual EU member states. As such, it exhibits substantial variation across Europe. In the UK, four main pharmaceutical wholesalers (Celesio, Alliance Healthcare, Phoenix and Mawdsley-Brooks) control the majority of the wholesale market. They purchase products from pharmaceutical manufacturers, distribute them around the UK and sell them to pharmacies. A few smaller regional wholesalers have less than 7% market share.[91] Unlike in most EU countries, the UK does not regulate wholesaler margins. This has resulted in its wholesale margins being amongst the lowest in the EU.

In recent years, 'short-line' wholesalers have emerged with the aim of undercutting established wholesalers by only stocking commonly prescribed generic and parallel imported drugs. 'Short-line' wholesalers will not stock drugs that are rarely used or expensive to store. The four main wholesalers now also appear to be entering this industry. For example, Alliance Healthcare has a subsidiary, OTC Direct, which specialises in 'short-line' wholesaling.[92]

Pharmacies receive remuneration based on domestic UK legislation. The UK government needs to ensure that pharmaceutical products are distributed throughout the UK, even in remote areas, and needs to reduce unnecessary visits to GPs and hospitals. The current remuneration scheme reflects these objectives.[93]

1.7 Summary

The UK has a world leading health and life sciences industry. The industry's growth is partly fuelled by factors not directly dependent upon the EU, such as rapidly increasing demand for pharmaceutical products from China and the US. Nonetheless, the sector is also highly concentrated in London, Oxford and Cambridge, reflecting the dependency of the sector on access to high skilled labour and collaboration with world leading universities. If either of these two factors are threatened by Brexit, the sector may not perform as strongly in the future.

In key growing subsectors, such as genomics, many companies rely on grants and VC funding, and focus more on intellectual property creation than revenue generation. The implications that Brexit will have on such companies is unknown and perhaps dependent on decisions taken by UK policymakers. The impact on grants, commercialisation, regulations and innovation will be discussed in detail.

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[91] Panos Kanavos, Willemien Schurer, and Sabine Vogler. "The Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices Report," 2013. http://eprints.lse.ac.uk/51051/

[92] Alliance Healthcare. "What we do."http://www.alliance-healthcare.co.uk/about-us/what-do-we-do

[93] Community Care - Medicines and Pharmacy Division. "Community Pharmacy in 2016/17 and beyond Final Package," 2016. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/561495/Community_pharmacy_package_A.pdf

2.0 EFFECT OF BREXIT LEAVING THE UK ON THE PHARMACEUTICAL INDUSTRY – POST-BREXIT

This section will focus on four main areas of impact of Brexit on the Pharmaceutical industry:

- Innovation
- Trade
- Regulation
- Talent

2.1 Innovation

The pharmaceutical industry is one of the UK's main motors for innovation. Investing more in R&D than any other sector in the UK (£4 billion in 2014[94]), the life sciences sector stimulates the creation of high skilled jobs across the UK, and the formation of partnerships and collaborations with academia and other sectors, which drives value for the UK.

The UK is a global reference in the life sciences industry, having discovered and developed 25 of the top 100 prescription medicines globally.[12] Nevertheless, to sustain the status of global leadership in the sector, it is essential to guarantee long-term funding, the brightest talent and the ability to collaborate at scale. Commercialisation of this research will require funding of small and medium enterprises (SMEs), from inception to sale, or Initial Public Offering (IPO).

There are many potential losses of leaving the EU, which will now be discussed.

2.1.1 Diminished innovation

FPs are the main EU funding mechanism for research, development and innovation, accounting for 78% of total EU research funding received by the UK between 2007 and 2013 (FP7)[95] or 3% of the UK's expenditure on R&D over the same period[96]. As a result of FPs and structural funds for research and innovation activities, the UK secured €8.8 billion in funding from the EU between 2007 and13,[97] earning €3.4 billion more than contributed [31].

Horizon 2020 is the current FP with a budget of €74.8 billion available for the period 2014 to 2020[98]. This amount is distributed based on criteria of scientific excellence,

[12] Business Monitor International. "Pharmaceuticals & Healthcare Q416 Round-Up," 2016.
[94] Office for Life Sciences. "Life Sciences Competitiveness Indicators," 2016
[95] European Commission. "Seventh FP7 Monitoring Report 2013," 2015.
[96] Office for National Statistics. "UK Gross Domestic Expenditure on Research and Development," 2015.
[97] European Commission. "EU Expenditure and Revenue 2007-2013," 2015.
[98] Carlos Frenk, Tim Hunt, Linda Partiridge, Jane Thornton, and Terry Wyatt. "UK Research and the European Union: The Role of the EU in Funding UK Research." *The Royal Society*, 2015. https://royalsociety.org/~/media/policy/projects/eu-uk-funding/uk-membership-of-eu.pdf

alignment with a number of strategic objectives ('grand challenges'), geographical and disciplinary diversity, and potential for commercialisation. Although the HM Treasury has committed to underwrite funding for approved Horizon 2020 projects applied for before the UK leaves the EU,[99] providing short-term reassurance to applicants from the UK's research and innovation base, access to EU funding beyond Horizon 2020 is still unknown.

Life sciences have a long research cycle and require long-term funding. Leaving the EU will likely result in the loss of access to EU funding, not just Horizon 2020 but other funding sources such as the European Structural and Investment Funds. This is likely to discourage scientists from conducting research at UK institutions and potentially reduce the number of UK start-ups, many of which are already contemplating their options post-Brexit[100].

2.1.2 Loss of global research leader status

Although 19% of the world's most cited life science academic publications in 2012 were produced by the UK, [27] 60% of all internationally co-authored papers are with EU partners[101]. Cross-border collaborations between EU member states are becoming increasingly paramount in achieving the scale required to make breakthrough discoveries.

Loss of EU membership presents a considerable obstacle in maintaining the UK at the forefront of global research. Furthermore, if non-EU countries see European scale as indispensable to meeting their objectives, it is likely that they will target partnerships outside of the UK. In addition to this, loss of alignment with the EU on data protection could further endanger the UK's leading position since the current UK Data Protection Act is insufficient to enable pan-European data sharing.

2.1.3 Falling R&D spending

There is a positive correlation between government spending on medical research and private R&D spending, a 1% increase in the former being associated with a 0.7% increase in the latter.[102] Any reductions in public funding could result in a decline in

[99] Greg Clark and Jo Johnson. "Safeguarding Funding for Research and Innovation," 2016. https://www.gov.uk/government/news/safeguarding-funding-for-research-and-innovation
[100] Sam Schechner. "Europe's Startups Reassess Britain After 'Brexit.'" *Wall Street Journal*, June 26, 2016
[101] Frenk, Carlos, Tim Hunt, Linda Partridge, Janet Thornton, and Terry Wyatt. "UK Research and the European Union: The Role of the EU in International Research Collaboration and Research Mobility," 2016. https://royalsociety.org/~/media/policy/projects/eu-uk-funding/phase-2/EU-role-in-international-research-collaboration-and-researcher-mobility.pdf
[102] The Policy Institute [King's College London]. "Public Medical Research Drives Private R&D Investment," 2016. https://www.kcl.ac.uk/sspp/policy-institute/publications/SpilloversFINAL.pdf

private R&D spending from pharmaceutical companies who, in 2014, spent 16% of their European R&D budget in the UK [103].

