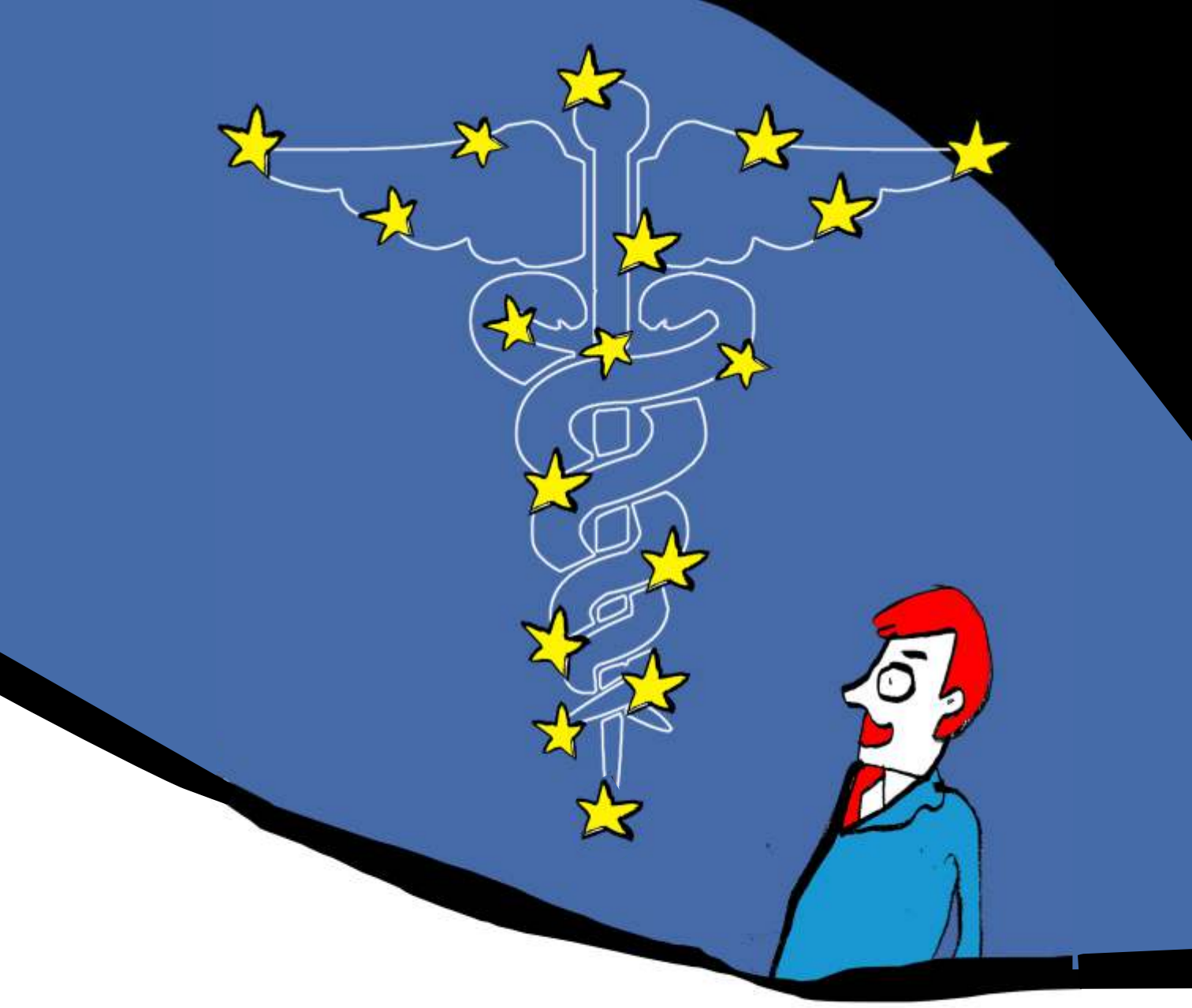
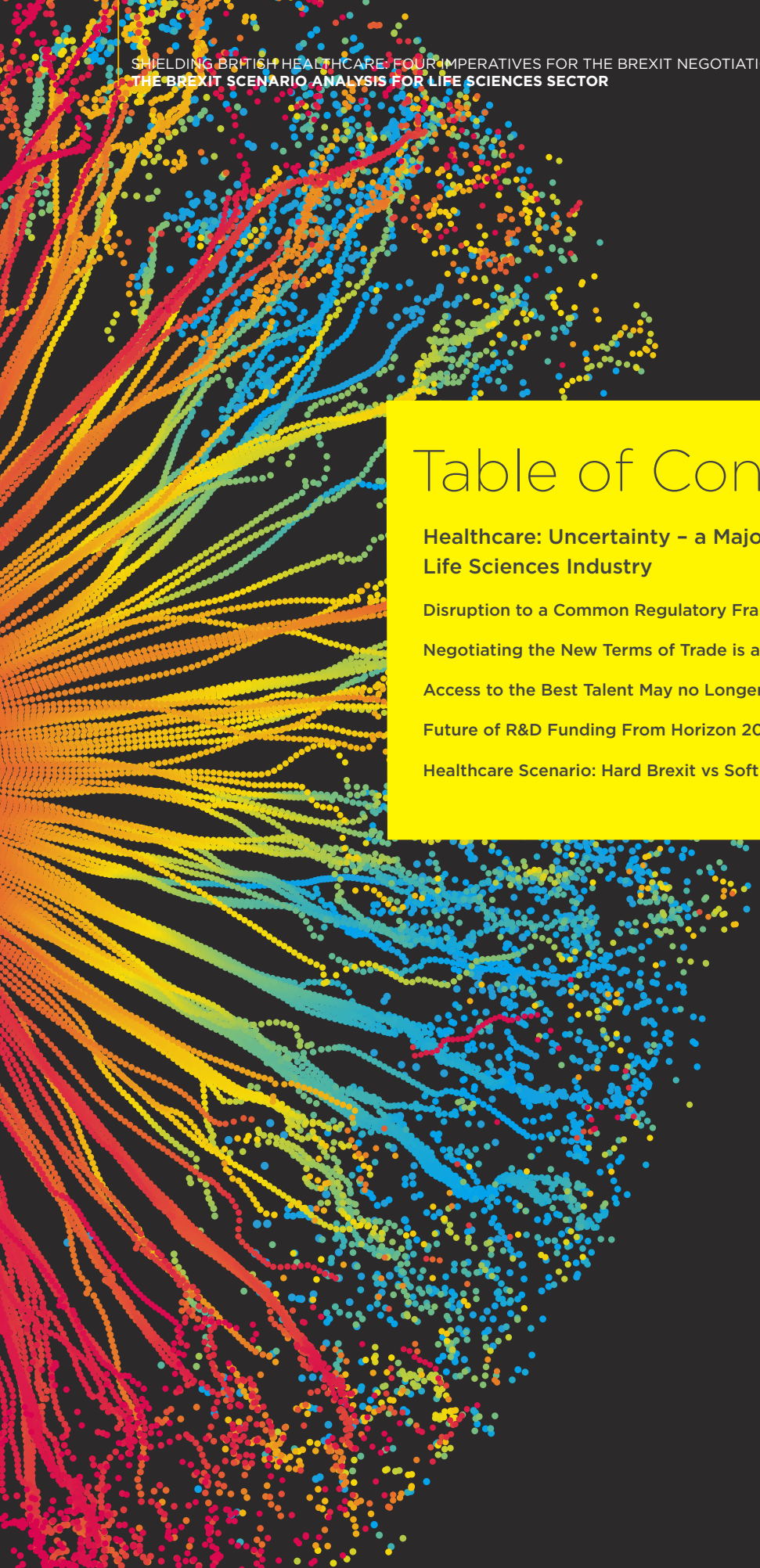


