HEALTHCARE & LIFE SCIENCES REVIEW

PHARMA BOARDROOM

A VOTE OF CONFIDENCE *PAGE 21*

UNITED KINGDOM

SEPTEMBER 2018

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PHARMA BOARDROOM

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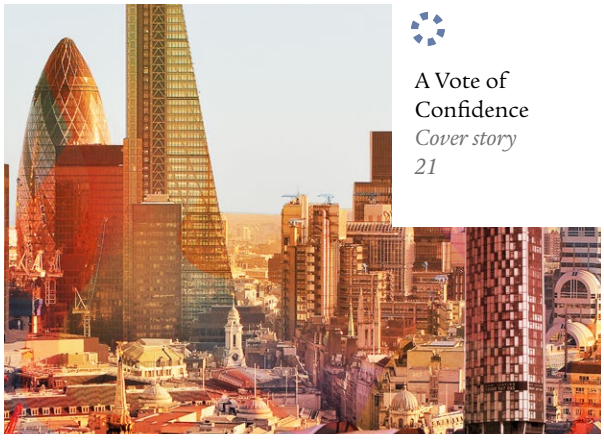

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KAREN OSBORN
CEO, International Glaucoma Association, UK

KEN SUTHERLAND
President, Canon Medical Research Europe

IN BRIEF

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KaNDy: Making the #Menopause a sweeter experience - The UK-based #biotech has raised £25 million to finance the Phase 2b trial of their breakthrough product in #womenshealth @KandyBiotech @GSK @OrbiMed @adventventures

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@Novartis gene-modifying therapy for children and people under 25 with #Leukemia has been approved by @EU_Commission @lizforacure #GeneTherapy #GENETALK #childrenscancer #ChildhoodCancerAwareness #cancer @NovartisCancer

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"I was put on @MSDintheUK's fast-track development programme. At the age of 25, I became their first field-based female sales manager." Angela McFarlane Market Development Director @IQVIA_UK - #digitalhealth #WomenInSTEM #NHS

Read the article

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#Brexit: Much ado about nothing? Mike Thompson, CEO of @ABPI_UK responded yesterday to the government's no-deal guidance to pharmaceutical companies. We bring you the views of big pharma bosses in the UK. #NoDealBrexit #BigPharma #BrexitBritain #pharma18

Read the article

Preface

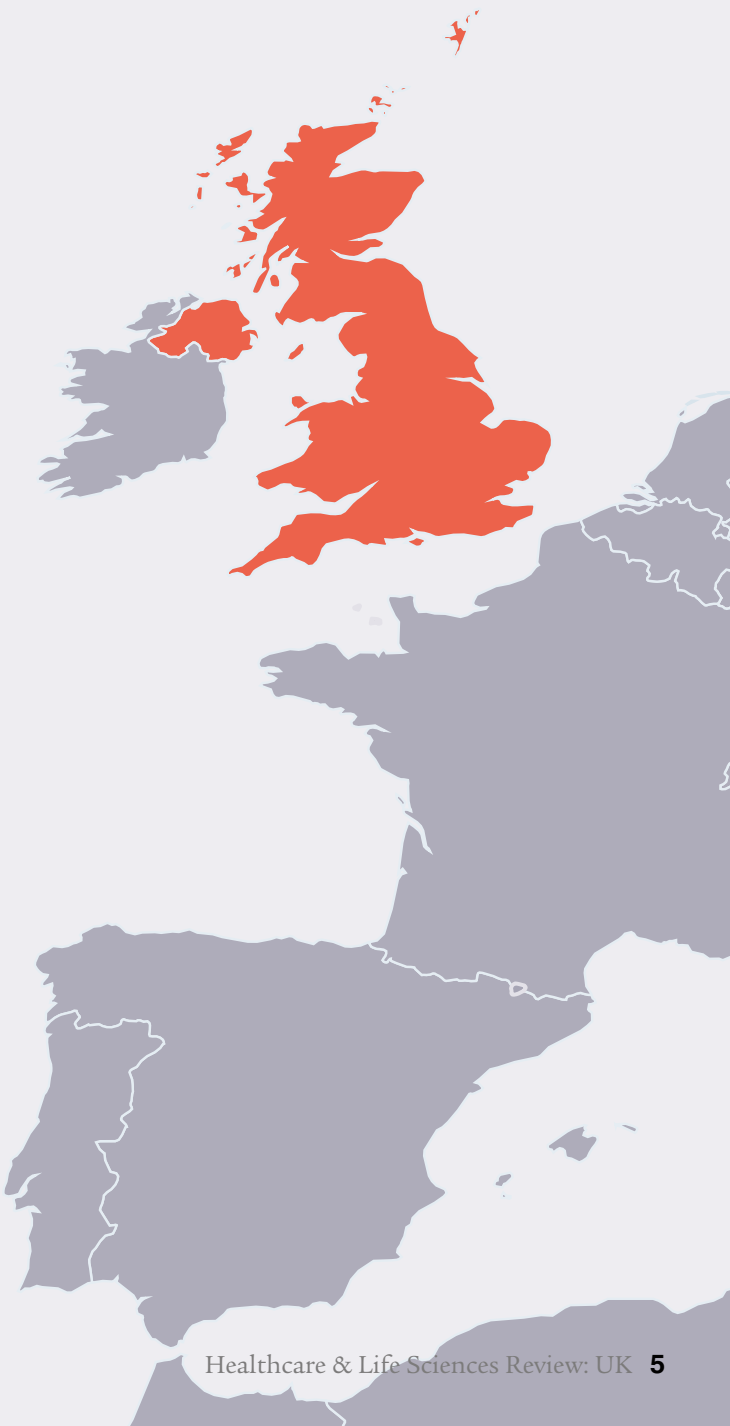
The UK, despite myriad uncertainties around its decision to leave the European Union, still stands as one of the world's premier life science investment destinations. With heavyweight medical science infrastructure and a well-earned reputation for elite-level innovation, the key industry stakeholders featured in this report explore how the nation is attempting to re-position itself post-Brexit; noting both the challenges and the opportunities of a unique situation.

Some of the main topics covered in HCLS Review UK 2018 include the implications of the government's ambitious 'Life Sciences Industrial Strategy' and subsequent 'Sector Deal' with industry, the multinationals committed to continuous investment in British R&D, as well as the inimitable UK National Health Service (NHS) and how it interplays with the country's innovation ecosystem.

Other key issues examined within are the prominent role played by British medical research charities, the 'catapult' organizations set up to propel innovation forward in cell and gene therapy among other niches, the continuing attractiveness of the UK as a manufacturing base, as well as a regional focus on what the country has to offer both inside and outside of the 'Golden Triangle' of Oxford, Cambridge and London.

Naturally, the picture is not completely rosy, and the UK faces a number of challenges, notably from the Brexit fallout, but also in terms of a slow innovation uptake from an underfunded and strained NHS and severe pricing pressures, especially in areas such as rare diseases, restricting British patients' ability to access potentially lifesaving treatments.

However, through the comments of government representatives, seasoned industry commentators, multinational country managers, homegrown entrepreneurs and research scientists, a picture emerges of a country in flux but set to retain its place at the top table of international science and innovation.



Distinguished members of the healthcare and pharmaceutical sectors,

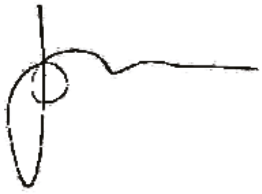
As Parliamentary Under Secretary of State for Health, it is my great honor to introduce the United Kingdom edition of the Healthcare & Life Sciences Review, which I consider an excellent opportunity to showcase the very real progress underway across the country in innovative drug development, smart healthcare and enlightened collaboration between industry, payers, providers and patients.

One of the tremendous advantages in Britain is that we possess three world-leading assets: our National Health Service, a thriving life sciences industry sector, and a formidable academic research base. Each one is recognized as world leading in its own right. The real opportunity that we have as a nation, irrespective of the future regulatory or trading environment, is to bring those three stakeholders together in concert. So long as we can ensure harmonious interactions between this triad of actors, we can establish a truly extraordinary and well-optimized public health trajectory.

In terms of our evolving relationship with the European Union, our intention is to have an associate membership of the EMA, which would mean a continuity of the kind of relationships that we have now, albeit on a different legal basis. I fi rmly believe that the reasons that companies will want to come here in the future are precisely the reasons that they want to come here now. As our well-defi ned Life Sciences Industrial Strategy clearly demonstrates, we continue to attract heavyweight investments into our local pharmaceuticals and medtech sectors. That is because the UK stands proud as a leading place to undertake scientifi c research, discovery, product development and high-end manufacturing. As a government, and as ministers, we are deeply committed to helping you – and the wider life sciences sector – to fl ourish. It's good for your businesses, it's good for UK plc, and most of all it's good for patients in the NHS.

With the UK Healthcare & Life Sciences Review 2018, I invite all members of the global pharmaceutical and healthcare communities to take a close look at Britain's dynamism and what it has to offer, and to consider how they can leverage their unique expertise and capabilities to support the continuous strengthening of our country's healthcare and life sciences vision.

Sincerely,



Lord O'Shaughnessy
Parliamentary Under Secretary of State for Health

UK MACROECONOMIC SNAPSHOT

Population
62.8 million

Area
242.514 sq km
(93.638 miles)

Life expectancy
78.6 years (men)
83.1 years (women)

GDP (PPP)
USD 2.914 trillion

GDP real growth rate
1.8% (2017)

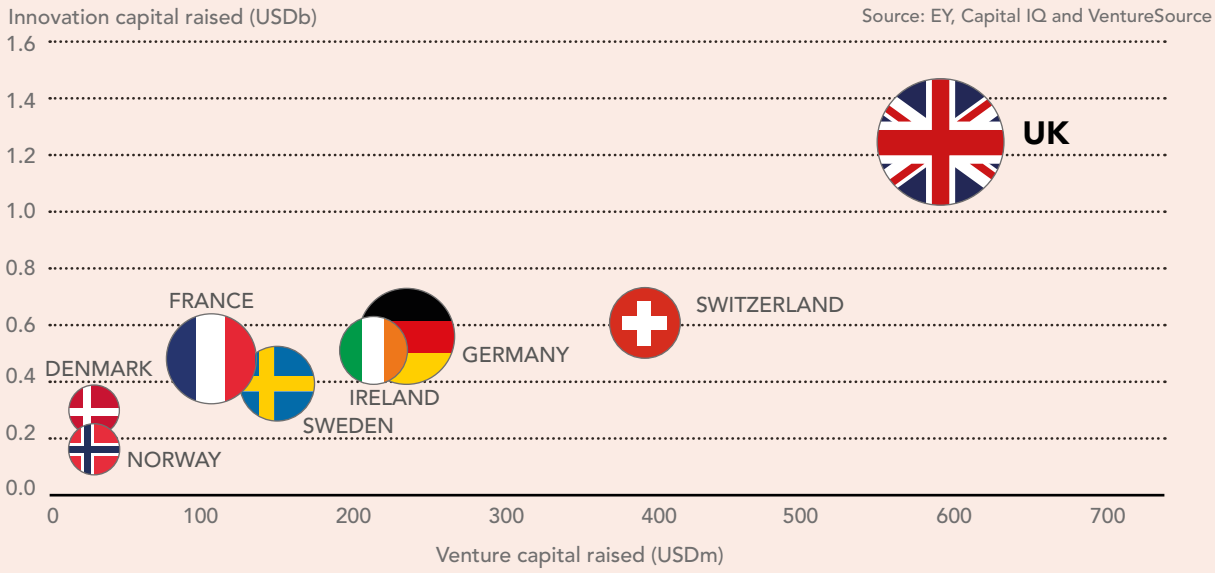
GDP per capita (PPP)
USD 44.100 (2017)

Unemployment rate
4.4% (2017)