The benefit of increased government expenditure on research quality can be demonstrated through Singapore's Agency for Science, Technology and Research (A*STAR), which was established in 1991. This body is credited with improving Singapore's output to the biotechnology sector by attracting top researchers from around the globe. Its success is believed to be rooted in the lack of strict regime and stringent control of research targets; investing in the best researchers, not merely the best research proposals, has led to an influx of researcher applications[104]. In 2016, it committed 19 billion Singaporean dollars (~£11 billion) to fund R&D until 2020.[105]

2.1.4 Deterioration of funding pipelines

The commercialisation and growth of SMEs rely heavily on the UK's VC, whilst also depending greatly on funding from the European Investment Bank (EIB) and the European Investment Fund (EIF); these constitute 25-40% of VC funds and attract further private investment[106]. If the EIB/EIF funding pipeline is broken, UK SMEs will suffer and it is likely that fewer start-ups will be created. Moreover, the loss of EU passporting rights for financial institutions, the weakening of the IPO market and increasing isolation from Foreign Direct Investment are likely to paralyse initiatives aimed at funding pipelines and restrict the capacity to raise funds in Europe.

2.2 Trade

Stability coupled with the mobility of goods and capital across borders are pillars of the global pharmaceutical industry. Supply chains commonly involve the free movement of goods across borders, a practice that is currently facilitated by a common regulatory system across the EU and the absence of border controls. The UK has particularly benefited from this as companies have been encouraged to establish bases in the UK due to the competitive fiscal structure offered.

Leaving the EU could severely damage commerce with the potential introduction of custom duties, import VAT and border controls likely to incur cost, cause disruptions to established trade routes and restrict the supply of medical technology. The UK could face a rise in the drug bill of its National Health Service (NHS), reduced private

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[103] European Federation of Pharmaceutical Industries and Associations. "The Pharmaceutical Industry in Figures," 2016. http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf

[104] "Singapore's Salad Days Are over." *Nature* 468, no. 7325 (December 9, 2010): 731–731. doi:10.1038/468731a

[105] Loke Kok Fai and Xabryna Kek. "Govt Commits S$19b to New 5-Year Plan for R&D Initiatives RIE2020." *Channel News Asia*. Accessed March 28, 2017. http://www.channelnewsasia.com/news/business/singapore/govt-commits-s-19b-to-new/2409426.html

[106] Steve Bates and Mike Thompson. "Maintaining and Growing the UK's World Leading Life Sciences Sector in the Context of Leaving the EU; "It Is Hard to Think of an Industry of Greater Strategic Importance to Britain than Its Pharmaceutical Industry"," 2016. http://www.abpi.org.uk/our-work/library/industry/Documents/UK-EU-Steering-Group-Report.pdf

investment and the departure of established companies, hence Simon Stevens, Chief Executive of NHS England, announcing that Brexit could represent a 'terrible moment' for the NHS[107].

Now, the losses in trade that could result from the UK exiting the EU will be considered.

2.2.1 Disruption and added costs

The costs of UK business trading with the EU has been greatly facilitated and minimized by the current regulatory alignment with the EU, as well as the absence of border controls and the EU Parent-Subsidiary and Interest and Royalties Directive. In 2015, life science goods accounted for £29.7 billion in imports and £29.5 billion in exports, of which 44% went to the EU alone. [39]

However, this could cease being the case if the UK abandons the EU. Considerable disruption and additional costs can be expected if UK-EU trade becomes burdened with the introduction of border controls involving the declaration and inspection of goods in addition to custom duties and import VAT throughout the manufacturing and supply chain stages. In the near future, companies could therefore be deterred from investing in the UK and those currently based in the UK may consider leaving. This would have a direct impact on the number of people employed in the UK pharmaceutical industry. In addition, cash flow could be further damaged if simplifications to the UK VAT system for manufacture and supply are not implemented.

Simplified custom procedures or 'self-assessment' are currently being explored by the industry and HM Revenue & Customs,[108] presenting some options in terms of minimising uncertainty and reducing administrative tasks. However, the most effective solution would require the creation of a streamlined, standalone customs system for UK-EU trade, an alternative likely to be unfavourable to most EU countries on grounds of cost and the principle of treating the UK no differently to other non-EU countries. Bilateral renegotiation would thus be necessary to recover, if possible, the current advantageous trade framework.

2.2.2 Endangering the accessibility and safety of medical technologies

The cumulative damage caused to trade could reduce UK patients' accessibility to medical technology and increase the NHS's bill. Furthermore, not committing to the full implementation of the European Falsified Medicines Directive (FMD) would

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[39] Steve Bates and Mike Thompson. "Maintaining and Growing the UK's World Leading Life Sciences Sector in the Context of Leaving the EU; "It Is Hard to Think of an Industry of Greater Strategic Importance to Britain than Its Pharmaceutical Industry"," 2016.

[107] Siobhan Fenton. "Brexit Price Surge Could Deny Patients Life-Saving Drugs on NHS." *Independent*, July 3, 2016. http://www.independent.co.uk/life-style/health-and-families/health-news/brexit-nhs-drug-prices-medicine-patients-effects-what-will-happen-a7117056.html

[108] Alex Barker. "UK Trade Sector Warns of Brexit Customs Disruption at Borders." *Financial Times*, October 24, 2016

deprive the UK of the EU's efforts to prevent falsified medicines entering EU countries and thus reaching UK patients.

2.3 Regulation

The EU's regulatory system is highly sophisticated and robust, providing the necessary scale and certainty for the development of innovative, effective and safe medical technologies. This system has been developed over the last 50 years with the close collaboration of the UK's MHRA, Notified Bodies, and Veterinary Medicines Directorate (VMD), providing expertise and capacity to handle part of the workload of the European Medicines Agency (EMA).

Although reassembling an independent regulatory system in the UK would be possible, the expertise, resources and time required would be considerable. This would still result in the UK becoming a less relevant market, whilst disrupting trade across borders and complicating efforts to stop falsified medicines from entering the country. GSK and AstraZeneca have already expressed their disapproval for such plans, preferring that the UK continues its established relationship with the EMA.[109]

There are multiple potential losses for regulation in the pharmaceutical industry following an exit from the EU.

2.3.1 Loss of certainty and scale

Losing alignment with EU regulation will inevitably entail the loss of the certainty and scale that accompanies it. Currently, regulation affects how the industry researches, develops, manufactures and delivers medical technologies, and it is critical for guaranteeing the safety and reliability of these products. The Association of the British Pharmaceutical Industry (ABPI) supports the current regulatory system, which is regarded as highly effective, but has expressed its concern regarding the potential additional bureaucracy that a new, independent UK regulatory system would create. [39]

Duplication of processes, increased costs and divergence of standards would make the UK an unattractive location for the development, manufacture and launch of new products. Even if this system were built upon with the aim of improving existing EU regulations, the UK would still be regarded as a 'second priority' market due to the higher costs, delays and disruptions associated with it.[110] It is important to note that the UK represents only 3% of global pharmaceutical sales;[111] it is not a large enough market to counterbalance the additional complications and costs.

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[39] Steve Bates and Mike Thompson. "Maintaining and Growing the UK's World Leading Life Sciences Sector in the Context of Leaving the EU; "It Is Hard to Think of an Industry of Greater Strategic Importance to Britain than Its Pharmaceutical Industry"," 2016.
[109] David Crow and Gonzalo Viña. "Pharma Companies Argue Against New UK Regulator." *Financial Times*, November 30, 2016. https://www.ft.com/content/713b61be-b6f8-11e6-ba85-95d1533d9a62

[110] [Personal Communication] "Professor Mads Krogsgaard Thomsen – Chief Science Officer of Novo Nordisk," January 2017.
[111] IMS Health. "IMS World Review Executive," 2016.

2.3.2 Health and Safety

If the UK becomes a 'second priority' market, patients' access to new medical technologies will be delayed and the availability of medical products and treatments currently in use could be threatened. An end to cooperation with the EU on matters of European pharmacovigilance (PV) and future medical device databases (EUDAMED) will diminish the ability of the UK to detect side effects and respond to safety issues. In addition, loss of access to the European Centre for Disease Prevention and Control (ECDC) could hinder the UK's ability to produce medicines that fight pandemics, and may delay the manufacture and supply of vaccines.