Shielding British Healthcare: Four Imperatives for the Brexit Negotiations

The Brexit Scenario Analysis for Life Sciences Sector

DECISIONPOINT™ by WNS



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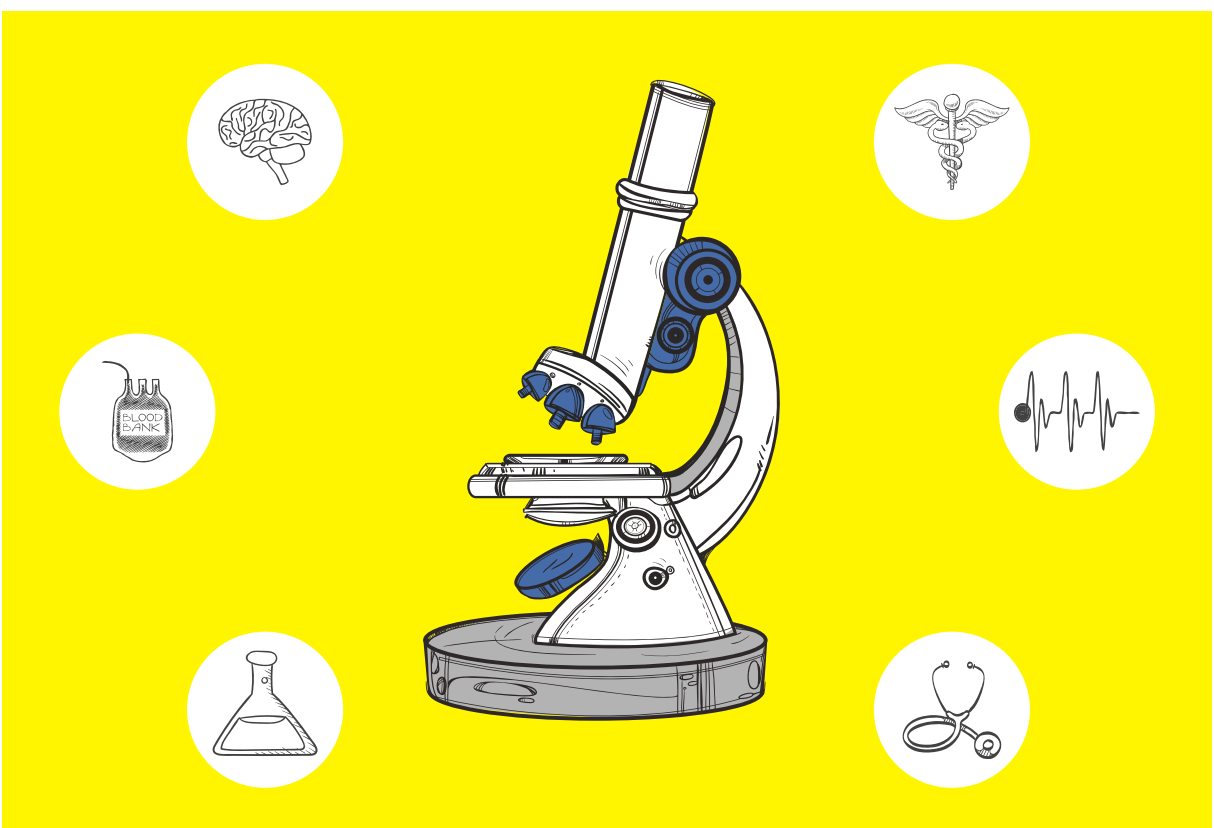
HEALTHCARE: UNCERTAINTY – A MAJOR CHALLENGE FOR THE U.K. LIFE SCIENCES INDUSTRY