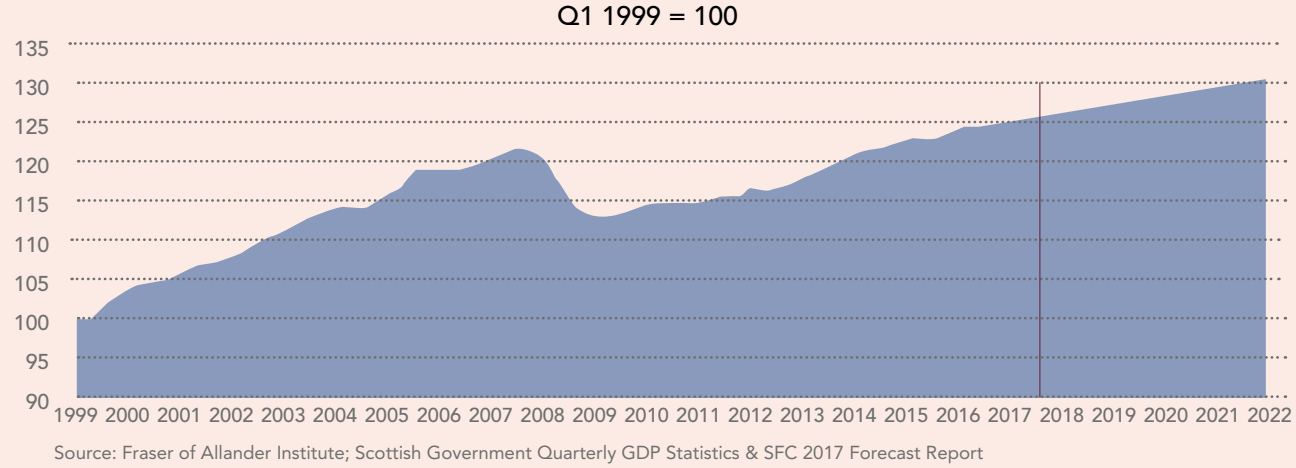
Source: UN, World Bank, CIA World Factbook

INNOVATION CAPITAL RAISED BY LEADING EUROPEAN COUNTRIES, 2016

SIZE OF BUBBLES SHOWS NUMBER OF FINANCINGS PER COUNTRY



UK GDP PER CAPITA (1999-2022)

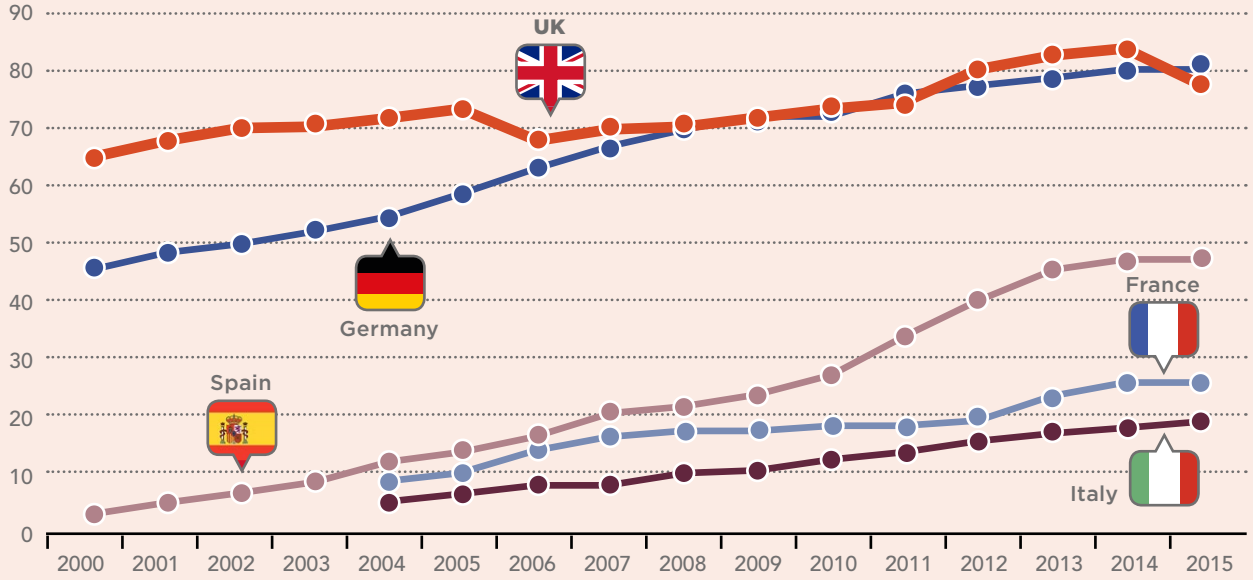


Source: Fraser of Allander Institute; Scottish Government Quarterly GDP Statistics & SFC 2017 Forecast Report

GENERICS PENETRATION: A EUROPEAN COMPARISON

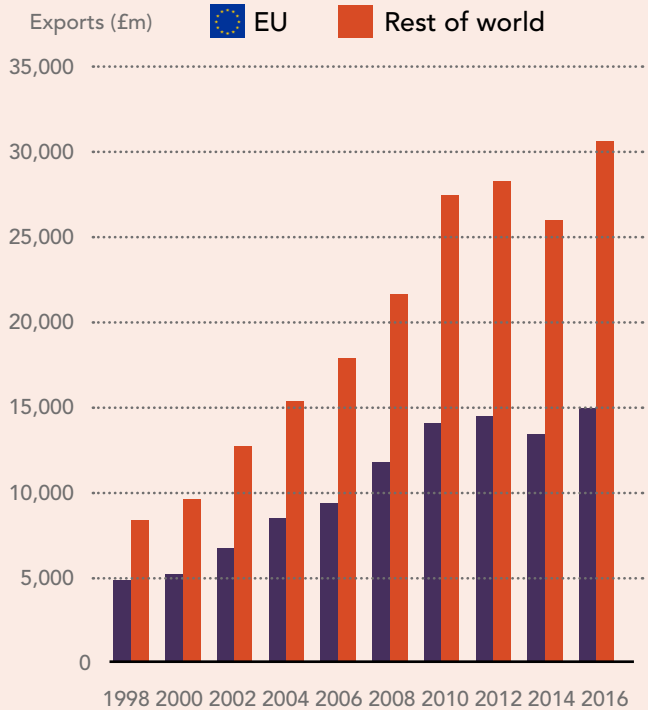
The share of the generics market in the United Kingdom is among the highest in Europe

Source: OECD Health Statistics 2017



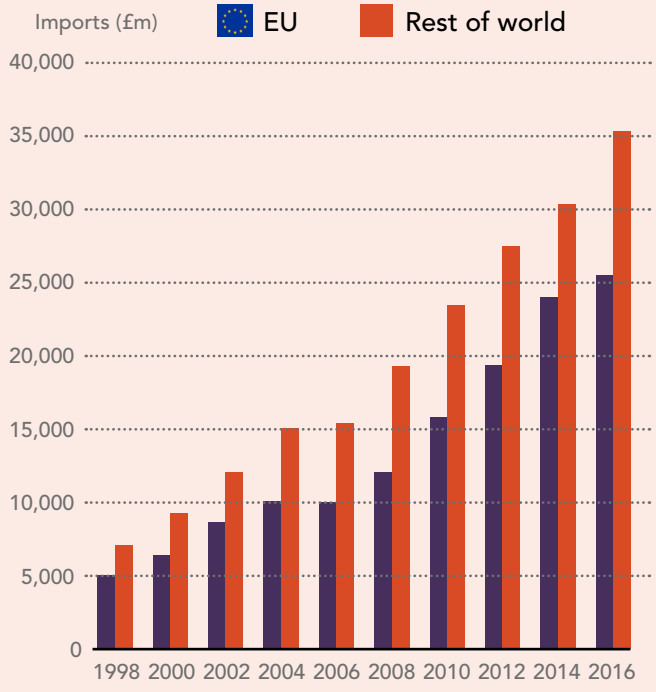
Note: Data for Germany, Spain and the United Kingdom are for reimbursed pharmaceutical market. Data for France and Italy are for total pharmaceutical market.

UK LIFE SCIENCE EXPORT VALUES



Source:UK Government Life Sciences Sector Report; ONS Balance of Payments data

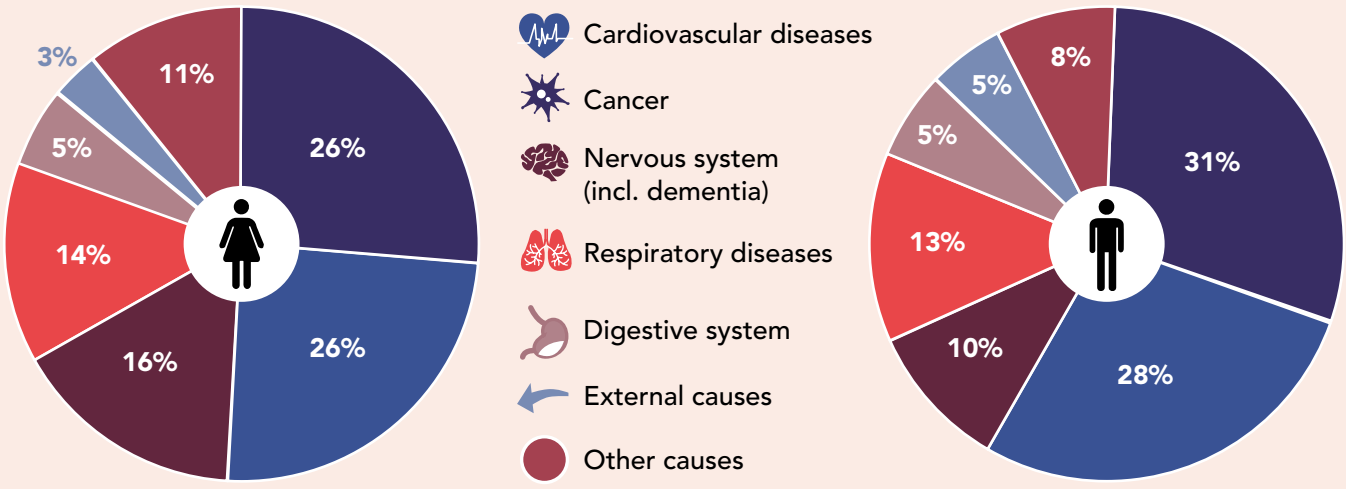
UK LIFE SCIENCES IMPORT VALUES



Source:UK Government Life Sciences Sector Report; ONS Balance of Payments data

UK EPIDEMIOLOGICAL PROFILE

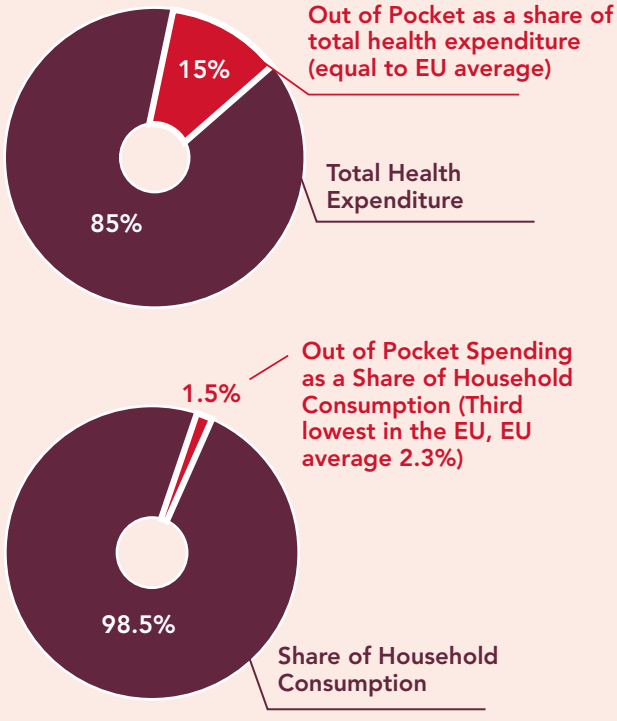
More men die of cancer and respiratory disease deaths are the highest in the EU



Note: The data are presented by broad ICD chapter. Dementia was added to the nervous systen diseases´ chapter to include it with Alzheimer´s disease (the main form of dementia)