2.3.3 Clinical Trials

In April 2014, a new Clinical Trials Regulation (CTR), Regulation EU No. 536/2014, was adopted by the EU with the aim of full implementation by 2018.[39] This CTR focuses on the simplification of current rules, streamlining applications for the conduction of clinical trials and their authorisation, and aiming to increase the transparency of the data produced.[112] Should the UK not adhere to Regulation EU No. 536/2014, innovation could be hindered as the opportunities for doctors and academics to conduct clinical trials will be restricted, and companies will begin to look elsewhere to carry out theirs.

2.3.4 Influence

The MHRA has a wide range of international links and is respected worldwide as one of the leading regulatory authorities for medicines and medical devices. The MHRA has shared its regulatory expertise with Malta, Latvia and the Czech Republic in a bid to help countries that have recently joined the EU develop the systems necessary to playing an active part in European regulation.[113] The MHRA was:

- the lead regulator in granting licensing to 7 out of 10 European medical products in 2007[114];
- a rapporteur in 15% of the procedures of the PV Risk Assessment Committee (PRAC) and the Committee for Medicinal Products for Human Use (CHMP) in 2015 [39];

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[112] Office Journal of the European Union. Regulation (EU) 536/2014 of the European Parliament and of the Council of April 16 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, Office Journal of the European Union (2014). http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0536

[113] Medicines and Health Regulatory Authority. "Safeguarding Public Health through the Effective Regulation of Medicines and Medical Devices," 2008. http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf

[39] Steve Bates and Mike Thompson. "Maintaining and Growing the UK's World Leading Life Sciences Sector in the Context of Leaving the EU; "It Is Hard to Think of an Industry of Greater Strategic Importance to Britain than Its Pharmaceutical Industry"," 2016.

[114] The Pharmaceutical Journal. "MHRA/EMEA: Rivalry or Partnership?" *The Pharmaceutical Journal* 279 (2007), 226. http://www.pharmaceutical-journal.com/news-and-analysis/mhra/emea-rivalry-or-partnership/10004834.article

- responsible for inspections that resulted in 25% of Good Manufacturing Practice (GMP) certificates issued in 2015 for sites outside the EU[39].

The UK's VMD has also played a notable role in regulation, acting as a Reference Member State in 43% of Mutual Recognition Procedures in 2015.[39] The loss of influence in the European system could deter regulatory experts from living and working in the UK, and result in the future implementation of regulations that are less favourable to UK interests, damage that will worsen if the EMA relocates.

2.3.5 Intellectual Property (IP)

The reduction or loss of protection of IP is likely to discourage investment in pharmaceutical and biotechnology innovation, a process characterised by its long duration and high cost and risk.

Currently, the EU benefits from highly supportive incentives such as:

- Supplementary Protection Certificates (SPCs) that extend the protection of patented active ingredients present in pharmaceutical or plant protection products, compensating for the loss of patent term that results from long development processes;
- Regulatory Data Protection (RDP), orphan designation – a status assigned to a medicine intended for use against a rare condition to ensure protection from competition once on the market – and rewards for investigations into paediatric uses and formulations.

It is also important to consider the impact on parallel trade. Despite Europe-wide harmonization, the European pharmaceutical market is divided into individual national markets, which results in the same product having different prices in different member states. Parallel traders buy the original product at low prices in EEA countries and resell it in other member states. This is only possible because patents are exhausted across the EU as soon as a product is placed on the market in any member state. In 2014, parallel imports accounted for 7.9% of UK's pharmaceutical sales.[36] If the UK does not remain part of the EU patent exhaustion zone, significant pressure will be added to NHS spending on medical products as cheap sourcing via parallel import will be eliminated as an option, accentuating price differences between the UK and EU countries.

2.4 Talent

The UK's privileged position at the forefront of the pharmaceutical industry is bolstered by its ability to attract, develop and retain talent, which would not be possible without pan-European collaboration and free movement across borders. This concentration of talent aids the creation of start-ups run by highly skilled individuals. They attract the interest of big pharmaceutical companies, in turn attracting more highly skilled individuals and driving a virtuous cycle.

The next wave of medical innovation will generate new, highly skilled jobs throughout the value chain. Whether the UK can continue to be a global reference in the life sciences industry will be determined by its ability to supply qualified individuals from home and, even more so, from abroad. The development and implementation of a talent pipeline will therefore be vital if the erosion of the UK's position is to be avoided.

The potential losses for talent brought by Brexit include the following.

2.4.1 Leadership

Approximately 17% of Science, Technology, Engineering and Mathematics (STEM) academics in UK research institutions are non-UK EU nationals.[115] Facilitating movement across borders is essential to ensuring the supply of talent demanded in current and emerging skill gap areas such as bioinformatics, genomics or Advanced Therapy Medicinal Product (ATMP) manufacturing. The UK's global reference status therefore depends on removing any barriers to attracting, developing and retaining talent. This includes the current state of uncertainty regarding the UK's future immigration policy and the unwelcoming image projected on foreign workers.

2.4.2 Headquarters

The UK is home to the EMA, the European headquarters of over a dozen global pharmaceutical companies, the global headquarters for GSK and AstraZeneca, and considerable R&D and manufacturing operations for Amgen and Pfizer. This has attracted and nurtured talent across the value chain in areas such as research, development, regulation, manufacturing and commerce. GSK and AstraZeneca, for example, will employ 15 and 50 university graduates respectively in 2017.[116] Outside of the EU, the UK may see its capacity to attract talent significantly reduced, which could potentially result in the relocation of operations, causing losses in job, economic contributions and innovation capacity.

[115] Campaign for Science and Engineering. "Immigration: Keeping the UK at the Heart of Global Science and Engineering," 2016. http://www.sciencecampaign.org.uk/resource/caseimmigrationreport2016.html

[116] GlaxoSmithKline. "GSK Graduate Jobs," 2017. https://www.graduate-jobs.com/scheme/gsk. Also: AstraZeneca. "Graduate Jobs & Schemes," 2016. https://www.graduate-jobs.com/scheme/astrazeneca

3.0 REGULATION OF MEDICINES

This section evaluates how the regulations surrounding basic research, clinical trials, drugs development and researchers could be affected.

3.1 Current Climate

Currently, market authorisation of new medications is regulated by the EMA which works closely with the UK's internal regulator, the MHRA. The MHRA is thought to have considerable influence over the EMA, given the UK's status as a net importer of medicines, its unique NHS, and strong and transparent health technology assessment systems performed by the National Institute for Health and Care Excellence (NICE). The EMA is currently headquartered in London and, as put forward in comments by the ABPI, 'co-location with the MHRA has reinforced and further enhanced the engagement and thought-leadership that the MHRA plays in European and global regulatory development'[117].

With Brexit, the EMA may be relocated outside of London. A decision by the EMA to move out of London will be detrimental to the market attractiveness of the UK for foreign pharmaceutical companies. Many pharmaceutical companies (such as GSK and Merck & Co.) are currently headquartered in London. However, in the words of Japan's Ministry of Foreign Affairs, the 'appeal of London as an environment for the development of pharmaceuticals would be lost' if the EMA relocates, which would in turn drive negative impacts on R&D.[118]

It is difficult to assess the extent to which the UK's pharmaceutical industry will continue to be regulated by EU laws once the UK leaves the EU. A large part of this rides on whether the UK will continue to be part of the European single market and support free movement of medicinal products, a decision for both the UK and the remaining EU member states to reach. The most likely outcome is that companies seeking to launch new products will have to apply separately for regulatory approval in the UK and in the EU. This will introduce delays to the system and may be detrimental to drug launches in the UK, as companies are likely to prioritise applying for regulatory approval in the considerably larger EU market.