The U.K. Life Sciences sector is a significant contributor to the strength of the U.K.'s economy. With a turnover of more than GBP 60 Billion a year, and exports and trade surplus worth GBP 30 Billion and GBP 3 Billion respectively,[1] the industry is of strategic importance to the U.K., as reiterated by British Prime Minister (PM) Theresa May - "It is hard to think of an industry of greater strategic importance to Britain than its pharmaceutical industry." The U.K. is one of the most attractive destinations for Life Sciences investment and activity globally - the result of the U.K.'s ecosystem of leading universities, National Health Service (NHS) collaborations, biotech start-ups and international pharma companies, allied to a supportive policy framework and deep financial markets.[2]

The referendum of June 23, 2016, to leave the European Union (EU) and the subsequent triggering of Article 50 has set the need to reinforce U.K.'s strengths, address the full implications of an EU exit and maintain a predictable operating environment.



1. U.K. EU Life Sciences Transition Programme Report for the U.K. EU Life Sciences Steering Committee, Maintaining and growing the U.K.'s world leading Life Sciences sector in the context of leaving the EU, September 2016.
2. Ibid.

DISRUPTION TO A COMMON REGULATORY FRAMEWORK

The way in which the U.K. Life Sciences industry researches, develops, manufactures and brings medical technologies to patients is regulated by the EU. This robust regulatory system, built with considerable U.K. influence and expertise, is critical to deliver safe, effective medical technologies. Continuing to be a part of the EU regulatory processes provides significant public health benefits for both the U.K. and the EU. For example, contribution of the U.K. to EU vigilance databases and to integrated EU vigilance processes enhances the quality and coverage of the vigilance system for Europe as a whole.