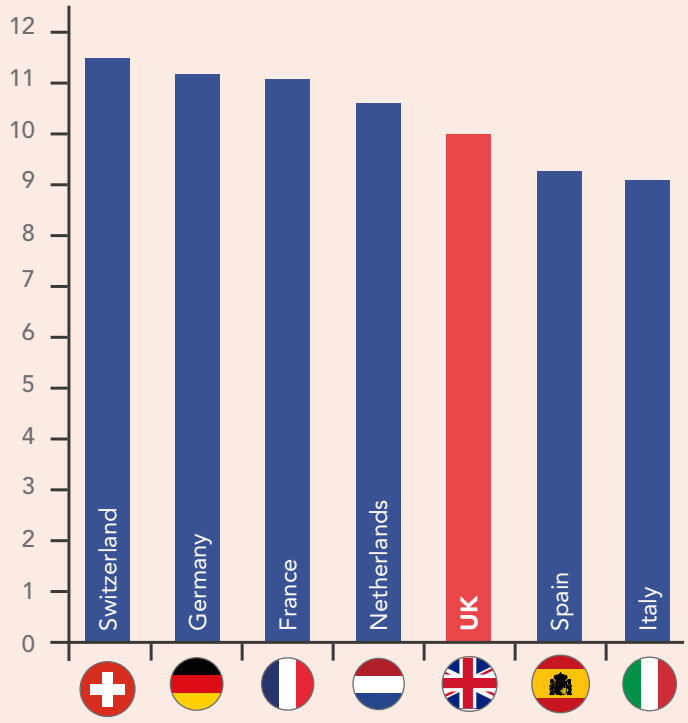
Source:OECD, European Observatory on Health Systems & Policies (2017)

OUT OF POCKET PAYMENTS



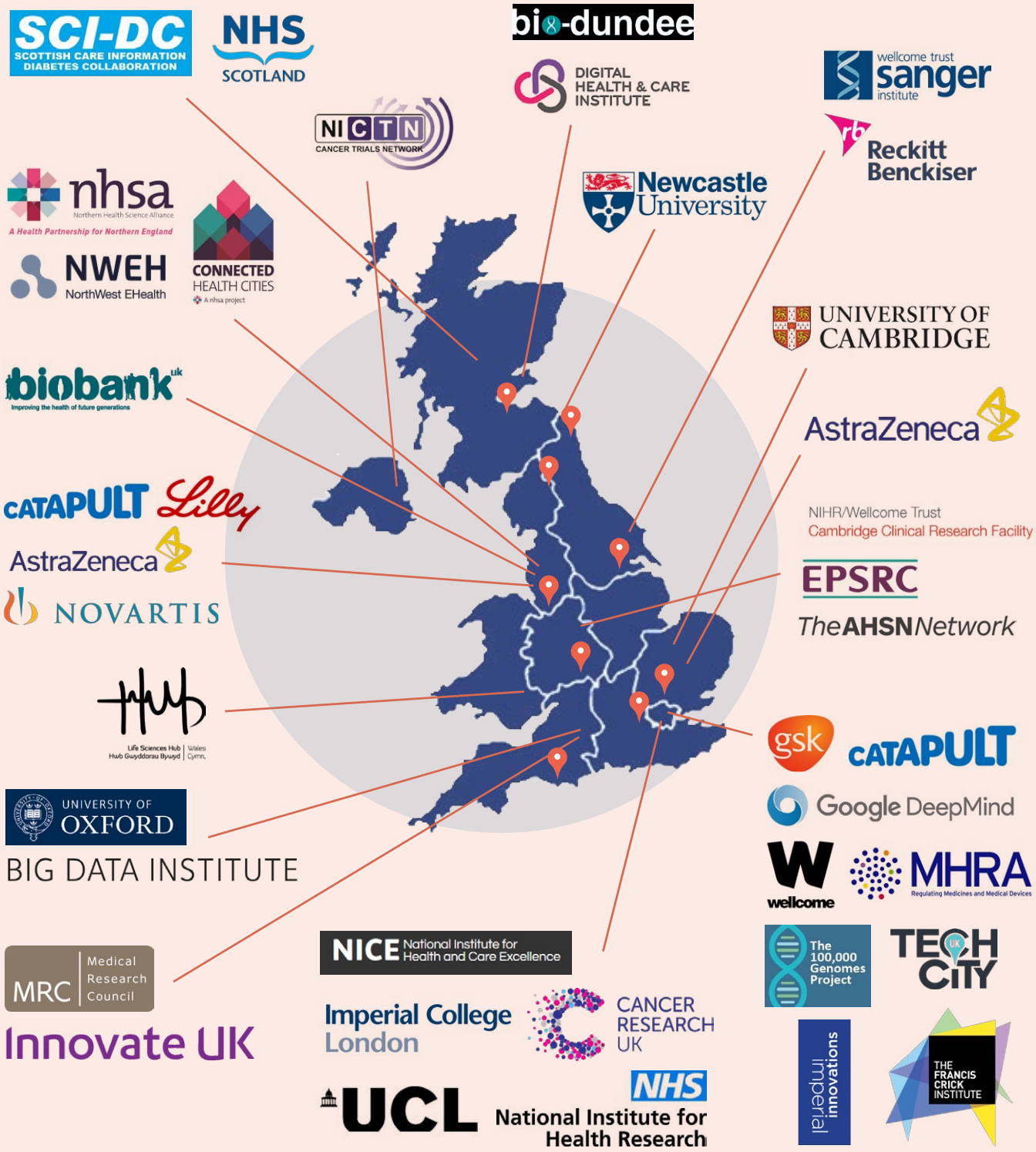
Source: OECD, European Observatory on Health Systems & Policies (2017)

HEALTHCARE EXPENDITURE AS A % OF GDP IN SELECTED EUROPEAN COUNTRIES



Source: Eurostat

THE UK LIFE SCIENCES ECOSYSTEM: A SNAPSHOT



Source: John Bell, Life Sciences Industrial Strategy

A TWO-WAY STREET

Lord O'Shaughnessy, parliamentary under secretary of state for health at the Department of Health and Social Care, discusses the potential opportunities that Brexit will bring for UK life sciences.

HCLS: In what ways does Brexit present an opportunity for UK life sciences?

LORD O'SHAUGHNESSY (LO): I am very optimistic. We want to continue to play that central role in the European regulatory department that the MHRA has always done. It does more work on licensing and pharma vigilance than any other agency in the Union. We understand that any negotiation is a give-and-take process. While we want to continue to be part of the overall European licensing environment, the quid pro quo for that is the MHRA contributing its expertise to the safety of European citizens.

It is absolutely a two-way street. If that is the case, then we will align ourselves with the European regulatory environment. In order to play a full role, we would be contributing to the cost of its functions. The opportunity in that sense, is to continue to lead that work and improve the regulatory environment in the EU. If there isn't a deal done, then that creates other opportunities to structure our regulatory environment in a different way to Europe. Our guiding principle in that is, whatever happens, patients cannot be getting products and treatments later or more slowly, but ideally, would be getting them more quickly than they do now. Industry certainly mustn't find it any more difficult to get their products to market here than they do currently.

HCLS: Why should companies keep their European headquarters in the UK after Brexit?

LO: First of all, as the Life Sciences Industrial Strategy shows, we continue to get major investments into the UK. That is because the UK is a leading place to do life sciences research work, discovery, product development and manufacturing. Our intention is that this environment will only improve regardless of what happens with Brexit.

Obviously, the relationship that we want to have with the EU is in everyone's interests in terms of patients here in the EU. It will mean that there will be no concern from a pharma company about having its headquarters here because they will still be able to access European markets as they do now. That is absolutely what the government is committed to.

HCLS: Where will the money to fund scientific research in the UK come from in the future?

LO: The Prime Minister was very clear about our desire to continue to be part of the EU research community and maintain linkages with Horizon 2020. The EU has already established analogous relationships with certain third countries outside of the EU such as Israel. Although the government has resolutely promised to underwrite any shortfall in future funding, our intention is actually even more ambitious, continue to contribute money and play our part in those kinds of exercises.

The Chancellor set a target for us of 2.4 percent of GDP being spent on R&D. We are keen to provide additional financing for research and compatible immigration rules that, regardless of Brexit, will enable the best and brightest minds to continue to come to our great academic institutions.

From our side, we are very committed to remaining part of European research networks and we fully expect our European counterparts to welcome this stance. Every negotiation has at least two parties and it would be foolhardy to try to double guess the terms of the eventual Brexit deal. Nevertheless, I believe that the signs are positive that we can strike a very good arrangement for science, innovation and research.

NHS BOSS OUTLINES KEY PRIORITIES AT ABPI CONFERENCE

Speaking at the Association of the British Pharmaceutical Industry (ABPI) Conference in London in the NHS's 70th anniversary year, Simon Stevens, chief executive of NHS England, highlighted how the organization is adapting to an environment in which patient expectations, drug development, therapeutic options and the UK's economic context are all changing.

As the NHS celebrates its 70th anniversary, Stevens was keen to underline the continued global significance of the organization, noting that "If you ask the Americans what makes them most proud about their nation, they will generally tell you it is their military. If you give the same question to the British, they will most likely think of the NHS! Indeed, our country's publicly funded health system is a remarkable organization that is on the cusp of celebrating 70 years of existence. Since its inception, the overarching concept of universal healthcare free at the point of delivery from cradle to grave has proved highly enduring and much admired."

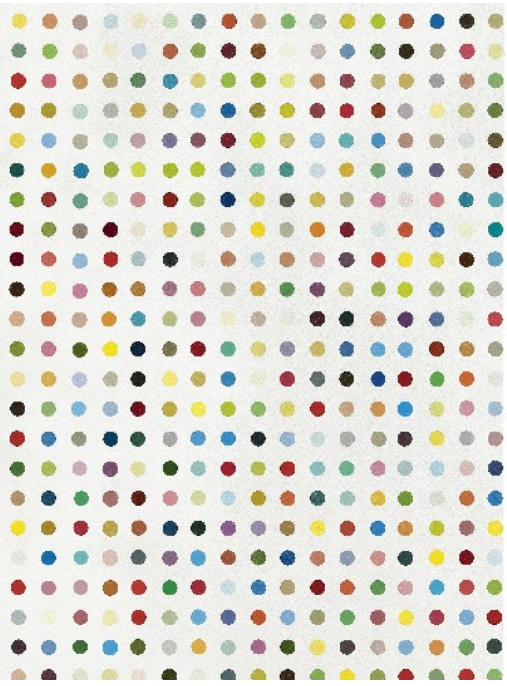
> **A HALLMARK OF THE SUCCESS OF THE SYSTEM, TO DATE, HAS ACTUALLY BEEN A STRONG ABILITY TO ADAPT TO THE TIMES**

However, Stevens warned that the NHS cannot remain static if it is to remain effective in carrying out this mission. He posited that, "On the contrary, a hallmark of the success of the system, to date, has actually been a strong ability to adapt to the times. If you think back 70 years ago, when the NHS first came into existence, some 23,000 people were dying from TB every year and around 32,000 TB patients would have been occupying hospital beds. Nowadays we face entirely different array of vulnerabilities with the principle threat arising no longer from infectious disease, but rather non-communicable co-morbidities."

SIMON STEVENS
chief executive, NHS England

Outlining his blueprint for the future, Stevens explained that the NHS has resolved to focus on five aspects over and above the wider life sciences agenda set out by Sir John Bell in the Life Sciences Industrial Strategy (LSIS). "Firstly, we seek to secure additional value gains through smarter deal making. To that effect, last April, the responsibility for negotiating bespoke funding arrangements for individual products in a flexible way was transferred from the Department of Health to NHS England. This represents a big step up from the old system of patient access arrangements under NICE. Innovative bespoke deals have already been concluded with companies like Roche, Alexion and PTC Therapeutics, which generate win-win-wins for taxpayers, patients and enterprises willing to go the extra mile," detailed Stevens.

"Secondly, we are determined that the comparative advantage Europe has in use of biosimilars will be fully



> **WE ARE COMMITTED TO GETTING SERIOUS ABOUT MEDICINES MANAGEMENT**

capitalized upon in Britain. We are committed to ensuring the NHS is one of the fastest adopters of any new biosimilars that offer better value than the comparator and equivalent therapeutic benefits. The targets that we have thus adopted are to ensure that 90% of new patients are placed on biosimilars as soon as market authorization comes through, and that 80% of existing patients have transferred to the biosimilar where appropriate within 12 months after that approval date. To achieve this, we will be designing an incentive mechanism for the hospitals and clinics to encourage treatment switchover. We estimate that these steps will save us GDP 300 million GBP by 2020."