Furthermore, whilst the MHRA has released a statement that it currently remains committed to playing a full and active role in European regulatory procedures for medicines and devices, its position beyond this interim period is unclear. Sir Michael Rawlins has expressed the MHRA's preference for working closely with the EMA and maintaining the current regulatory system, even to the extent of contributing to the

[117] Bates and Thompson. "Maintaining and Growing the UK's World Leading Life Sciences Sector in the Context of Leaving the EU. "It Is Hard to Think of an Industry of Greater Strategic Importance to Britain than Its Pharmaceutical Industry"," 2016.
[118] Zachary Brennan. "Japan's Ministry of Foreign Affairs: Don't Move EMA Headquarters From London." *Regulatory Affairs Professionals Society*, 2016. http://www.raps.org/Regulatory-Focus/News/2016/09/06/25773/Japan's-Ministry-of-Foreign-Affairs-Don't-Move-EMA-Headquarters-From-London/

deliberations of the Scientific Advisory Committee[119]. Ultimately however, the extent to which the MHRA will engage with the EMA will be determined by the UK Parliament's Scientific Advisory Body.[120]

Regardless of the UK's path in terms of EU market access (be it an EEA, EFTA or WTO trade agreement), there will be an increased authorisation burden for the UK as drugs that have already been centrally approved by the EMA will need additional authorization in the UK. However, these problems could be circumvented by various administrative streamlining measures such as those used by Liechtenstein, Norway, Iceland and Switzerland. For example, Liechtenstein uses processes that automatically approve medicines authorised by the EMA, whilst Norway and Iceland remain under the EMA's umbrella.

If separate regulatory processes exist for the UK and the rest of the EU, companies seeking to launch new products will have to apply separately for regulatory approval in these regions, which would introduce delays to the system. This might even be detrimental to drug launches in the UK, as companies are likely to prioritise applying for regulatory approval in the considerably larger EU market; the UK makes up just 3% of the world's market for new medicines.

Sir Michael Rawlins has expressed his view: 'One of the biggest worries I have about Brexit and standing alone as a regulator is that we are only 3% of the world market for new drugs and, if we are not careful, we are going to be at the back of the queue.'[121] Dr David Jefferys, speaking on behalf of the ABPI and as Vice President of Eisai Co., a Japanese pharmaceutical firm, announced: 'The early innovative medicines will be applied for in the USA, in Japan and through the European system, and the UK will be in the second, or indeed the third, wave - so UK patients may be getting medicines 12, 18, 24 months later than they would if we remained in the European system.'[122]

Conversely, some scientists take a more positive view, arguing that Brexit provides an opportunity for more liberal regulatory rules that will permit drugs to be launched more quickly in the UK.[123] Supporters of this view argue that Brexit presents global pharmaceuticals companies with a simpler way of gaining approval for their drugs in the UK since a national agency could independently dictate whether medicines are safe,

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[119] BBC World Service. "BBC World Service - World Update: Daily Commute, Brexit Watch: Public Health After Brexit," 2017. http://www.bbc.co.uk/programmes/p04tmcp0#play, first aired 22 Feb 2017
[120] BBC World Service. "BBC World Service - World Update: Daily Commute, Brexit Watch: Public Health After Brexit," 2017.
[42] Crow and Viña. "Pharma Companies Argue against New UK Regulator." *Financial Times*, November 30 2016.
[121] The House of Lords Science and Technology Committee. "The Impact of Brexit on Regulation and Standards," 2017. http://www.parliament.uk/business/lords/media-centre/house-of-lords-media-notices/house-of-lords-media-notices-2017/house-of-lords-media-notices-january-2017/lords-committee-to-take-evidence-on-impact-of-brexit-on-regulation-and-standards/
[122] Rob Merrick. "Brexit Will Put UK Patients at 'Back of Queue' for Vital New Drugs, Health Experts Warn." *The Independent*, February 10 2017
[123] Megan Boxall. "Brexit and the Pharmaceutical Industry." *Investors Chronicle*, November 10 2016. http://www.investorschronicle.co.uk/2016/11/10/shares/sectors/brexit-and-the-pharmaceutical-industry-oZwUvT2tqnPDPCpgRBa8vI/article.html

effective and affordable in one single, streamlined process.[42] Sir Michael Rawlins has also suggested the possibility of launching a system where new medicines are given provisional licenses, whilst collecting more real world data to ensure the UK's market attractiveness attractive for pharmaceutical companies.[124]

3.2 Regulation of medical devices

Much like medicines, medical devices are regulated by the EMA and the MHRA. The Medical Devices Directive (MDD) similarly attempts to apply EU-wide standards to medical devices. This means that, at present, devices licensed in one EU country can be sold throughout the EU. This 'lowest common denominator' system allows manufacturers to deliberately register their products in countries with lower standards.

With Brexit, the MHRA is likely to impose tighter standards on medical devices, putting in place regulations that the EMA failed to install due to resistance by member states. This will benefit larger pharmaceutical companies with more sophisticated R&D and manufacturing infrastructure for ensuring products are of a high quality. Simultaneously, these regulations may create barriers to entry for new start-ups that lack the capital to produce high quality products to meet the more stringent regulations.

It is also possible that, in real terms, there will be few changes. The UK, whilst representing a mere 3% of the global biomedical industry, has a reach far greater than that thanks to its renowned NICE health technology assessments, largely regarded as the 'gold standard'. The UK's transparency, rigorous evidence-based health technology assessments and cost containment measures demanded by the NHS mean that many countries are inclined to follow its lead in evaluating and adopting nascent health technologies.

NICE, specifically the NICE Technology Appraisal Committee, is extremely influential in this area. Ultimately, the real determinant of the extent to which particular technology is adopted in the UK healthcare market is its appraisal by NICE and not its ability to cross the lower bar of regulatory approval; hence, changes to regulation of medical devices may not translate into actual impact on device sales.

3.3 Movement of People

Present estimates show that 17% of researchers in the pharmaceutical industry are EU nationals and that 72% of UK-based researchers have spent some time honing their research skills in non-UK institutions.[48] Freedom of movement of labour is a fundamental principle of the EU common market, and Brexit will almost certainly bring with it new immigration controls. The policy of free movement has been instrumental in offering many researchers the opportunity to gain education and experience working in overseas laboratories or institutions in the EU. Similarly, many pharmaceutical companies are multinational and rely on movement of research and support staff

[124] BBC World Service. "BBC World Service - World Update: Daily Commute, Brexit Watch: Public Health After Brexit," 2017.

between branches in different countries. Whilst these processes will be hindered, it is hard to quantify the full impact of Brexit in this area; much depends on the Home Office's future policies concerning the ease of labour flow.

Nevertheless, the government remains committed to ensuring researcher mobility is protected. The House of Lords concluded that researcher mobility is 'of critical importance to the UK science community, including academia, business and charities', and that 'researcher mobility must be protected if UK science and research is to remain world-leading'.[125] A parliament report on the implications and outcomes for science and research concluded by stating: 'We understand that the Government is not yet able to offer firmer guarantees regarding future immigration rules for researchers but remind them that this is essential in order to continue to attract top-quality researchers to the UK […] there is clear agreement that researcher mobility is a crucial component of the UK's successful research and science sector.'[126]

3.4 Clinical Trials Directive and Clinical Trials Regulation

EU legislation aims to standardize regulation of clinical trials but, in practice, there is often inconsistent implementation of the CTD due to difficulties coordinating the 28 member states, problems with commission guidance being issued late, and a lack of clarity regarding many definitions in the legislation. These factors have led to difficulties running large multinational and multi-centre trials.