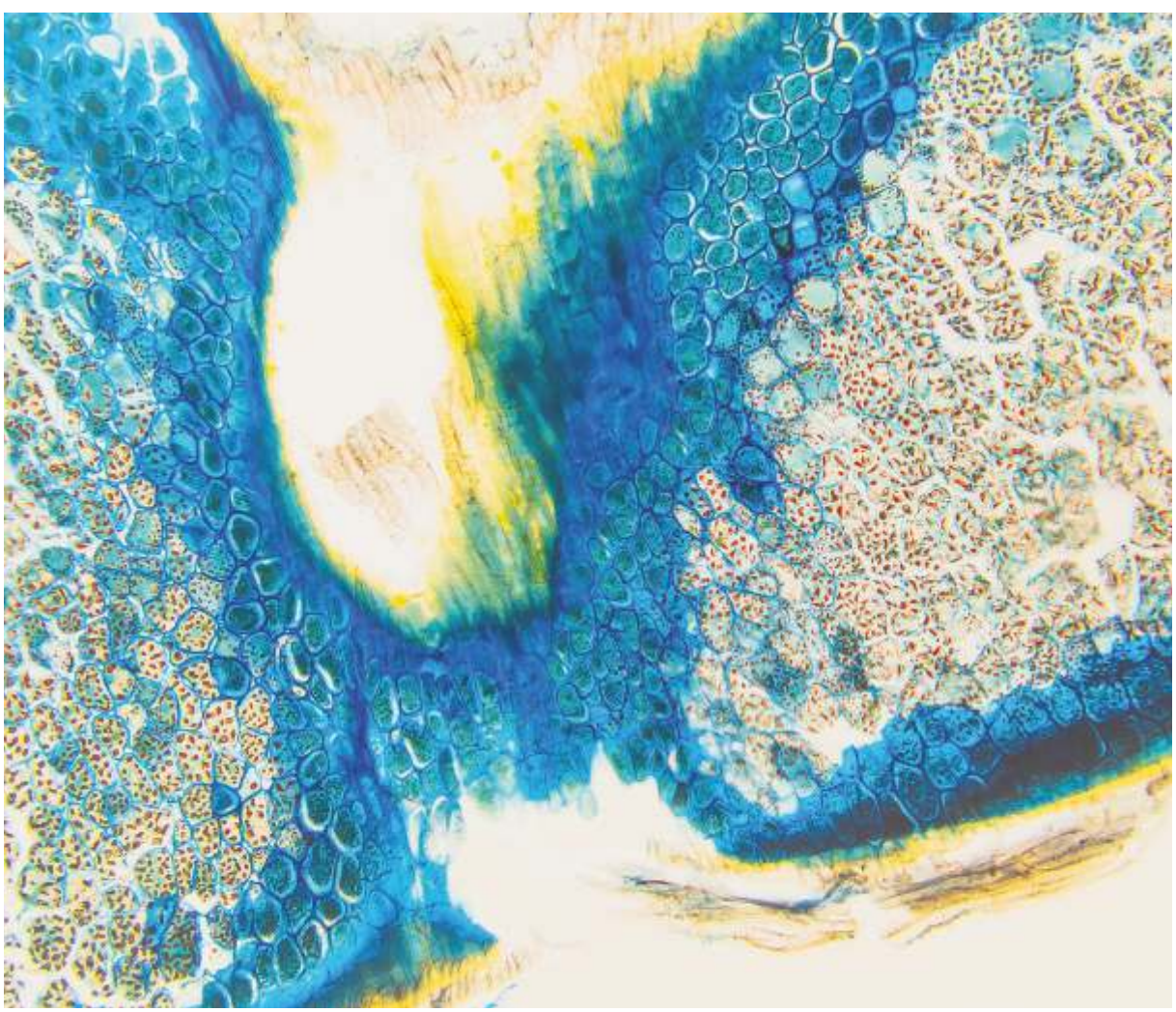
If U.K. regulations were to diverge from those of the EU, duplication of processes, increased costs and a divergence in standards will make the U.K. a less attractive place to develop, manufacture and launch new products.[3] Even an improved U.K. healthcare system independent of the EU will strain the economy. Increased healthcare costs, delays in developing new medicines or treatments in the absence of a regulatory authority will erode trust. This also poses concerns about the U.K.-based pharma companies and their relationships with the London-based European Medicines Agency (EMA). The EMA will potentially need to relocate somewhere in the EU, and the U.K. will most likely have to create its own domestic regulatory agency.[4] The U.K. runs the risk of being downgraded to a second priority market with regard to new products and research.

The result will be that generic and biosimilar drugs will appear in the U.K. market later than in the EU. Before exiting the single market, the U.K. must actively engage in the review of EU pharmaceutical incentives to preempt any weakening of these incentives. Changes like those highlighted above will negatively impact companies who wish to invest in the U.K. or even continue to exist as part of the supply chain. For global companies, the U.K. market is not sufficiently large to signify consequential additional costs, at 6-7 percent of global pharmaceutical sales.[5]

3. Ibid.
4. Article by BioSpace.com, 'How Brexit is affecting U.K.'s drug companies, including GlaxoSmithKline (GSK), Gilead (GILD) and AstraZeneca PLC (AZN)', June 2016.
5. European Federation of Pharmaceutical Industries and Associations, The Pharmaceutical Industry in figures, Key data 2017.

The EMA will potentially need to relocate somewhere in the EU, and the U.K. will most likely have to create its own domestic regulatory agency

Protection of Intellectual Property Rights will also form a major part of the Brexit framework. Protections are key to incentivizing the lengthy, risky and expensive process of pharmaceutical and biotechnology innovation. "Europe benefits from a high standard of Intellectual Property (IP) incentives in the form of Supplementary Protection Certificates (SPCs) (compensating for the amount of patent term that is lost during the lengthy development process of a pharmaceutical product), Regulatory Data Protection (RDP), orphan designation (for rare diseases) and rewards for investigations into pediatric uses and formulations. EU pharmaceutical incentives are currently being reviewed and it is important that the U.K. actively participates in that review, prior to leaving the EU, to prevent IP incentives being weakened."[6]



6. U.K. EU Life Sciences Transition Programme Report for the U.K. EU Life Sciences Steering Committee, Maintaining and growing the U.K.'s world leading Life Sciences sector in the context of leaving the EU, September 2016

NEGOTIATING THE NEW TERMS OF TRADE IS A CHALLENGING TASK

The U.K.'s trade environment is driven by indirect taxation, embedded throughout the manufacturing and supply chain. This includes both cash flow costs (arising from the delay between paying out Value-added Tax [VAT] and entitlement to recover the input VAT) and irrecoverable costs (including customs charges and the administrative costs of compliance). These costs are currently minimized in relation to the U.K./EU trade. The current aligned regulatory environment and lack of border controls facilitate ease of trade. Significant disruptions and cashflow impacts to trade could arise if trade between the U.K. and the EU becomes subject to customs duties, import VAT and border controls (in the form of import/export declarations and inspections/goods testing) without introduction of VAT simplifications.