"Thirdly, we are examining thoroughly how to retool and remodel care delivery so as to be able to speedily integrate the medicines of the future. We are cognizant of the fact that new generation therapeutic modalities are not just silver bullets that you can bring in via the conventional modes of drug administration. On the contrary, they are going to require the entire care delivery pathway to be reconfigured. We are therefore committing to mobilizing our care provision and delivery systems around the new treatments. CAR-T cancer therapies will very much be the poster-child for this restyled modus operandi and these sorts of cutting-edge treatments are penciled in to be available in the UK as early as the autumn."

"Obviously, there is going to be vigorous discussion over affordability within the HTA process because many of these gold-standard treatments come at a pretty hefty price tag, especially when you consider the other care needed to administer them and manage potential side effects. The NHS will not be waiting around for that pricing negotiation and pharmaco-economic process to exhaust itself before we start putting in place the delivery capabilities to take on these novel treatments. We are already forging ahead and building up the requisite infrastructure such as specialized treatment centers. It's important to remember that CAR-T style treatments involve the collection and adaptation of the patient's own cells and then their reintroduction back into the body. The facilities needed to handle such techniques, plus the support structures to deliver the appropriate wrap-around care are therefore quite specific and cannot be created overnight. It also requires education and training of skilled clinical teams. That is precisely why we are preparing ourselves so as to be able to hit the ground running."

"Fourthly, we are engaging with patients about the new styles of therapy that will be coming on-stream providing that reimbursement authorities can get the pricing right. A precondition to introducing these novel formulas is the holding of full and transparent discussions about risk profiles of what could genuinely be seen as breakthrough therapies."

"Fifthly, we are committed to getting serious about medicines management so as to create sufficient financial headroom with which to afford cutting-edge, latest generation treatments. There are many steps we can take to make ourselves more financially sustainable. Medicines wastage is a significant area where improvement is required both locally and nationally. It is estimated that GBP 300 million of medicines wastage occurs in primary care alone. Much of this inefficiency arises because of the complexities of poly-pharmacy in which patients suffer from multiple simultaneous conditions that could be handled much better via holistic treatment plan. We have therefore decided to directly fund clinical pharmacists and GPs in care homes in the hope of improving medicines management."

CHARITY: A UNIQUELY BRITISH MODEL

One notable quirk of the British life sciences ecosystem is the importance of its not-for-profit sector. Indeed, in 2017, UK charities poured GBP 1.6 billion (USD 2.1 billion) into medical research; more than both the Medical Research Council (MRC) and the National Institute for Health Research (NIHR). Simon Gillespie, chief executive of the British Heart Foundation (BHF) – which each year commits GBP 100m to new research – points out that the importance of charities in the UK is deeply embedded: "The UK has a very long history and tradition in supporting charities. Famously, the first piece of charity legislation was the Statute of Elizabeth in 1601, so it is quite old as a legal concept."

On the enduring success of the British charity model, Hilary Evans, chief executive of Alzheimer's Research UK (ARUK), notes that, "In the UK, when people want to help those affected by diseases like Alzheimer's, they often go to charities rather than the state. They want to be involved in something and surround themselves with other people with the same mindset." Evans strongly feels that medical research charities fill a gap left by both the state and industry. "I don't think there is a risk in leaving public health issues to the will of the people and donors," she postulates. "It allows you to raise a huge amount of money to do things a little differently. I don't think any government would do some of the things we've done, which have been very successful. We aren't politically driven as any government funding would be, which allows us more freedom to be innovative."

AISLING BURNAND

CEO, Association of Medical Research Charities (AMRC)

SIMON GILLESPIE

chief executive, British Heart Foundation (BHF)

British research charities do not, however, exist in a bubble and can play a vital role in the research efforts of both industry and government. Aisling Burnand, CEO of the Association of Medical Research Charities (AMRC), posits that, "charity investment has a significant impact in its role as a lever that de-risks a particular area of research and opens it up for further funding." She continues, "In many cases, charities identify an unmet

patient need, where no one else is operating in that space, and then enter early on. That funding then de-risks the early-stage research, allowing other actors to come in. Sometimes it works the other way around and charities might piggyback on public-sector or private funding."

THE CHARITY-INDUSTRY INTERSECTION

One particularly risky area of research is Alzheimer's Disease. Indeed, the failure rates for Alzheimer's drugs has been 99.6 percent over the past decade and Pfizer joined a host of other Big Pharma companies by quitting Alzheimer's research in January 2018 in favor of surer bets in cancer and cardiology. ARUK's Evans therefore feels her organization has an important role to play in keeping the disease on researchers' priority lists. She notes that, "We launched our 'Defeat Dementia' Campaign in 2014 with the objective of raising GBP 100 million to ramp up ambitions around dementia research. We needed to be much more strategic in terms of how we funded medical research and to work much more closely with government and industry to bring about new treatments." In another cross-sector collaboration, Evans points out that ARUK is "one of the founding partners of the UK Dementia Research Institute, established in 2016, which will be a UK-wide flagship institute pulling together some of the best scientific research happening across six universities across the UK. It is a jointly funded initiative, with GBP 150m of government funding through the Medical Research Council, GBP 50m from ARUK and another GBP 50m from the Alzheimer's Society."

HILARY EVANS

chief executive, Alzheimer's Research UK (ARUK)

MICHELLE MITCHELL

CEO, Multiple Sclerosis (MS) Society

Another charity that has prioritized and formalized its industry collaboration is the Multiple Sclerosis (MS) Society. Its CEO, Michelle Mitchell, is keen to highlight the commonalities between charities working in the MS field and private companies developing treatments. "At a global level we work with the Progressive MS alliance. We have an industry forum and industry partnerships whereby, on a non-competitive basis, we all have something distinctive to contribute to achieving our goal, which is finding new treatments for progressive MS," she notes. "We see the solution as charities, industry scientists and researchers working together." Mitchell does though stress the need for transparency in these non-profit/for-profit collaborations, saying that, "it is important that we have the right type of relationship and that our relationship is thoroughly regulated. It has to be transparent and there should be no conflict of interest."

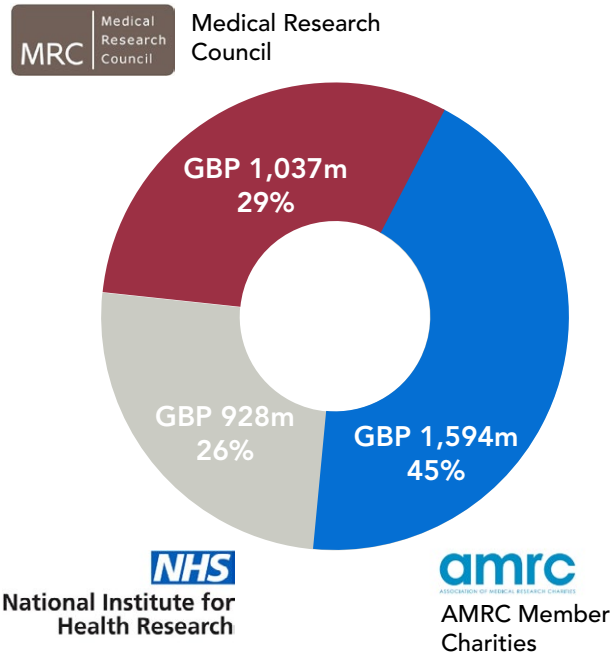
The BHF's Simon Gillespie is also cautious about greater industry interaction, noting that, "We have always traditionally had an arm's-length relationship with industry. We don't take money from industry and therefore

> **INDUSTRY IS PART OF THE SOLUTION AND IN THE COMING YEARS, BHF WILL BE MUCH MORE PUBLIC IN RECOGNIZING THAT WE HAVE TO WORK TOGETHER.**
>
> — **Simon Gillespie** BRITISH HEART FOUNDATION

we preserve our independence. In fact, preserving our independence of thinking and that trust from the public is essential to us." However, Gillespie does acknowledge that the world of medical research is changing and, "Increasingly, as we are moving more into translational medicine and the clinical medicine space, we are bumping more often into industry. The last thing we want to do is get to a situation where we end up detracting from patient benefit. Industry is part of the solution and in the coming years, BHF will be much more public in recognizing that we have to work together."

CHARITY SECTOR R&D SPENDING

- In 2015/16, AMRC charities contributed 45% of non-industry spend on R&D, with the MRC and NIH contributed 26% and 29% respectively.
- Expenditure by AMRC member charities increased from GBP 1,443m in 2015 to GBP 1,594m in 2016.
- All types of non-industry R&D spend increased between 2012/13 and 2015/16, with: – AMRC charities' expenditure increasing by 23% – MRC spend increasing by 21% – NIHR spend increasing by 8%
- The relative contribution of each organisation has remained roughly constant since 2012/13



Note: Spend by health departments in Scotland, Wales and Northern Ireland not illustrated

Source:UK Office for Life Sciences; AMRC, MRC and NIHR annual reports 2016

NEW STRATEGIES AND CHARITY 2.0

Not only is the charity sector working more with private industry, it is taking its cues from it. As the AMRC's Burnand notes, "We are now seeing charities behaving more like investors, with Parkinson's UK and Alzheimer's Research UK as examples. Such organizations are either putting in money to have more 'shots at the goal' by moving into the translational space while they might have historically worked more in the basic research space, or they are acting as 'honest brokers' and aligning investment from a variety of partners around an unmet patient need."

Burnand also highlights charities' adoption of new investment models, such as integrated funding. "Charities are starting to say things like: 'we will invest this amount of money, but we would like to recoup a particular level of investment which will then go straight into funding more research,'" she articulates. "At the far end of the spectrum, you have models that work in a similar way to venture capital. Examples include Parkinson's UK's Virtual Biotech, the Brain Tumour Charity's Brain Tumor Fund, and the Dementia Discovery Fund."

Furthermore, the digitalization wave sweeping across the entire healthcare and life sciences industries has not left charities untouched. The AMRC has coined the innovative digital organizations operating in the charity space, 'Charity 2.0' and Burnand describes that, "This is still something relatively new and untested that we are all trying to grapple with, but we are seeing some promising new initiatives. Arthritis Research UK is trialing a chatbox-type technology to deliver tailored information at home and many new ideas were showcased at our 'Delving into Digital' conference in February. The conference showcased examples of digital projects including apps and artificial intelligence being developed by AMRC member charities and facilitated links with digital technology companies and public-sector representatives."

A LONG-TERM GAME CHANGER

Something rather remarkable happened last year, and it has the potential to be a long-term game-changer for the UK.

We already have the largest bio-pharmaceutical research cluster outside the east and west coasts of the USA. It is an incredibly diverse and vibrant eco-system which connects, amongst others, world-class universities, medical charities, teaching hospitals and life sciences companies, large and small.

Last year the sector came together under the leadership of Sir John Bell to create the Life Sciences Industrial Strategy which sets out a blueprint for the future. Now normally, these types of documents are best described as worthy. This document is different. It is truly remarkable because it provides a world-class analysis of what needs fixing today and a compelling roadmap to take the UK through a future where the science behind new technologies is advancing at a faster pace than ever before.

At the centre is the NHS and the potential for millions of patients to be research patients, many of whom already benefit from a wide range of clinical trials. This pharmaceutical investment supports the NHS; gives patients the chance to be involved with developing the latest medicines and vaccines; and upskills our world-leading clinicians.

Early on in my career, I remember speaking with a leading clinician about the impact our HIV medicines were having on him and his patients. He said the introduction of triple therapy meant that patients who had come to his hospital to die were, in a short period of time, now able to go home – and even back to work. Those sorts of stories are so powerful that they never leave you. It's also the reason why supporting the life sciences sector and the NHS are so important.

What became clear by working together behind a single strategy was that we can drive a virtuous circle that accelerates the adoption of innovation, delivers improved health outcomes for patients, and crucially improves productivity within the NHS. This strategy will enable us to make life-saving and life-changing discoveries of the future.