The incoming CTR should mitigate these problems, although the legislation has not yet come into force. In 2014, the EU replaced the 2001 CTD with the improved CTR, which sought to rectify concerns raised by many stakeholders that complicated legislation and rules were actively impeding research. The CTR, which member states are not obliged to transpose into their national legislation until 2018, aims to introduce a single EU portal for clinical trials, allowing those in the industry to apply centrally and receive approval to conduct trials in all member states. The smaller and less lucrative UK market risks being relegated to secondary importance if applying separately to clinical trial applications there proves costly and complex.

In theory, there are considerable benefits to standardising regulation across the EU. Standardisation allows pharmaceutical companies to run larger multinational trials and collect robust and comparable datasets. Should the UK have independent rules and registration processes that do not match those in the EU, pharmaceutical companies may willingly or unwillingly exclude the UK from future multinational trials.

With Brexit, the UK will need to devise independent regulation for clinical trials and, whilst this poses an additional administrative burden, it also affords the UK an opportunity to draw up its own legislation, which may reduce the red tape currently

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[125] House of Lords Science and Technology Select Committee. "EU Membership and UK Science." https://www.publications.parliament.uk/pa/ld201516/ldselect/ldsctech/127/127.pdf

[126] Roberta Blackman and Nicola Blackwood. "Leaving the EU: Implications and Opportunities for Science and Research Seventh Report of Session 2016–17." *Labour*, 2016. https://www.publications.parliament.uk/pa/cm201617/cmselect/cmsctech/502/502.pdf

associated with setting up clinical trials, and facilitate research carried out by pharmaceutical companies.[127] The EU is notoriously slow at updating its regulation (it took almost 20 years to change the CTD) and, without the need to coordinate with other parties, UK regulators may prove far more responsive to the changing research landscape. It is expected that there will still be a degree of collaboration and standardisation with the EU, but, on the whole, the future landscape looks to be one more favourable to clinical trials research. Parliament has also raised the opportunity for reform, whilst noting the need to balance this with the benefits that consistency in regulation brings.[57]

[57] Blackman and Blackwood. "Leaving the EU: Implications and Opportunities for Science and Research Seventh Report of Session 2016–17." *Labour*, 2016.
[127] UCL. "Written Evidence for Select Committee - UCL," 2016. http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/leaving-the-eu-implications-and-opportunities-for-science-and-research/written/36083.html

4.0 CONSIDERATION OF POST-BREXIT MODELS

4.1 Initial overview

The UK's pharmaceutical industry incorporates twenty global pharmaceutical companies, as well as many smaller ones, which are supported by a strong bioscience science industry and start-up market.[128] The EU's single framework for regulating and improving pharmaceutical products has contributed to a track record of patient safety and productivity, and a strong export market, 43% of which goes to the EU[59]. London, Cambridge and Oxford are especially crucial to the UK's pharmaceutical industry in terms of manufacturing and R&D, London alone providing 15,000 of the 70,000 jobs in this sector[129].

4.1.1 EMA

A potential impact of Brexit will be the relocation of the headquarters of the EMA. Currently located in London, the EMA is a decentralised body responsible for protecting and promoting public and animal health. This is achieved through regulation of pharmaceutical companies across the EU.

The EMA has already forecast potentially significant disruptions to its operations following Brexit but it remains unclear as to whether a relocation will take place or what other changes will emerge in terms of the UK's relationship with the EMA.[130] The example of the EMA is telling of the wider uncertainty surrounding Brexit and the impending changes facing the pharmaceutical industry. If the EMA, one of the key organisations governing the EU pharmaceutical industry, were to physically leave the UK, it would likely be caused by or signify the legislative cutting of ties between the UK and the EU, whereby the UK pharmaceutical industry would cease to be dictated by EU legislation and likewise have no say in these laws.

A consideration of the Norwegian and Swiss models can give an idea of some of the most obvious paths that the UK could take as it forges a new relationship with the EU and its pharmaceutical sector specifically.

4.1.2 Research funding

The UK currently receives research funding from the EU, notably by way of Horizon 2020, the EU's current FP for Research and Innovation, which aims to drive economic growth and create jobs through investment in scientific research. Such programmes

[128] HM Treasury. "HM Treasury Analysis: The Long-Term Economic Impact of EU Membership and the Alternatives," 2016. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/517154/treasury_analysis_economic_impact_of_eu_membership_print.pdf
[129] London's Economic Plan. "London's Pharmaceutical Industry," 2016. http://www.uncsbrp.org/pharmaceutical.htm
[130] Monika Benstetter. "EMA Management Board: Highlights of December," 2016. http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2016/12/WC500218416.pdfs

have enabled the EU to establish a collaborative network of research initiatives and become a world leader in scientific research ahead of both China and the US, a feat that has ultimately benefitted the UK.[131]

There are three existing models that could provide a solution that would allow the UK to continue receiving this funding and benefitting from its association with EU-driven scientific research actions. These models pertain to countries that are not EU member states but are nevertheless permitted to receive EU funding and participate in the activities supported by this funding. A further, and likely, route will be that the UK negotiates its own model with the EU as it seeks to protect its current and future research funding. It should also be noted that, even if the UK were able to adopt an existing model, such as that of an 'associated country', additional negotiations will be inevitable.[132]

4.1.3 Associated countries

These are non-EU member states that have stipulated a formal agreement on full or partial association with an EU research funding programme. It should be stressed that each programme necessitates its own separate negotiations and that 'associated countries' have varying relationships with these research programmes. In other words, there is no single 'associated country' model.

To be involved in these programmes in the same manner as EU member states, these countries must pay a fee which is calculated based on their GDP and on further negotiations. It is probable that, in monetary terms, these countries can gain more than they contribute, as is exemplified by Switzerland. Nevertheless, whilst these countries can receive and benefit from EU research funding, they cannot influence the direction of these programmes as access does not grant them a voice in the European Council or European Parliament. This is the key difference between EU member states and 'associated countries'.

Since the referendum result, lobbying on the part of Universities UK (UUK) has sought to put pressure on the UK government to push negotiations for 'associated country' status [63]. This would secure the UK's current participation in Horizon 2020 in a similar manner to other 'associated countries'.[63] As of September 2016, there are 16 'associated countries' working with EU research funding programmes. They include those inside the EEA and/or the EFTA, namely Norway and Switzerland, and those outside of them such as Israel and Turkey. [63]

4.1.4 Non-associated third countries

[131] Mike Galsworthy and Rob Davidson. "Debunking the Myths about British Science after an EU Exit." *LSE Blogs*, December 2015. http://blogs.lse.ac.uk/brexit/2015/12/05/debunking-the-myths-about-british-science-after-an-eu-exit/

[132] John Morgan. "Brexit: Could UK Join EU Research System as 'associated Country'?." *Times Higher Education*, July 2 2016

These are non-EU member states, such as Afghanistan and Argentina, that are not formally associated with EU research funding programmes and consequently not represented on the programmes' management committees. However, organisations and participants from these countries can become partners with the programmes and receive funding.

Non-associated third countries fall into two groups:

- Developing countries: research organisations in some 130 developing countries are automatically eligible for funding.[133]
- Industrialised countries and emerging economies: participants from these countries must independently finance their actions within the programmes. For some countries, this has involved co-funding the activities of participants who have been selected to partake in Horizon 2020.
- In exceptional circumstances, industrialised and emerging economies can receive EU funding if:
    - there is a bilateral agreement between the country and the EU (sometimes the case for participants from the US);
    - the country is explicitly identified in the relevant programme and call for proposals as being eligible for funding;
    - their participation is deemed by the European Commission to be essential for carrying out the action.