Pan-European cooperation is essential to help reduce the risk of falsified medicines reaching U.K. patients. This risk would increase should the U.K. opt out of fully implementing the planned European Falsified Medicines Directive (FMD).[7]

The U.K. could also lose access to Free Trade Agreements (FTA) negotiated by the EU in the absence of a bilateral deal. Loss of Swiss FTA, in particular, will have a significant impact on Swiss-based Life Sciences companies which operate in the U.K.

Such changes would also make it less attractive for companies to make future investments or stay in the U.K. as integrated supply chains that rely on ease of movement of goods and capital across borders. If foreign investment in the sector and exports to the EU decline, the industry will be unable to sustain current employment and the number of jobs in the Life Sciences industry may fall.[8]

Changes like these could hinder U.K. patients from accessing medical technologies, leading to an increase in the cost to the NHS.

If the U.K. is unable to maintain trade with the EU on terms equivalent to those of a full member of the EU Customs Union, it will have to provide for a significant transition period and create a supportive environment for trade to mitigate increased costs and risks. This can be done by adopting customs duties rates that don't exceed those currently set by the EU and negotiating FTAs with non-EU countries independently.

Brexit could also bring some potential benefits to the U.K. Life Sciences sector. Depending on the terms of any trade agreement, the U.K. may also have increased freedom as a result of a release from EU state-aid laws. This creates an opportunity to directly fund industry at the government's discretion. If the U.K. is not able to gain access to a customs and VAT union, the U.K. government would have the freedom to amend the U.K. VAT legislation to benefit the Life Sciences industry. This could be in the form of simplification to avoid import VAT cashflow costs for clinical trial sponsors.[9]

7. Ibid.
8. Ibid.
9. Ibid.


Peterborough
CAMBRIDGE
Royston
Harlow
LONDON
Croydon
Maidstone
Guildford
Crawley
Basingstoke
Salisbury
Winchester
Petersfield
Horsham
SOUTHAMPTON
Lymington
HAVANT
BRIGHTON
Worthing
PORTSMOUTH
Newport
E05

ACCESS TO THE BEST TALENT MAY NO LONGER BE POSSIBLE

Ease of movement across the EU enables the Life Sciences sector to attract the talent it needs. This is particularly crucial in skills gap areas such as clinical pharmacology and bioinformatics. In the future, the ability to attract top talent will be critical if the U.K. is to become a leader in emerging skills areas such as device technologies, digital health, physiological modelling, genomics and Advanced Therapy Medicinal Product (ATMP) manufacturing.

Barriers to attracting and retaining the right talent pose a fundamental risk to the U.K.'s position as world-leading Life Sciences environment, putting the entire Life Sciences ecosystem in the U.K. at jeopardy and ultimately risking long-term erosion of the U.K. science base. Currently, non-U.K. EU nationals constitute approximately 17 percent of Science, Technology, Engineering and Mathematics (STEM) academics at U.K. research institutions.[10]

Uncertainty over the position of EU workers to remain in the U.K. and the U.K.'s future immigration policy is making it difficult to attract and retain talent.[11] "The U.K. is the European headquarter location of choice for global pharmaceutical companies, with over a dozen based in the U.K. including Eli Lilly, Gilead, Astellas, Takeda, Eisai and Otsuka. GSK and AstraZeneca also have their global headquarters in U.K., with AstraZeneca being helmed by a French CEO. MSD, Amgen and Pfizer also have significant U.K. Research and Development (R&D) or manufacturing operations. This has helped foster a deep talent base across the value chain in areas including research, development, regulatory, manufacturing and commercial skills. These skills find homes within a range of organizations in the U.K. Life Sciences sector including regulators, industry, research institutes and support services. However, as U.K.'s position as a gateway to Europe is challenged, there is a risk that these operations will move to Europe – eroding the U.K. Life Sciences ecosystem and resulting in lost jobs and economic contributions."[12]

10. CaSE, Immigration: Keeping the U.K. at the heart of global science and engineering, January 2016.
11. Article by Financial Times, 'Brexit: An experiment full of risk for British science', August 2016.
12. U.K. EU Life Sciences Transition Programme Report for the U.K. EU Life Sciences Steering Committee, Maintaining and growing the U.K.'s world leading Life Sciences sector in the context of leaving the EU, September 2016.