This work, and our desire to get the best outcome for patients and public health through Brexit, has brought all stakeholders in the life sciences ecosystem closer together than ever before. We are looking for opinion formers across the political spectrum, who also want the same future, to engage in this exciting dialogue and make our NHS and our life sciences ecosystem a world leader. For this next wave of innovation to be truly transformative, the Government needs to deliver the Life Sciences Industrial Strategy in full.

Mike Thompson
ABPI

> **"CLEAR BY WORKING TOGETHER BEHIND A SINGLE STRATEGY WAS THAT WE CAN DRIVE A VIRTUOUS CIRCLE THAT ACCELERATES THE ADOPTION OF INNOVATION, DELIVERS IMPROVED HEALTH OUTCOMES FOR PATIENTS, AND CRUCIALLY IMPROVES PRODUCTIVITY WITHIN THE NHS**

UK CHAMPION

Recently joining the UK operations of AstraZeneca after a varied international career, Laurent Abuaf shares his vision of the UK as a life sciences reference market, what to expect from AZ's future pipeline, and what it takes to successfully manage a UK affiliate.

Laurent Abuaf
COUNTRY PRESIDENT, ASTRAZENECA

HCLS: What is the scope of operations of AstraZeneca in the UK today?

LAURENT ABUAF (LA): For AstraZeneca, our roots lie in Great Britain and Sweden, and, consequently, our footprint in the UK is second to none in biopharma. Our new R&D headquarters in Cambridge will regroup all scientific sites around Cambridge into one, which will allow us to further foster collaboration with academia. 70 percent of all AstraZeneca medicines have either been invented or developed in the UK, which goes to highlight our historic footprint and scientific past in this country.

Next to the science offering, we also have important manufacturing and development operations in the North-West corridor, in Macclesfield. From there we turn our molecules into medicines, manufacturing supply for 130 countries globally.

Those are just some of the elements that illustrate how crucial the UK is for AstraZeneca but also how important AstraZeneca is for the UK: we represent one percent of all British exports.

To AstraZeneca, the UK is critical, owing to the intellectual capital and high science it showcases as opposed to the size of the market. Being able to leverage this, as well as the incredible data available here, allows us to identify the right patient for the right study, and make the UK into a unique place for us.

"THOSE ARE JUST SOME OF THE ELEMENTS THAT ILLUSTRATE HOW CRUCIAL THE UK IS FOR ASTRAZENECA BUT ALSO HOW IMPORTANT ASTRAZENECA IS FOR THE UK: WE REPRESENT ONE PERCENT OF ALL BRITISH EXPORTS.

HCLS: What can we expect from AstraZeneca's pipeline moving forward?

(LA): As a company, we concentrate on three core therapeutic areas: cardiovascular, renal & metabolic (CVRM), then respiratory and oncology.

For example, in CVRM, we have several investigational molecules pushing through, including a GLP1-glucagon-based molecule that presents a double mode of action. Phase IIa data for MEDI0382, recently published in the Lancet, showed that after six weeks of treatment this treatment significantly improved glycaemic control and reduced body weight compared to placebo. Separately, we are also working on a technology that will revascularize the cardiac muscle following myocardial infarction. It's still early days but this is really exciting.

HCLS: What do you believe are the skills you will need to manage the UK operations of AstraZeneca in a successful way?

(LA): I believe that maintaining the patient focus while developing resilience will be of the utmost importance. At AstraZeneca, I see an innovative spirit and great creativity firmly anchored in our ways: good ideas make their way to the top. This is essential for the future of any company, and I am proud that we have the capacity at our company and in the UK to unlock potential. It is easy to be distracted by the system, but patient focus has to remain our mantra.

We want to be a success. I feel excited, blessed and to a certain degree stressed by the task in front of me, but I retain the confidence that the UK will continue to be a hub on the life sciences map.

CEO PROFILE

UP FOR THE CHALLENGE

Christine (Chris) Fox, VP general manager UK and Ireland at Amgen discusses the rationale behind taking on the management of a UK affiliate in challenging times and the specificities of Amgen's company culture.

With the full implications of Brexit on the country's life sciences industry still unclear, the UK stands as one of the most challenging roles for a country manager anywhere in the world. However, for Amgen's Chris Fox, two months into her first country manager position and in her first role outside of North America, "the challenging nature of the situation is exactly why I took on this role!" Fox continues, "As an affiliate, we have a great reputation internally within Amgen for innovating, partnering and collaborating – and now I've seen it for myself and I'm excited to lead the team in taking that to a whole new level. I am learning a lot and we have a great caliber of talent here. I'm looking forward to building on their perspective in a health system that I don't know as intimately. I also look forward to using my experiences to develop talent, so we will all be learning together."

In terms of first impressions of the UK market, Fox posits that, "Everyone tells you how complicated the UK market is and that is true – it's one of the reasons I took the job. There is a lot of complexity, layers, established norms but it's also evolving at the same time. There is a deep public pride in the NHS, which is sometimes undermined by this complexity, but the political nature of healthcare is something you find in all markets – it just plays out slightly differently."

> **"EVERYONE TELLS YOU HOW COMPLICATED THE UK MARKET IS AND THAT IS TRUE – IT'S ONE OF THE REASONS I TOOK THE JOB.**

Fox also has responsibility for Amgen's Irish affiliate; a challenging brief, especially given that Ireland is set to remain under the jurisdiction of the European Medicines Agency after Brexit, while the UK leaves. She is, however, keen to play up the synergies between the two countries, noting that "Ireland used to be where the UK is now – market access was slow, but there was an openness to doing business and companies could eventually bring innovative products to market. In the last couple of years, that has vastly changed, but Ireland is now coming out of that period. What makes managing our joint affiliate work from an Amgen perspective is the cross-functional teamwork and the fact that the same portfolio is represented in both markets, although Ireland is in a different stage of its journey. The spirit we have in Ireland is also very translatable and there is a healthy competition between the two teams!"

CHRIS FOX
GENERAL MANAGER UK AND IRELAND, AMGEN

AstraZeneca

What science can do

Circulating tumour DNA

AstraZeneca has pioneered the use of circulating tumour DNA (ctDNA) in the diagnosis of cancer. Pieces of DNA break off from a tumour and circulate in the bloodstream where they can be analysed to give genetic information about a patient's tumour. This allows healthcare professionals to determine the right treatment for the patient using a minimally invasive blood test.

VVPM ID: GB-12846 Date of Preparation: July 2018

UK

A VOTE OF CONFIDENCE

Britain's GBP 64 billion (USD 83 billion) life science market has long ranked proudly as one of the most alluring pharma prospects within Europe not just courtesy of a very decent 3.3 percent growth rate, but also because of the country's heavyweight medical science infrastructure and a well-honed reputation for elite innovation.

The life sciences sector's value to the national economy stands uncontested. "I consider it absolutely no exaggeration to say that the life sciences sector constitutes one of the last big remaining bastions of British industry. Many of the other traditional heavyweight industries have been gradually hollowed out and relocated to other parts of the globe, but with life sciences, the hub remains staunchly implanted within the UK," remarks Terry O'Regan, Biogen vice president and managing director of the UK and Irish affiliates.

Yet the overarching vibe is hardly one of a local industry content to rest on its laurels. "With the NHS celebrating its 70th anniversary, a fiercely ambitious and forward-looking life sciences industrial strategy (LSIS) entering into force; and an historic opportunity to take our sector global with the advent of Brexit, these are profoundly exciting times for anyone involved in the British pharmaceutical or biotech community," muses Mike Thompson, CEO of the Association of the British Pharmaceutical Industry (ABPI).

LORD O'SHAUGHNESSY
parliamentary under secretary of state for health

SIMON STEVENS
CEO, NHS

ENDURING APPEAL

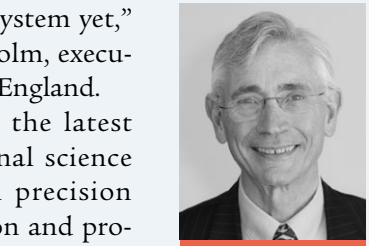
The UK's perpetual attraction for multinational pharma thus transcends matters of market dynamics, notwithstanding resilient consumer demand and the country's 66.5 million-strong population, and reflects just as much its defining characteristics as a fertile ground for drug discovery and trendsetting. "The UK is an important country for Gilead, not just because of its size as an attractive pharmaceutical market, but because of the power of the UK to shape and influence trends across the world. The UK has a tremendous science base and a thorough understanding of how to value healthcare innovation. This makes us uniquely positioned from a global perspective," concedes Hilary Hutton-Squire the company's general manager covering the British Isles.

Indeed, a number of acclaimed institutions stand out for their pioneering and ground-breaking spirit. Britain's national genome apparatus (UK Biobank and Genomics England), for instance, is busy sequencing some 100,000 whole genomes from NHS patients with rare diseases, and their families, as well as from patients with common cancers. "My expectation is that we will ultimately be credited with creating a dataset of de-identified whole genome sequences matched with clinical data at a scale absolutely unprecedented in the entire world.... France, Denmark and Japan may have their respective projects in the pipeline, but simply no-one other than the British is operating at scale in a real health system yet," reveals Sir John Chisholm, executive chair of Genomics England.

"When it comes to the latest techniques in medicinal science such as personalized precision medicine, the collection and processing of big data and gene-based therapies, Britain is certainly managing to ride the crest of the wave and position itself right at the vanguard with its huge capacity in connecting data sets and records," observes Janssen's general manager Mark Hicken.

Then there are certain therapeutic area niches in which the UK is very much regarded as blazing new trails, while the uniquely centralized structure of the NHS helps to secure sufficient critical mass to build up the requisite hubs of expertise. "For conditions

MIKE THOMPSON
chief executive, ABPI



SIR JOHN CHISHOLM
executive chair, Genomics England

The Golden Triangle: World Class Academia Meets Industry

Most of the activity and productivity in the UK's life science sector emanates from the so-called 'Golden Triangle' of cities known for their elite academic and research institutions – Oxford, Cambridge and London – according to Bidwells, a British consultancy. 600 life science companies operate in the region, ranging from multinationals to start-ups and with a combined market capitalization of GBP 5.7 billion (USD 7.5 billion). AstraZeneca moved its global headquarters to Cambridge in 2016 to be closer to this scientific base. Country President Laurent Abuaf explains that, "Having our corporate headquarters in Cambridge allows us to create and access an ecosystem of science, innovation and academia. We are also re-joining our roots as a company, with our MedImmune R&D arm already being located in Cambridge. We know that collaboration within a buzzing environment where we can meet intellectual capital is what triggers great innovation and science."

Industry-academia synergies are well established in Oxford, as Richard Barker, former director general of the ABPI and a leading voice in British life sciences, details. "We now have the Oxford Sciences Innovation (OSI) fund of GBP 550 million (USD 720 million), that will support spinning out technologies from the University of Oxford (which remains the best funded medical school in the country) into companies," he proclaims. "They've already created several companies in life sciences, and we are slowly beginning to align the thinking in academia with the needs of industry."

London is a global innovation hub and financial center, allowing biotechnology start-ups access to new ideas and technologies as well as investment capital. Steve Bates, CEO of the UK BioIndustry Association (BIA) declares that "London is the largest city in Europe, and the flexibility and opportunity it represents are impressive. I often joke that platform nine and three quarters is where the magical journey starts – not just for Harry Potter – because on one side of King's Cross Station we find the Francis Crick Institute, the most significant biomedical organization in Europe, and on the other side we find Google Deep Mind's campus; they combine to form a magical setting! The access and application of Big Data to cell biology for innovative companies, coupled with London's status as a vibrant city make it a fantastic place to live."

like neurodegenerative disease, Britain's Institute of Neurology is generally regarded as a global pioneer and this stems partly from the clinical structure of our country. Due to the way our NHS is organized, anyone afflicted with a rare neurological disease in the southern half of the country is referred to this particular hospital

KEY INFRASTRUCTURE AND INSTITUTIONS

NHS
The UK's National Health Service, founded in 1948 on the principle that services should be comprehensive, universal and free at the point of delivery.

NICE
The National Institute for Health and Care Excellence, the UK's main Health Technology Assessment Body, proving national guidance and advice to improve health and social care, and is considered a world leader in its field.