4.1.5 European Research Council and the Marie Skłodowska-Curie funding

This option welcomes applications for funding from individual researchers from any country in the world providing they are seeking the opportunity to work in Europe for a certain period of their career. The initiative claims to support researchers irrespective of their career stage or nationality. This could enable the UK to continue receiving EU research funding but only from the perspective of individuals as opposed to UK organisations or the country as a whole.

4.1.6 Final points

Horizon 2020 ends in 2020 when it will be succeeded by FP9. Whether and how the UK will participate in future EU research programmes after exiting the EU is unclear. The above-mentioned options are those that currently exist but this does not preclude that another model might be found. This will of course depend on the negotiations that are just beginning to take shape.

[133] "Horizon 2020: Work Programme 2016-2017 (General Annexes)." *European Commission Decision C* 6776, no. 13 (2015). http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016-2017/annexes/h2020-wp1617-annex-ga_v1.0_en.pdf

4.2 The pharmaceutical industry

In considering the post-Brexit options for the UK pharmaceutical industry, there are three key variations to be discussed: EEA (specifically Norway), EFTA (specifically Switzerland) and WTO.

4.2.1 EEA

The EEA, established on the 1st of January 1994, currently includes Norway, Iceland and Liechtenstein. These counties implement EU legislation, such as free trade (except for agriculture and fisheries in most cases) and free movement, acknowledge EU administrative decisions, contribute to the EU to help level social and economic disparities across member states, and pay custom taxes and other administrative costs. However, they cannot vote in the European Parliament and have no say in its laws.

4.2.2 Norway

The EEA model can be considered as a poor deal for Norway since it is so similar to that of EU member states. However, Norway has retained some autonomy over its pharmaceutical sector. It has its own Medicines Agency (Statens legemiddelverk), which is a subsidiary to its national healthcare organisation and is responsible for marketing authorisation, classification, vigilance, pricing, reimbursement and providing information on medicines to prescribers and the public. This is not so different to the UK where there is the NHS and the MHRA responsible for marketing medicines.

Although being part of the EEA means that Norway must adhere to EU regulations regarding marketing authorisations, its own Medicines Agency can influence the work of the EMA as EU member states can.[134] In addition, Norway has control over its own pricing and reimbursement, which is different for out- and in-patients, unlike for the rest of the EU.[65] There are therefore subtle differences in how Norway operates compared to that of EU member states, which could make it easier to sell this as a solution to the majority who voted for Brexit. In addition, considering that the UK's existing framework is similar to Norway's, it is feasible to envisage the UK transitioning to this model.

4.2.3 Advantages of the EEA model for the UK[135]

The EEA model would likely be the easiest option for the UK pharmaceutical industry, allowing for a transition to a legal framework only slightly different to the current

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[134] Helga Festøy and Anne Helen Ognøy. "PPRI Pharma Profile," 2015. https://legemiddelverket.no/Documents/English/Price and reimbursement/PPRI_Pharma_Profile_Norway_20150626_final.pdf

[135] Vincenzo Salvatore. "The Impact of Brexit on the Pharmaceutical Industry: Some Preliminary Considerations." *Pharmafile*, 2016. http://www.pharmafile.com/news/505928/impact-brexit-pharmaceutical-industry-some-preliminary-considerations

model, whilst incentivising pharmaceutical companies to remain in the UK. An analysis of Norway suggests that the EEA model can succeed in maintaining and even attracting key players in the pharmaceutical industry; as of 2015, all major pharmaceutical companies were present in Norway with nine having production facilities there, the largest being GE, Takeda and Fresenius Kabi[65].

4.2.4 Legislative/organisational

If the UK does not join the EEA, it risks becoming a third party, external to the EU and the EEA where pharmaceutical companies can rely on centralised legislation and access to information. The UK will no longer be entitled to these frameworks and its pharmaceutical sector will be disrupted as a result. Without this continuity, pharmaceutical companies may be forced to seek regulatory approval from the UK and the EU separately, which would prove unfavourable to the UK since these companies will have much more to gain by appealing to the EU's 500 million patients over the UK's 60 million[55].

Adopting an EEA model would therefore protect the status quo, allowing for continued organisation and efficiency between the UK and the rest of the EU in terms of R&D, clinical trials, manufacturing, marketing, distribution etc. This model would also enable pharmaceutical companies that are only based in the UK to benefit from the new reform coming into force in 2018 which will introduce a single EU portal for clinical trials. This will ensure a harmonised process for approval of clinical trials across the EU, and enable participating nations to access and share clinical trial information on an EU database.[136]

4.2.5 Business/economic

If the UK attains membership to the EEA, it effectively retains its status within the EU. This incentivises those EU pharmaceutical companies with registered offices or manufacturing sites in the UK, as well as those that conduct clinical trials in the UK, to continue their activities in much the same manner. Without this security net, these companies will have to demonstrate that their work complies with EU standards, which could prove time-consuming and expensive, possibly resulting in these companies leaving the UK.

This is especially relevant to those EU pharmaceutical companies that have no offices or manufacturing plants outside of the UK. Unless the UK joins the EEA, these companies will likely relocate to EU or EEA countries in the pursuit of operational ease and business security, as it will be disruptive and time-consuming to establish new legislative practices within a changing business environment to boot. Joining the EEA

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[55] Megan Boxall. "Brexit and the Pharmaceutical Industry." *Investors Chronicle*, November 10, 2016.
[136] Privolnev, Yulia. "Brexit's Impact On The Global Pharmaceutical Industry Future Access To The EU Common Market." *Pharmaceutical Online*, 2016. https://www.pharmaceuticalonline.com/doc/brexit-s-impact-on-the-global-pharmaceutical-industry-future-access-to-the-eu-common-market-0001

should therefore protect the UK pharmaceutical industry from the organisational chaos and economic detriment of pharmaceutical companies leaving the UK.

4.2.6 EFTA

The EFTA was formed in 1960 and, today, comprises Switzerland, Norway, Iceland and Liechtenstein. It allows for these four states to be incorporated into the EU's single market. The EFTA is a prerequisite for joining the EEA. As Switzerland is not also a member of the EEA (the Swiss rejected the idea in 1992), it has its own bilateral agreements with the EU, which took two years to finalise and cover all areas from trade to transport. The complexities of applying a similar model to the UK would therefore engender momentous negotiations.

4.2.7 Switzerland's model (and what it signals for the UK)

'Switzerland may guard its political and cultural independence fiercely, but its scientific sector has a strongly international flavour.'[137]

Switzerland is a rich country and that is partly thanks to its pharmaceutical industry, which is geared towards high value exports and supported by expert research. Switzerland is home to some of the world's most successful pharmaceutical companies, such as Novartis and Roche, and noted for its scientific and academic institutions, which attract expertise from across the world and contribute to the respect garnered by the Swiss pharmaceutical sector.

Despite not being an EU member state, Switzerland has also benefitted from EU FPs, such as Horizon 2020, which offer grants for research. The UK also has a strong reputation in the areas of science and research, and has received proportionately high funds through these programme (£67 billion alone through Horizon 2020). In fact, the UK receives more funding from the European Research Council than any other EU country and has priority access to scientific facilities across Europe, putting it at risk of losing a predicted £8.5 billion over the next four years[138].

The British Prime Minister, Theresa May, has suggested that the British government will make up the potential losses in EU research funding.[55] There is also the possibility of non-EU countries buying into Horizon 2020 arrangements.[139] These suggestions, however, will not come without controversy, given how clear and decisive a role austerity played in the referendum.