FUTURE OF R&D FUNDING FROM HORIZON 2020 NEEDS TO BE DETERMINED

Horizon 2020 is the biggest EU Research and Innovation program ever with nearly GBP 80 Billion of funding available for over seven years (2014-2020) – in addition to the private investment this money will attract. Seen as a means to drive economic growth and create jobs, Horizon 2020 has the political backing of Europe's leaders and the Members of the European Parliament.[13]

Her Majesty's Treasury's commitment to underwrite funding for Horizon 2020 projects secured while U.K. was an EU member provides important short-term reassurances that the U.K. science base is a secure partner for EU projects.[14] However, access to EU research funding beyond the Horizon 2020 round of funding is still unknown. Life Sciences has a long research cycle, and requires a long-term funding solution. Lack of European Research Council funding would discourage top scientists from conducting their research at U.K. institutions, whilst the removal of transnational research grants could also reduce the number of U.K. start-ups. Even if the U.K. retains access to Horizon 2020 funding, other funding sources, such as the European Structural and Investment Funds (ESIF) invested in projects such as Cardiff University's Brain Research Imaging Centre, will be lost following its departure from the EU.

The U.K.'s ineligibility to lead EU-wide research collaborations will erode its position as a global research leader. It currently plays a dominant role in EU-wide collaborations, for example, leading the highest number of Innovative Medicines Initiative (IMI) projects (which speed up the development of better and safe medicines for patients, boosting innovation in Europe). Non-EU countries may also now target their collaborations outside of the U.K. if they believe the European scale is critical to success.[15]

The U.K. has the most developed funding pipeline in Europe. The U.K. Venture Capitalist (VC) ecosystem is critical to commercializing and growing Small and Medium Enterprises (SMEs), providing GBP 630 Million in 2015 to the Life Sciences SMEs.[16] These VC firms are heavily reliant on the European Investment Bank (EIB) and the European Investment Fund (EIF) funding, which makes up 25-40 percent of VC funds and plays a role in catalyzing further private investment. Loss of access to EIB/EIF funding will result in reduced VC funding for the U.K. SMEs, and in fewer start-ups. Further, the loss of EU passporting rights for financial institutions would limit their ability to raise funds across Europe.[17]

13. European Commission, 'What is Horizon 2020?'
14. U.K. EU Life Sciences Transition Programme Report for the U.K. EU Life Sciences Steering Committee, Maintaining and growing the U.K.'s world leading Life Sciences sector in the context of leaving the EU, September 2016
15. Ibid.
16. Ibid.
17. EU-U.K. Steering Group, Interview with VC Expert, 2016

HEALTHCARE SCENARIO: HARD BREXIT VS SOFT BREXIT

The snap election in June 2017 resulting in the surprise outcome of a hung parliament and May's subsequent move to form a minority government with the support of the hardline Democratic Unionist Party (DUP) of Northern Ireland has cast a shadow over Brexit talks. With uncertainty created by the election outcome and the formation of a minority government by May after securing a deal with the DUP, it will be difficult for pharma companies to make long-term investment and hiring decisions. Future market direction of pharma depends on what form Brexit will take.

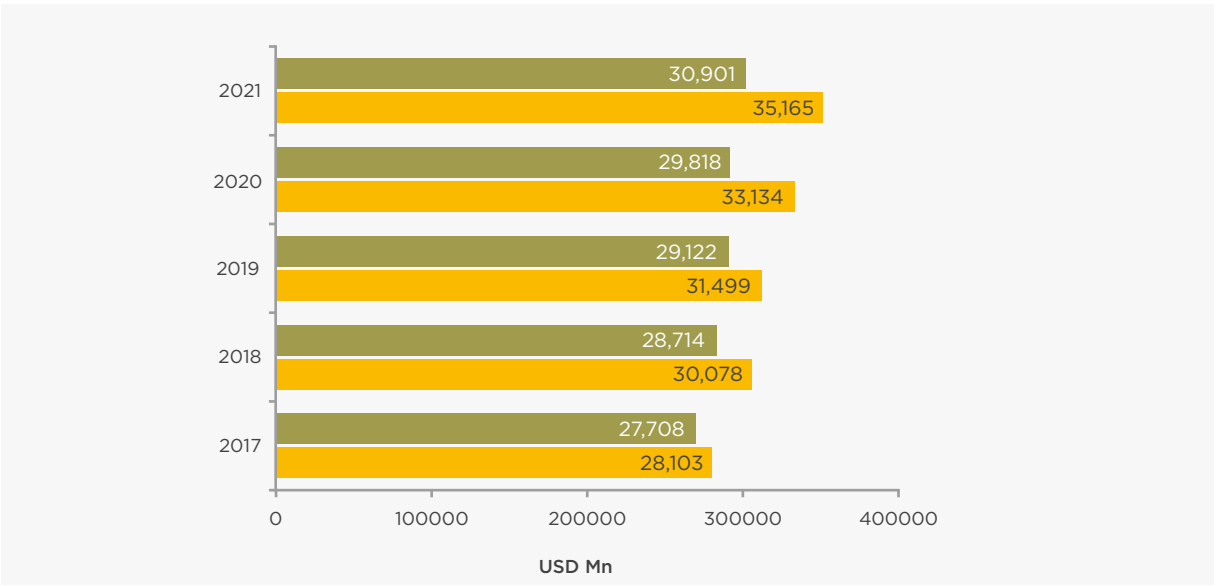
We will look at the future market for pharmaceuticals in two scenarios: 'Hard Brexit' and 'Soft Brexit'. Hard Brexit, as envisioned by May, means leaving the EU without access to the European single market. A document issued jointly by the European Commission and the EMA states that in the event of a hard Brexit, medicines and substances used in the manufacture of medicines made in the U.K. will be treated as imports by the EU, forcing pharma companies to consider all options for the location of sites, systems and staff, to meet the requirements of EMA and other regulatory bodies. In particular, Britain's lucrative generic medicines industry would be hit by the mooted treatment of finished medicines as imports. In such a scenario, we expect pharma sales from the U.K. to hit a sharp downturn in the forecast period from 2017-2021, with import tariffs curbing the demand for pharma sales, coupled with a rapidly depreciating pound which will act as an inflationary squeeze on pharma spending.[18]