Francis Crick Institute
The largest single biomedical laboratory in Europe with 1,500 staff, including 1,250 scientists, and an annual budget of over £100 million.

Genomics England
Set up and owned by the UK Department of Health to run the 100,000 Genomes Project, which aims to sequence 100,000 genomes from NHS patients with a rare disease and their families, as well as patients with cancer.

UK Biobank
Based in Stockport, Greater Manchester, UK Biobank is a large long-term biobank study investigating the respective contributions of genetic predisposition and environmental exposure to the development of disease.

Google DeepMind
Acquired by Google in 2014, DeepMind is a company working at the cutting edge of artificial intelligence. Its technology is already being used for numerous applications in healthcare

STEVE BATES
CEO, BioIndustry Association (BIA)

which has been invaluable in enabling us to ramp up our knowledge base," points outs John Hardy, professor of neuroscience at UCL and co-recipient of the 2018 Brain Prize for ground-breaking research on the genetic and molecular basis of Alzheimer's disease.

Nor can one overlook the UK's distinctive enabling ecosystem for biotechs. Not only does Britain possess the so-called "Golden Triangle" – the third largest technology cluster in the world outside Silicon Valley and Boston – but no less than three of the world's top ten leading universities. "All in all, Britain offers a pretty compelling proposition for life sciences entrepreneurs and researchers wanting to operate at the bleeding edge of new drug discovery. If we consider funding, the UK has consistently ranked as the most active country for biotech capitalization in Europe. What's more, there is an extensive and broad-based heritage of experience chiefly because pharmaceuticals have been a significant part of the UK economy for decades," ventures Steve Bates, CEO of the BioIndustry Association (BIA).

PUTTING DOWN DEEP ROOTS

Given this context, it is perhaps little wonder, then, that many multinationals have developed extensive R&D footprints on the ground. "Amongst J&J's 5,000 UK employees, approximately 1,000 are dedicated to Janssen, with some 500 active in R&D related functions rendering us the largest single foreign investor in life sciences in the UK. Moreover, the J&J Innovation Centre based in London constitutes our European hub and constitutes one of only four global research centres responsible for identifying and accelerating early stage external innovation by establishing unique collaborations," details Janssen's Mark Hicken.

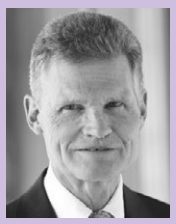
EWAN MCDOWALL
general manager, Ipsen UK and Ireland (July 2014 – June 2018)

CHRIS FOX
vice president and general manager UK and Ireland, Amgen

Amgen meanwhile maintains a 300-strong local R&D team, which coordinates clinical trials across Europe that account for over 60 percent of the company's total world volume. "This work plays a significant role in advancing our innovation and securing European approvals for our medicines. Many of our UK R&D team hold global and international roles and contribute to Amgen's global R&D strategy. I know that Amgen has always recognized the value of the UK in providing access to world class science talent and now that I've had a chance to work alongside them, I can see why. It's great having so much knowledge right here on our doorstep," exclaims newly appointed vice president and general manager, Chris Fox.

Then there is Roche, which invests more than half a billion pounds in early R&D in the UK on an annual

Core take-aways from the Life Sciences Industrial Strategy (LSIS)



SIR JOHN BELL

- Moonshot Programmes: Fashioning two to three entirely new industries over the next decade, by investing in "high risk/high reward" initiatives and funding pioneering research.
- Fundamental Research: Working with industry to increase spending on R&D to 2.4 percent of GDP by 2027, and then to three percent over the longer term with a view to attracting 2,000 new discovery scientists to the UK.
- Translational Science: Supporting a 50 percent increase in the number of clinical trials over the next five years
- Capability Engineering: Creating four UK companies valued at over GBP 20 billion market capital within a decade.

RICHARD ERWIN
general manager, Roche Products Ltd

basis. "I think there are two reasons why Roche has been committed to the UK. Firstly, there is great talent here, we are able to attract and retain the best staff. Our people are ultimately what make us a great company. Secondly, the UK has some of the world's greatest institutions across science and clinical medicine and it is great to be able to access that expertise," explains its country manager, Richard Erwin.

What's more, the investments continue to flood in. Ipsen, an ambitious French mid-cap player that has been busy of late converting a classic business model into a commercial powerhouse and efficient launch machine in oncology, has been betting big on deepening its UK R&D presence. "Our British operations nowadays constitute one of three strategic focal points for the company globally, and encompass an R&D facility on the outskirts of Oxford, commercial capabilities in Slough and a manufacturing site in Wales that generates our neuroscience drug Dysport® for global distribution... All in all, this is a pretty substantial commitment with about 600 employees, and 200 patents filed from our R&D site," recounts Ewan McDowall, general manager of Ipsen's UK and Ireland operations from July 2014 to June 2018.

"Our strategy is consciously to leverage the UK's status as a global life sciences epicentre looked up to by the rest of the world, by mobilizing great partnerships with academia and thought leaders and through making full use of the opportunity to attract top talent," he adds.

LSIS: BLUEPRINT FOR THE FUTURE?

Ever attentive to the need to preserve and extend the UK's competitive leadership, in August 2017, the British government unveiled its Life Sciences Industrial Strategy – the product of a comprehensive, independent cross-sector review into the long-term future of the industry led by Sir John Bell – the recommendations of which were subsequently codified with a far-reaching "Sector Deal" between industry and the state.

Alongside calls for an increase in conventional research funding, initiatives to boost home-grown pharma manufacturing and a target of importing an additional 2,000 discovery scientists from around the globe to work in domestic labs, the LSIS has raised eyebrows for proposing to set up a Health Advanced Research Programme (HARP) to invest many hundreds of millions of pounds in high-risk, high-reward "moonshot" projects. The aim would be to "create two to three entirely novel industries over the next ten years" around emerging disciplines such as the deployment of artificial intelligence and virtual reality to transform pathology and imaging.

BRYAN MORTON CBE
executive chairman & founder, EUSA Pharma

"Essentially we are seeking to emulate the Americans who have proven to be very good at this... They perform the research and deploy that as a way to then dominate an entire sector. They've already done it very effectively with satellites and GPS and managed to generate many

Doing now what patients need next

We believe it's urgent to deliver medical solutions right now – even as we develop innovations for the future. We are passionate about transforming patients' lives. We are courageous in both decision and action. And we believe that good business means a better world.

That is why we come to work each day. We commit ourselves to scientific rigour, unassailable ethics, and access to medical innovations for all. We do this today to build a better tomorrow.

We are proud of who we are, what we do, and how we do it. We are many, working as one across functions, across companies, and across the world.

We are Roche.

In the UK Roche employs nearly 2,100 people in pharmaceuticals and diagnostics. For more information please go to www.roche.co.uk

Roche

RXUKCOMM01275(1) Date of preparation August 2018

multiples of what was initially invested," reasons Bell who, among other roles, acts as chairman of the Office for the Strategic Coordination of Health Research (OSCHR).

The industry's response to these developments has predictably been enthusiastic. "Our members firmly believe this is the correct approach for our industry: we worked very closely to support Sir John Bell in developing the initial strategy document, and the private sector has already demonstrated its staunch support for the delivery of the strategy through the first Sector Deal," confirms the ABPI's Mike Thompson.

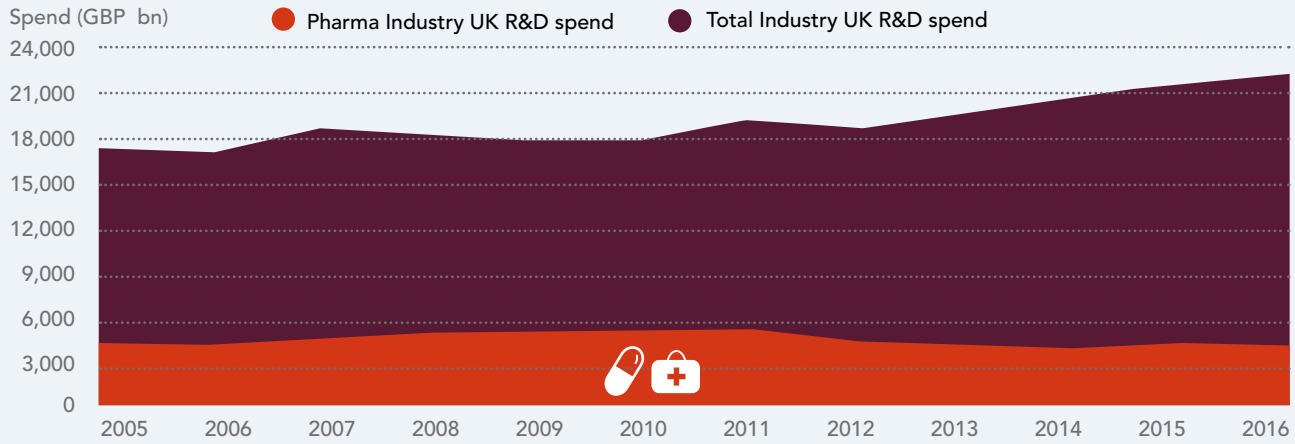
Such sentiment seems to be mirrored across the board. "I really believe in the LSIS. I think it is something the UK is capable of delivering and something that should be a clear priority for the industry and government. We have long been strong advocates of seeing accelerated strategies implemented in the British approach to the life sciences," declares Bryan Morton, executive chairman and founder of EUSA Pharma, a speciality drug developer focused on oncology and rare diseases.

He believes that the LSIS can go a long way towards filling in the gaps that prevent Britain from realizing its full life sciences potential. "Firstly, I hope these initiatives will inspire a public market that is more receptive to, and understanding of health technologies, and secondly that they will improve its speed of translating great ideas from the academic field into robust commercial opportunities. Previously, British industry has created dynamic companies only to subsequently sell them on to big American corporations. This is something I believe can change so long as we can construct several British healthcare companies with significant size and value. In order to do that, we have to do a better job not only at mentoring British entrepreneurs to be more global, but also to improve funding with experienced, focused investors," he muses.

Some actors have voiced concern, however, about the proper financing and implementation of the proposals and will not have been reassured by a House of Lords Science and Technology Select Committee

PHARMA INDUSTRY R&D SPENDING

- Pharmaceutical industry UK spend on R&D in 2016 was GBP 4.1bn
- Pharmaceutical industry R&D spend represents a fifth of total industry R&D spend in the UK
- Between 2005 and 2011, pharmaceutical industry UK R&D spend grew steadily to a peak of GBP 4.9bn in 2011, followed by a decline to GBP 3.8bn in 2014. Spend grew by 8% in 2015 and stabilised in 2016
- Pharmaceuticals' share of total industry R&D spend in the UK increased from 25% to 29% between 2005 and 2010. Pharmaceuticals' share decreased from 29% to 19% between 2010 and 2016 as a decline in pharma spend (by 23%) coincided with a substantial increase in total industry spend. (by 17%)

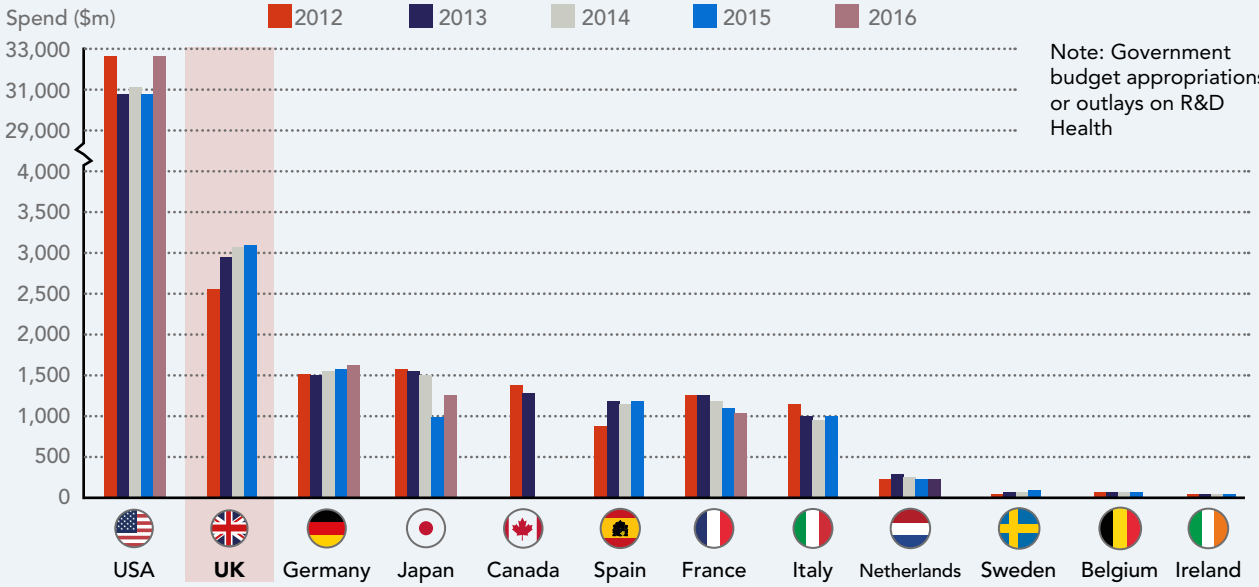


Note: Data is not available for medical technology industry spend

Source: UK Office for Life Sciences; UK Business Expenditure on Research and Development (BERD) 2016 survey, Office for National Statistics (ONS)

GOVERNMENT SPENDING ON HEALTH R&D

- UK government spend on health R&D was USD 3.1bn in 2015, an increase of a fifth from 2012
- The UK maintained its position as country with the second highest level of expenditure on health R&D behind the US
- UK spend is more than double that of its competitors, with the exception of the USA
- Expenditure in the USA remained at an order of magnitude of over 10 larger than expenditure in comparator countries



Source:UK Office for Life Sciences; OECD Research & Development statistics

ERIK NORDKAMP
managing director, Pfizer

hearing in April which judged the government's execution of the LSIS to so far be "both incoherent and inadequate".