Industry similarities and Switzerland's economic success outside of the EU make it is unsurprisingly that many leave campaigners are championing a Swiss-inspired model

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[137] Jo Whelan. "Switzerland's Thriving Pharmaceutical Industry." *New Scientist*, May 2006

[138] Karen Taylor. "What Would Brexit Mean for the Pharma Industry? - Health Solutions." *Deloitte Health Solutions*, 2016. http://blogs.deloitte.co.uk/health/2016/02/what-would-brexit-mean-for-the-pharma-industry.html

[139] Pallab Ghosh. "Paul Nurse: 'Research Needs Free Movement to Thrive'." *BBC News*, 2016. http://www.bbc.co.uk/news/science-environment-36667987

as Brexit negotiations take shape. However, it seems highly unlikely that the EU will facilitate furthering these aspirations; in 2010, it was already referring to a relationship with Switzerland 'which has become complex and unwieldy to manage and has clearly reached its limits'[140].

In addition, leave campaigners are motivated by what they view as Switzerland's privileged position in terms of its unique relationship with the EU, yet many of them overlook the fact that the Swiss model aligns with many EU structures, laws and values. For example, in 1999, Switzerland accepted free movement of persons. Recently, Switzerland did indeed act to reinstate quotas on foreign workers. However, it was effectively punished by the EU which froze its Horizon 2020 grants and stalled its Erasmus+ student mobility scheme.[141] This is a strong indication of the likelihood of failure if the UK attempts to negotiate entirely on its own terms.

4.2.8 WTO

Debate on this subject points to a third solution for the UK post-Brexit, that of the WTO, which is in fact the model that the UK will automatically revert to on exiting the EU[67]. This would be the most drastic option whereby the UK would abandon its European premise and use the established trade rules and norms of the WTO to forge bilateral trade agreements with the EU, resulting in a model similar to the rest of the world (that includes tariffs on trade with the EU, customs taxes etc.).[59]

This option could potentially offer the UK flexibility and the clean slate that leave campaigners rooted for, but it is the most ambiguous at this stage and would likely take many years to implement. For example, the UK could theoretically follow Canada which, after seven years of negotiations, signed the EU-Canada Comprehensive Economic and Trade Agreement (CETA) in 2013 and now profits from 98% tariff-free trade with the EU. Vicky Ford (Conservative MEP and Chair of the European Parliament Committee for the Internal Market and Consumer Protection) has stated that it is 'much more important to look at the so called "non-tariff barriers" which reflect the bureaucratic red tape faced by companies exporting into other markets and to recognise that the level of ease British companies currently have when selling into other EU markets is much, much greater than that which is now offered to Canada in CETA.'[142]

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[59] HM Treasury. "HM Treasury Analysis: The Long-Term Economic Impact of EU Membership and the Alternatives," 2016.
[67] Privolnev. "Brexit's Impact On The Global Pharmaceutical Industry Future Access To The EU Common Market." *Pharmaceutical Online*, 2016.
[140] General Affairs Council Meeting. "Council Conclusions on Eu Relations with EFTA." Brussels, 2010. https://eeas.europa.eu/sites/eeas/files/council_iceland.pdf
[141] Patrick Wintour. "EU Tells Swiss No Single Market Access If No Free Movement of Citizens." *The Guardian*, July 3 2016
[59] HM Treasury. "HM Treasury Analysis: The Long-Term Economic Impact of EU Membership and the Alternatives," 2016.
[142] Vicky Ford. "Vicky Ford: The Canada Deal Is Not the Model Brexit Negotiations Should Follow," 2017. http://www.conservativehome.com/platform/2017/02/vicky-ford-the-canada-deal-is-not-the-model-brexit-negotiations-should-follow.html

4.2.9 Final considerations

With a world-class reputation for R&D, manufacturing and the trading of medicinal products, the UK is a focal point of the EU pharmaceutical industry. A business strategy that will mitigate risks to these areas and work to prevent pharmaceutical companies from abandoning the UK is needed. Ultimately therefore, it is in the UK's interest (and, as some would argue, the rest of the EU's) to seek a model that will ensure continuity as much as possible. This makes sense economically and should protect access to medicine and healthcare for UK citizens and others in the EU who use them.

The UK government must balance seeking these negotiations with the demands of the majority of voters who favoured leaving the EU. However, it would be unwise to assume that the UK can pick and choose which EU principles and legislative structures it will keep, given the EU's response to Brexit[143]. Inevitably, free movement of medicinal products has to come with free movement of persons, and resistant Switzerland is proof of this. Neither an EEA or an EFTA model for the UK's pharmaceutical industry can avoid the accompaniment of free movement of persons.

Since the leave campaign was bolstered on promises to curb immigration and gain border control,[144] the prerequisites that come with adopting either an EEA or an EFTA model will surely heighten the controversy and division surrounding Brexit negotiations. As John Springford, Director of Research at the Centre for European Reform, puts it, 'We are being asked to imagine that MPs, many with UKIP at their heels, would ask their constituents to sign up to the very EU policy they had rejected in the referendum.'[145] However, without doing so, the UK's pharmaceutical sector and, with it, public health will be hit hard.

It should also be asked: is it really appropriate to compare the UK to Norway and Switzerland when demographically and economically these are very different nations? The former has a population of 5.1 million, the latter's is 8.2 million. The UK has a population of 64.7 million and a GDP of $2.678 trillion compared to that of Norway and Switzerland at $512.6 billion and $685.4 billion respectively. The economic impact of having to be a 'rule taker' as opposed to a 'rule maker' on issues such as free movement is therefore likely to be far greater for the UK than for Norway or Switzerland.[59] This is especially relevant to the UK's pharmaceutical sector which is currently the ninth largest in the world and was amongst the country's five most important contributors between 2008 and 2014.[60]

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[143] Tom Goodenough. "Jean-Claude Juncker Comes out Fighting over Brexit." *The Spectator*, July 26 2016
[144] Alan Travis. "The Leave Campaign Made Three Key Promises – Are They Keeping Them?" *The Guardian*, June 27 2016
[59] HM Treasury. "HM Treasury Analysis: The Long-Term Economic Impact of EU Membership and the Alternatives," 2016.
[60] London's Economic Plan. "London's Pharmaceutical Industry," 2016.
[145] Charles Grant and John Springford. "Can the UK Join Norway in the EEA?" *Policy Review*, June 2016

There is also the historical and societal context. Switzerland and Norway never voted to leave the EU because they were never member states in the first place; Switzerland rejected joining the EU in 2001 with a vote of 76.8% and Norway likewise turned down the idea on smaller margins in referendums in 1972 and 1994.

Whilst the current political climate is inspiring claims that history is repeating itself through populist notions and far-right gains, Brexit set a precedent and there is no history that can guide the course of action to be taken.

5.0 EXCLUSIVE INTERVIEW: PROFESSOR MADS KROGSGAARD THOMSEN, CHIEF SCIENCE OFFICER OF NOVO NORDISK

5.1 What is the impact of Brexit?

The EMA has a well-functioning facility in London with 900 employees. However, 15 of their best experts have left, some before everything surrounding Brexit was confirmed, and there is fear that more will leave. In the short term, people are already predicting that they may face some geographic issues and have to move in the future.

The EMA has dependents internationally and their issue is that they do not want to move to a country where they cannot attract the same high quality workforce. The UK is known for its academic credentials, institutions and pharmaceutical companies. The latter of these means that people can work for both the companies and the agency; not many countries can offer this.

In the long term, much depends on whether there is a re-building of this established high quality network. It has taken twelve years to build up the EMA to where it is today. You can argue that it takes a very short time to break down structures but a very long time to build them. Whilst we hope for a smooth transition, in the worst case scenario, there will be time and quality impacts on medicines and vaccines.