A soft Brexit, with access to the single market, would mean that pharma companies in the U.K. will be able to continue business operations and sell across the EU without imposition of tariffs. We expect pharma sales to slide at a steady rate during the remainder of 2017 in the wake of regulatory and investment uncertainty. As the Brexit framework with continued access to the EU single market reaches its final stage, pharma sales will stabilize and grow at an even pace during the remainder of the forecast period from 2019-2021.

18. Article by Financial Times, 'EU Pharma agency warns of post-Brexit levies', June 2017

Exhibit 1

Pharmaceutical Sales



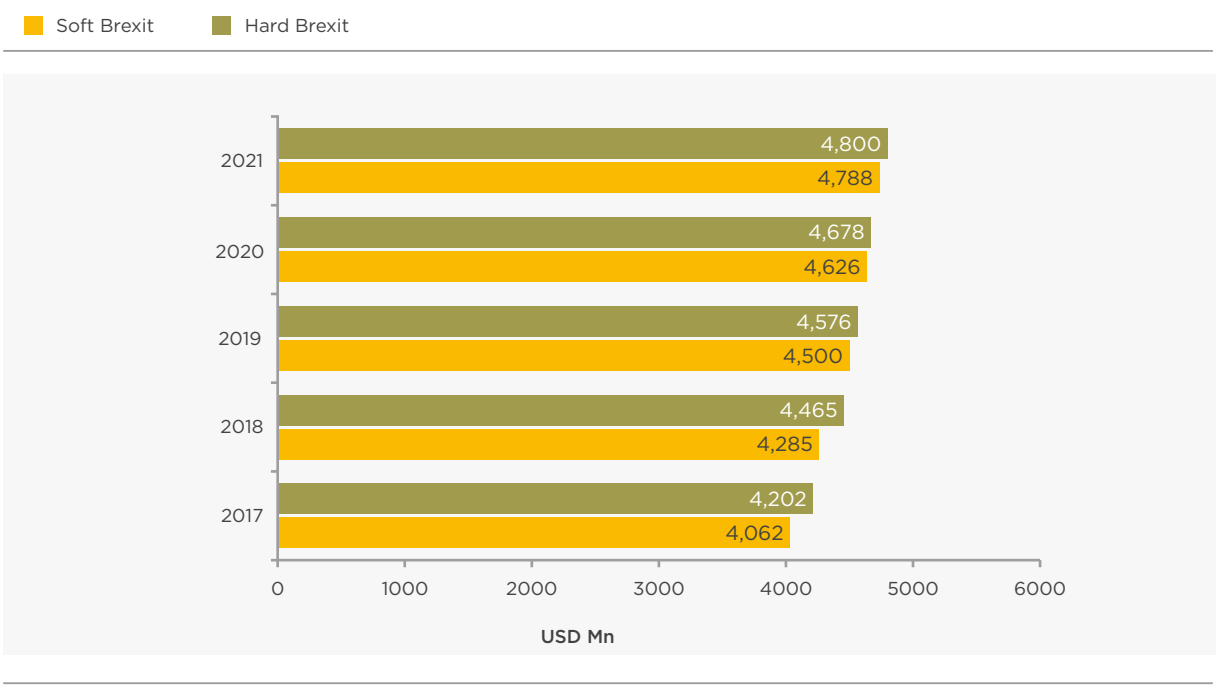
Source: OECD; WNS DecisionPoint™ forecast

We will look at the future market for pharmaceuticals in two scenarios: 'Hard Brexit' and 'Soft Brexit'.

A hard Brexit could mean increased costs for the NHS as a result of limited patient access to medical technologies due to a large number of pharma companies shifting operations and supply chains out of the U.K. to elsewhere in the EU. Increased NHS costs will put additional pressure on public spending on healthcare, a major component of total healthcare spending in the U.K. With an increasingly ageing population adding to healthcare costs, we estimate healthcare spending per head to rise rapidly in the forecast period, particularly over 2019-2021 when the Brexit arrangement is finalized.