"We're immensely positive about the fact that the LSIS has been published and are eager that it should be implemented in full. For the vision to materialize, however, it will be essential to adopt the right governance and an effective implementation plan that co-opts the commitment of the NHS," warns Pfizer's managing director Erik Nordkamp.

Roche's Richard Erwin is similarly forthright about tempering expectations. "We're moving in the right direction. I am convinced it is hugely important that government listens when British business points out what has to be improved. We are in need of a committed plan, and the Life Sciences Industrial Strategy was a start, but it is just a start."

THE NHS: PRIDE OF THE NATION

LAURENT ABUAF
country president UK marketing company, Astra Zeneca

Many commentators are quick to point out the linkages between Britain's enduring leadership in life sciences and the existence of as remarkable and exclusive an institution as the NHS. "Within the UK, the NHS is a source of immense national pride and for very good reason... unlike with equivalent apparatuses in countries such as Germany or France, genuinely free healthcare is administered to all citizens from cradle to grave without anyone ever receiving a doctor's bill in the post," enthuses AstraZeneca's Laurent Abuaf.

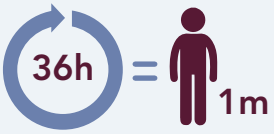
Moreover, "when you consider that the UK boasts quite a unique ecosystem – a NHS that is universal and free at the point of delivery, thus one of the most advanced and comprehensive health data sets – then it is hardly surprising that the UK has achieved worldwide acclaim for its innovation in early phase drug discovery," points out Biogen's Terry O'Regan.

Indeed, according to Sir John Chisholm, it is absolutely no coincidence that the UK ranks as the only

THE NHS: KEY FIGURES

NHS

The NHS is available to anyone who is a UK resident - currently some **64m people**



The Service treats **one million** patients every **36 hours**

Top 5 largest workforce

It employs **1.6 million** people - putting it in the top five of the **world's largest workforces**

TERRY O'REGAN
vice president and managing director UK and Ireland, Biogen

market worldwide to date with a working genomics structure. "The initial premise behind establishing Genomics England was that we possess something in this country that frankly does not exist anywhere else: a single payer market and nationwide, fully publically funded healthcare system that attends to citizens' health needs over the entirety of their lifespan...If we scrutinize the two behemoths in this world: the USA and China, we immediately become aware of how fragmented their approach to public health is. It is difficult to pull them together into a coherent approach. The strong advantage to working in this country is the extraordinarily strong coherence emanating from the commanding heights and pervading the entire apparatus." he exclaims.

"Because we remain one NHS, our health system is singularly placed to become the most advanced health system in the world – one where technology addresses the user need – making care better for patients, but just as importantly making life better for staff," agrees newly appointed health minister, Matthew Hancock.

The advent of artificial intelligence-based diagnostics is perhaps a case in point. "NHS patient records can be seen to be especially suited for driving the development of powerful algorithms that could transform healthcare," muses Sir John Bell. "Considerable value lies in the datasets used to train algorithms on tasks ranging from speech recognition to diagnosing disease. As the world's largest publicly funded health service, the NHS finds itself blessed with one of the most comprehensive health datasets in existence. Akin to what Google is doing in other sectors, Britain actually possesses an equivalent unique position in the health space," he exclaims.

CHAMPION OR IMPEDIMENT?

The LSIS, of course, assigns the NHS a role as lead protagonist and primary vehicle for materializing the UK's ambition as a world leader in life sciences. "The strategy highlights the potential of the NHS, which we are not currently capitalising on. One of the central features is that we move to harness NHS as an engine for innovation, embedding a culture of research, improving the adoption of new ideas and technologies and ensuring timely access to these," explains Sir Robert Lechler,

Vaccination Nation

HUGO FRY
managing director, Sanofi

The UK stands out as a global leader both in terms of the development of new vaccines as well as its national inoculation programs.

Hugo Fry, managing director of Sanofi UK, notes, "It is often overlooked, but the UK is delivering some of the best healthcare in the world in terms of vaccines." Fry continues, "The UK has a culture of vaccination and preventative medicine around vaccination that is second to none. The British Meningococcal C Vaccine program was copied around the world. The UK also has the second-best coverage of flu vaccination in the world – the highest being Korea. I think it is the joined-up way the immunization program is structured. There is NHS England, which is one of four pillars of the healthcare structure. But you also have Public Health England, which is very strong, and the Joint Committee on Vaccination and Immunization (JCVI) which is responsible for making recommendations about vaccines and vaccination programs to the government."

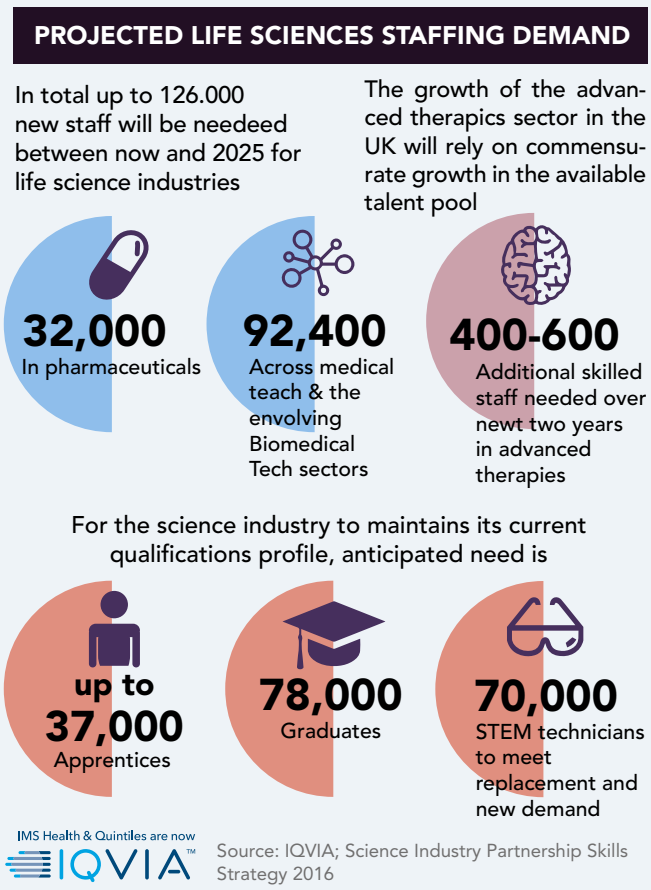
Against this backdrop, Sanofi UK has doubled down on vaccine development and rollout in the country. Fry posits that, "The healthcare system also plays a role, and of course you have the benefit that prevention has on healthcare strategy. You can therefore, in the UK, bind these elements together; the structure put in place, plus the focus on prevention and understanding the value of prevention. There is a good understanding throughout the UK. This is one of the strategic reasons we remain focused on vaccines, because there is a real opportunity for growth. We have a good pipeline, and the UK is particularly well disposed to adoption and the fast uptake of innovation in vaccines, which is not something we hear all the time in the medicine space. As a population, we are vaccine-focused."

president of the Academy of Medical Sciences (AMS). Such sentiments are reinforced by under secretary of state Lord O'Shaughnessy. "We require the NHS to be embracing new technologies that come through the R&D base here, as in not just adopting innovation initially, but actually harnessing it in full and mainstreaming it," he confirms. However many analysts remain sceptical that the institution can ever really become a proper agent of change.

A longstanding refrain that is commonly voiced has been that Britain's healthcare apparatus is too underfunded and stressed to shoulder such an onerous task. "The NHS appears to be very fatigued. When you talk to people who work there and sit across from healthcare professionals at any level, you get a sense that it is very labour-intensive for them to deliver care to patients. The cost constraints and what they need to spend their time on makes daily business very tricky. They are working for a good cause but finding it rather difficult to bring that value to fruition. We try to be sensitive to that and offer solutions which will ease some of that strain where possible," candidly observes Amgen vice president and general manager, Chris Fox.

"The NHS is never going to realistically become an innovation engine, because that is simply not its role. Its task is to provide the healthcare. The challenge it has been facing for decades is the squeeze on financing, as growth in the NHS budget has been notoriously slow, and flat in recent years. In parallel, it has been facing a massive growth in demand as demography changes and this has led to the organization not having a chance to really consider the innovation agenda and this is what has to be unblocked if the LSIS is to realise its ambitions," clarifies sir John Bell.

Fortuitously, the recent announcement of the British government that the NHS will be receiving an extra GBP 20bn (USD 26bn) a year in real-terms funding (once inflation is taken into account) by 2024, representing an average increase of 3.4 percent every year on the GBP 114bn (USD 148bn) budget for the next five



> **AS THE NHS TURNS 70, WE CAN NOW FACE THE NEXT FIVE YEARS WITH RENEWED CERTAINTY**
>
> — **Simon Stevens** NHS ENGLAND

years, goes a long way to alleviating the worries relating to the institution being too undercapitalized to deliver on its objectives. In the words of Simon Stevens, the institution's CEO: "As the NHS turns 70, we can now face the next five years with renewed certainty. This multi-year settlement provides the funding we need to shape a long-term plan for key improvements in critical services and the execution of our vital function."

Nonetheless structural hurdles still abound and there are many indicators that an organization that was conceived in the post-war, welfare state period is struggling to keep abreast of the times. While many of contemporary society's daily activities are now conducted online - from shopping to socialising - the NHS remains heavily reliant on older, often obsolete, technologies with the service infamous for its status as the biggest purchaser of pagers, fax machines and stamps in the world!

"There can be absolutely no doubt that the NHS will have to adapt to an evolving landscape if it is to deliver world-class healthcare befitting of a country at the vanguard of pioneering advances in medical science. Preserving business-as-usual can no longer be an option. The challenge for the NHS—which is actually an agglomeration of five independent organizations—is to drive this change. It is incredibly difficult to enact change through an organization constructed in this manner. While I have little doubt in the future longevity and a staying power of this iconic institution, the major task at hand is going to be all about mastering the evolution process," affirms the ABPI's Mike Thompson.

"The UK is in a truly amazing position and only second to the US when it comes not only to science, but also to technology, however we are still waiting to see whether the NHS is serious about championing

innovation... in order for companies to continue to see incentive to invest, I think there has to be a vision of sorts. The NHS has to visualise that healthcare will look very differently in five years' time and act accordingly. We can already see that younger generations are eager to adopt new ways of accessing care, and many initiatives are under way, but the NHS is a 70-year old structure and henceforth intrinsically resistant to change," shrewdly concludes Chris Stirling, chairman and partner of KPMG's global life sciences practice.