5.2 What concerns you the most (excluding the EMA)?

We have collaborated with Oxford for many years. That has led to the next step which is to build a research centre within the University. The research centre will have 100 workers and we want the best – not only the best English, but the best in the world – to be there.

We are listening to the debate in the UK but you cannot have the cake and eat it at the same time. People do not want the influx of manual workers but then how can they expect the flip side, that of the scientists, the highly qualified workforce? Just the thought of facing a boundary when coming to the UK can be a problem in itself.

The movement of staff within a company will mess with timelines. Whilst we have reassurances from Downing Street about the protection of the highly skilled workforce, we cannot assume that the EU will agree with this conditional policy.

We have thought about this extensively and even considered moving elsewhere such as to Stockholm where there is also strong science. This brings me to my next risk factor: a lot of funding and many scientists are not from the UK. If this dynamic changes, then the output and the rankings can be at risk.

Those people who say that Oxford and Cambridge were doing well before the EU need to understand that it was in a different era; it was before globalisation. The world of science is completely global and free-flowing. This is why I fear for UK universities.

In the UK, the top level of education is very good and has always been recognized as one of the best in the world. However, if you can no longer attract the funds, then you will lose ability, resources and partners. There is also a potential loss of cross-border collaborations.

Under the Innovative Medicines Initiative (IMI), our group and GSK can act as the coordinating companies for building bonds between different pharmaceutical companies. The rest of the EU has lots of countries with companies: Germany, France, Denmark etc. The Swiss have built their own 'pharma-universe', but they did so over a century and that is their own story; it is not easy to replicate.

5.3 *What is Brexit doing for current projects?*

From my understanding, when it comes to current projects, what is ongoing is ongoing. We, as Danes in the EU, expect that what we are participating in will continue to the end. In general, there are a lot of uncertainties and we do not know how the UK and the EU will interact.

5.4 *Is research in early phases being affected?*

Basic research will be affected if the Oxbridge and London universities start diminishing in importance due to issues in funding and recruiting (either legal or perception). If this ends up becoming a reality, then we will see a negative spiral from these extremely prestigious organisations. For instance, the Crick in London has achieved an enormous amount in a short time, partly due to EU funding. If that is disrupted, there will be even greater pressure from Asia, particularly demand for basic research.

When we considered where to put our next global research centre, the UK was still one of the top three places for the reasons discussed but so was China. In Shanghai, they have a strong ability to attract international scientists, who are at least as able as in the UK, and then they can get the step ahead. Issues can therefore come to basic research or the translation of this research.

5.5 *Does the industry have a say in the negotiations?*

I believe not. Andrew Witty, outgoing ex-CEO of GSK, has been sending letters to Downing Street expressing how the situation should be handled. I think the problem is that the EU has the stronger hand right now. So the best the industry can do at present is inform the politicians as best as possible. This should have happened before the vote. The least the pharmaceutical industry can do now is to inform the decision makers and the negotiators about what is at risk and how to avoid it.

5.6 *What are the next steps that you would like to see policymakers take to mitigate any problems?*

Speaking from personal experience, we need a very strong statement from Downing Street that health science and bio/pharma tech is of huge importance to future UK growth and job creation.

5.7 *Is there anything positive coming from this Brexit negotiation?*

No. The only positive would be if the EMA came to Copenhagen. Even if they did come to Copenhagen, would we then think we had solved the issues and be glad for the UK's departure? Not at all.

5.8 *Do you foresee financial implications on your company?*

None upfront. However, the lack or loss of competence will lead to delays and then you lose time with the patent. For every year you delay a product approval, you lose one year's patent protection. The impact of this will be seen on sales. It all depends on whether the EMA can operate in this interim period. I do know that the head of the EMA (NAME) is trying to control the situation. There may be an impact that we cannot see right now, but what we do know from meticulous reporting of their actions is that the EMA functions extremely well; they are punctual with the right decisions. This cannot change.

6.0 MOVING FORWARD

In 2011, the UK economy benefited by about £30 billion from pharmaceutical and chemical exports to the EU,[146] which is just one of many figures serving to underpin the importance of investigating the impact of Brexit on this industry. The research conducted for this report has yielded several policy recommendations that have the potential to maintain the UK's attractiveness as a pharmaceutical hub post-Brexit.

6.1 Negotiate an 'associated country' status in the EU's research funding programmes.

This will guarantee access to the EU FPs and enable the UK to maintain its current dominance in the life sciences R&D sector. It will also sustain and encourage further collaborations between UK and European scientists, alleviating concerns over the uncertainty involved in working with UK-based partners. If the UK is to remain at the forefront of scientific innovation, it must work to preserve international collaborations.

6.2 Negotiate bilaterally favourable trade agreements for drugs and medical devices with the EU.

The EU is an essential market for pharmaceutical companies in the UK. To prevent the exodus of pharmaceuticals companies currently based in the UK, the government must renegotiate trade conditions with the EU that are comparable to those pre-Brexit. This calls for a new streamlined customs system for UK-EU trade with low fee and administrative burden. This will also be important in preventing a sharp rise in the costs of drugs imported from the EU.

6.3 Mirroring the medicines regulatory approval process with the EMA, whilst retaining the MHRA's capacity to intervene.

This would bypass the need for pharmaceutical companies to seek separate product approvals in the UK. By opting to follow the EMA's guidance, albeit with MHRA discretion for specific regulatory matters, the UK would incentivise pharmaceutical companies to remain in the country and prevent a delay in drugs reaching the UK market.

6.4 Assurance of free movement of high skilled professionals across UK-EU borders.

This will maintain the high skill level of the workforce in UK universities and the industry as a whole, whilst providing British nationals with the freedom to work, study and gain experience across the EU. This option will appeal to multinational pharmaceutical companies who wish to quickly and easily relocate staff across

[146] Melanie Edwards. "The Pink Book 2012," 2012. http://webarchive.nationalarchives.gov.uk/20160105160709/http://www.ons.gov.uk/ons/rel/bop/united-kingdom-balance-of-payments/2012/bod-the-pink-book-2012.pdf

international facilities. Free movement of professionals will therefore encourage foreign pharmaceutical companies to preserve their UK-based facilities. This will alleviate concerns regarding their EU staff members and their ability to attract and recruit the best in the field. Finally, such an agreement should encourage further foreign investment in the UK.

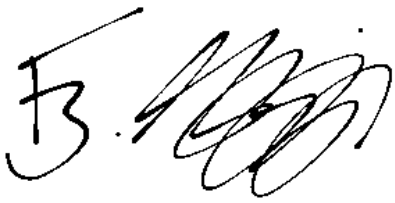
7.0 CONCLUDING REMARKS

Over the last 75 years, the UK has become a global leader in pharmaceutical research, science and development. The success of this industry is of utmost value to the country and millions of benefiters worldwide. The standing of UK pharma will depend on maintaining the foundations that uphold strong virtues of intellectual discovery, collaboration and regulation.

The process of Brexit provides exciting opportunities to excel further in the initiation and translation of basic science research. Underpinning this however, must be incentives for institutions and industry leaders to continue their work in the country. There can be no decrease in the provisions of monetary and intellectual capital to the UK pharmaceutical industry. If this is not maintained, there may be relocation of resources to mainland Europe and Asia.

In the wider scope of negotiations, the pharmaceutical industry will be impacted by decisions in medical regulation, freedom of movement, trading, custom blocs, institutional funding and intellectual property law (amongst other areas). It is not possible to predict how these will cumulatively affect progress in this field, but it is imperative that they are actively considered in negotiations with the pharmaceutical industry.

On first presentation of this report, one response to concerns raised was that 'excellence breeds excellence'; such complacency risks overlooking the fact that 'easiness breeds excellence' also.



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