Exhibit 2

Healthcare Spending Per Capita



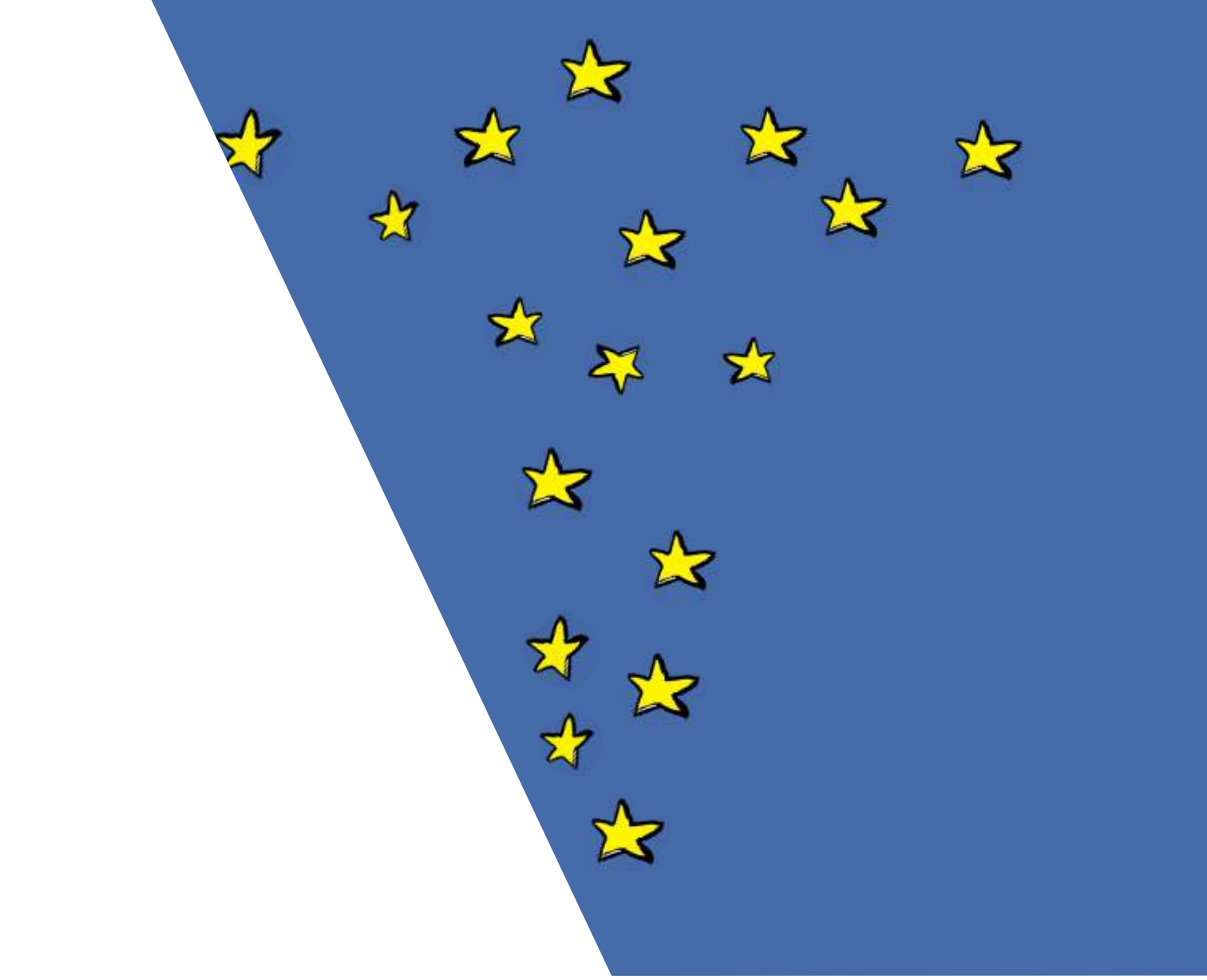
Source: OECD; WNS DecisionPoint™ forecast

The future of the U.K. Life Sciences industry is at stake in the Brexit negotiations. Pharmaceutical companies will have to make strategic plans regarding location of headquarters, supply chain processes and future drug and processes and future drug and clinical trials. The NHS will need clarity regarding EU immigration and direction of research funding from the EU. With the new government in place and formal Brexit negotiations underway, it will be interesting to see how the future of Life Sciences industry will be determined by the final deal the U.K. strikes with the EU.

About DecisionPoint

Making key decisions that improve business performance requires more than simple insights. It takes deep data discovery and a keen problem solving approach to think beyond the obvious. As a business leader, you ought to have access to information most relevant to you that helps you anticipate potential business headwinds and craft strategies which can turn challenges into opportunities finally leading to favorable business outcomes.

WNS DecisionPoint™, a one-of-its kind thought leadership platform tracks industry segments served by WNS and presents thought-provoking original perspectives based on rigorous data analysis and custom research studies. Coupling empirical data analysis with practical ideas around the application of analytics, disruptive technologies, next-gen customer experience, process transformation and business model innovation, WNS aims to arm you with decision support frameworks based on 'points of fact.' Drawing on our experience from working with 200+ clients around the world in key industry verticals, and knowledge collaboration with carefully selected partners including Knowledge@Wharton, each research asset comes up with actionable insights with the goal of bringing the future forward.



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