CHRIS STIRLING
chairman and partner of global life sciences practice, KPMG

NHS-INDUSTRY COLLABORATION

This is, however, precisely an area in which industry can assist. Already there are many examples in the med-tech sphere of private enterprise working hand in hand with the NHS to introduce state-of-the-art diagnostic devices and to reconceptualise care pathways with a view to rendering healthcare provision more effective and sustainable. "Johnson & Johnson have established a partnership with Bart's Hospital to run their orthopaedic department. Medtronic, meanwhile, have managed to strike similar deal in cardiology at Hammersmith Hospital, while Leica and Philips have been participating in the establishment of a centre for digital pathology harnessing artificial intelligence capabilities. Under the agreed terms the company generally not only provides the kit, but also actively engages in the provision of services and the risk burden is shared. This goes well beyond sales of devices and extends along the healthcare continuum so that the focus is ultimately centered on end outcomes and the patient experience," confirms Lord O'Shaughnessy.

CRAIG WALLACE
general manager UK and Ireland, Santen

JEAN-YVES BRAULT
country manager, Mylan

LARS BRUENING
CEO, Bayer UK and Ireland

Bayer's experience is perhaps emblematic of this approach. "Our priority is very much to improve patient care and communicating with physicians and establishing a harmonious working relationship with the NHS is absolutely critical in this... Right now, we are proud to have no less than 30 joint working projects with the NHS. For example, we identify patients for stroke prevention. They are registered in the system, the information is there, but they have to be identified and we see it as our role to do so," confides the company's CEO for the UK and Ireland, Lars Bruening.

"Moreover, the state's ambition is to apply the same sort of methodologies to the relationship with pharma companies at a moment when drug developers are demanding a deeper level of interaction than hitherto the case. Many pharma firms are now striving to go beyond pushing pills. They are keen to get closer to the patient and to play a proactive part in ensuring the good adherence of the medications that they are supplying," elaborates O'Shaughnessy.

Indeed, examples of this nature are also becoming increasingly widespread. Santen, for instance, has been collaborating to rationalize eye care. "In some parts of the UK, we are already working in tandem with the NHS to modify treatment pathways. We aim to avoid referring to hospitals people with mild conditions, but require GPs, optometrists and pharmacists to be more confident in assessing conditions," recounts general manager, Craig Wallace.

Mylan, meanwhile, has been delivering up compelling value propositions from its generics portfolio so as to help free up sufficient financial headroom for the NHS to redeploy funds in affording cutting-edge, latest generation treatments such as costly, but effective CAR-T cancer therapies. "We strongly believe that Mylan is well positioned to be a solution provider and partner to the NHS. The launch of our generic version of Seretide® for asthma patients three years ago is an example of savings generated to the system. Today, it is generating between £10-12 million in savings to the NHS, just by providing patients with another treatment option with the same molecule," explains the company's managing director, Jean-Yves Brault. "Every generic we introduce in the market provides healthcare professionals with a new option and creates more access for patients while taking off pressure on NHS' budget management. That is how we believe we can be perceived as a solution provider to the challenge of healthcare... The recent introduction of our Glatiramer Acetate 40mg/ml is yet another example of Mylan's contribution to improving access for patients, providing more treatment options for

JON NEAL
managing director UK and Ireland, Takeda

healthcare professionals and helping the NHS optimise the available funds," he adds.

"The key to a long-lasting positive collaboration with the NHS is the willingness to compromise," opines Takeda's managing director, Jon Neal. "As a company, you have to be willing to accept some level of compromise on price, more so than in other countries. However, once past that hurdle, you also reap the benefits. You might for instance be able to gather data you will be able to make strategic use of in other markets around the world," he notes.

It is, of course, worth bearing in mind that there are a great many different components of the NHS with which to interact with as opposed to a single, unified, monolithic block. "For AstraZeneca, the NHS has become a critical and longstanding partner. It is, however, not one entity, and we find ourselves having to engage with it simultaneously on national, regional and local levels. The crucial point here is that if you want to collaborate with the NHS, you need to be open to understanding their agenda: they have a patient-care and cost-effectiveness perspective, with a local needs dimension adding to it," counsels Laurent Abuaf.

> **"THE KEY TO A LONG-LASTING POSITIVE COLLABORATION WITH THE NHS IS THE WILLINGNESS TO COMPROMISE**
>
> — **Jon Neal** TAKEDA

INNOVATION: SLOW ON THE UPTAKE

While the UK has firmly established itself as a global power in basic science and research, when it comes to

GARY HENDLER
chairman & CEO EMEA, Eisai

actually bringing state of the art technologies to the domestic market, the path is strewn with hurdles.

The managers of multinational affiliates in the UK are singing from the same hymn sheet when it comes to the disconnect between innovation and access. As Laurent Abuaf, AstraZeneca's country president, illuminates, "The UK has what it takes to be a global life sciences leader, from a scientific capital perspective, from an infrastructure perspective and, more recently, from a political intention perspective – but this political intention needs to transform into real decision-making." Lord Philip Hunt of the Labour opposition describes improving uptake of innovation as "the one issue above all else that I would tackle as a Health Minister ... We know that we are a little bit slow to adopt new ideas, despite the fact we are brilliant at developing them."

Bayer's Lars Bruening explains the reasons behind UK's slow uptake of innovations thusly: "Firstly, the system as such is not encouraging fast uptake and the division of responsibilities between local and national level does not make things easier. Secondly, we observe a certain conservatism from physicians when we get excited about a new innovation." For Eisai's Gary Hendler, NICE's capacity constraints have been the main obstacle to faster uptake. He states, "Without a NICE recommendation, obtaining reimbursement from the NHS – the UK's single payer — is very difficult and its standards are world renowned. But NICE cannot master the number of applications submitted in a timely manner." However, Hendler does concede that "Recently, NICE has addressed those capacity concerns, involving industry earlier in the process."

Furthermore, companies producing new or innovative technologies have found it especially difficult to gain product approval. Janssen's Mark Hicken explains, that "New medical technology with phase II data is often viewed as immature in health economic terms. This entails a more challenging conversation with NICE, particularly in the oncology space."

Making an international comparison, Roche's Richard Erwin laments that, "For many, the UK market is seen as one of the most challenging in healthcare. Not in terms of sheer size, such as the US or China, but in terms of market access and uptake of innovative new products. In Germany, for example, access is often rapidly granted, and uptake of innovative breakthrough products guaranteed; however, the UK ranks low in international comparisons for access to new medicines. Sometimes, even when access is granted, uptake can be slow." Haseeb Ahmad of Novartis develops this point, noting that "Unfortunately, in the UK, we live in a society where patients often have to wait to even see a secondary care consultant and cannot access innovation readily available in other countries. Indeed, patients in France or Germany are five times more likely to get access to a medicine within its first year of launch than UK patients."

HASEEB AHMAD
country president, Novartis

Terry O'Regan of Biogen – the manufacturers of Spinraza, an innovative treatment for spinal muscular atrophy – points out that despite an expanded access program for the drug being implemented, patients still

> **DESPITE THE PROVISION OF FREE DRUGS; INFRASTRUCTURE AND CAPACITY CHALLENGES STILL NEEDED TO BE OVERCOME BEFORE PATIENTS COULD RECEIVE THEM**
>
> — **Terry O'Regan** BIOGEN

struggled to receive it. He recalls how "despite the provision of free drugs; infrastructure and capacity challenges still needed to be overcome before patients could receive them. It was, quite frankly, seriously heart-breaking to hear that a breakthrough therapy with the potential to fundamentally change the course of disease was not immediately available, but, resolution was found, and many children are now being treated through this program."

MSD's managing director, Louise Houson, believes that industry needs to partner more with authorities to counter this slow uptake of innovation. She posits that, "For the UK to remain a very attractive market in post-Brexit times, we have to ensure rapid uptake. I believe the solution lies in partnerships. The aforementioned challenges concern the industry, as well as the NHS, NICE and the Department of Health and Social Care (DH). We have a responsibility to partner to overcome the current affordability challenge faced by the NHS to work towards a more flexible system with rapid uptake at its core."

AstraZeneca's Abuaf strikes a similar chord: "we have to figure out, as an industry and together with academia and officials, how we can strike the perfect balance between ensuring that the best innovation reaches patients in an affordable manner and encouraging innovation on the other side. There is no easy answer, but I see that the foundation for discussion is here in the UK and that ultimately, everybody has the health of patients on their mind. This will lead all of us to make the right decisions moving forward."

LOUISE HOUSON
managing director
UK and Ireland, MSD

Mike Thompson of the ABPI, points out that firms are already helping to speed up the process from their side by compiling the right documentation. He comments, "As an industry, we recognize that NICE does a tremendous job as an HTA body to assess productivity. Companies themselves are also getting noticeably better at bringing forward information that demonstrates not only the improved patient outcomes they are delivering, but also their instrumental role in driving efficiency within the public health system."

PRICING: AT THE LIMIT!

The main obstacle facing pharmaceutical companies operating in the UK is, however, the country's pricing structures. SOBI's Neil Dugdale opines, "Prices in the

NEIL DUGDALE
vice president and general manager UK and Ireland, Sobi

STEWART PEARCE
managing director UK and Ireland, Otsuka

UK market have been driven down significantly over the past years. While this is a good thing for taxpayers and should mean greater access to innovative medicines for patients, it has a sum of negative repercussions. First and foremost, we have to ask ourselves, how long is such a system with constant price-cuts sustainable? The looming threat is that, at some point, companies will have to make the decision to not launch highly innovative products in the UK, because it does not make sense to them financially."

Otsuka's Stewart Pearce agrees on the difficulties of navigating the UK's pricing structures. "It is hard to get through NICE without drafting out confidential discount schemes," he notes. "As a reference market, we display a gross price, visible to other markets, in addition to the net price required for NICE negotiations. To us, the barriers we have to surmount to bring a product to the UK are hence twofold as we need to consider reimbursement just as much as the impacts our pricing in the UK will have on other markets we want to launch in." Pearce continues, "Moreover, in the UK we do not only encounter a tough launch phase, we cannot even count on a nice tail for our products as in other markets such as Spain. For pharmaceutical companies, both ends of the lifecycle of their products are extremely tough in the UK."

HILARY HUTTON-SQUIRE
general manager UK and Ireland, Gilead

Roche's Richard Erwin is even more pessimistic. He asks, "We do ask how a country like the UK can justify having some of the lowest thresholds for ICER (incremental cost-effectiveness ratio) amongst developed nations. As a British citizen, I find this unacceptable; the value the UK places on a year of life gained is one of the lowest in the developed world." Erwin continues, "The current ICER thresholds are challenging to navigate. In some cases we have offered free access to our medicines, but this just is not a sustainable business model." AstraZeneca's Abuaf adds that, "NICE cost-effectiveness thresholds are some of the lowest in Europe and have not changed since 1999, despite inflation, which can be challenging when trying to bring innovative medicines to the UK."

Gilead's Hilary Hutton-Squire pinpoints the main discrepancy in pricing thusly: "Today, I see an issue arise because there should be a difference between the areas where it is easiest for procurement bodies to drive down costs, and the areas where we value innovation the most," she moots. "However, we often see that the areas where it is easiest to drive down costs are the areas where we value innovation the most, in new medicines and innovations. As opposed to medicines that have been around for a

long time, they are medicines in highly specialized areas and often one-off treatments as opposed to chronic treatments."

PRICING WOES FOR RARE DISEASES

Indeed, for rare disease specialists, the situation is particularly difficult. Biogen's Terry O'Regan outlines the alarming figures: "of the 143 rare disease therapies approved within the EU, a mere 68 were available on the NHS in 2016. Equally concerning is the fact that it takes on average two and a half years for approvals to be attained." Sobi's Neil Dugdale adds, "Within NICE, there is a 'one-fits-all' approach to treatment appraisal, as it was designed to analyse the cost-effectiveness of products treating thousands of patients. In rare diseases however, we see patients gaining access to treatments that could either cure or extend their life substantially with a good quality of life, significantly later than most other developed economies."

Dugdale elucidates that, "in rare diseases, patients have to wait an average of five years to get a diagnosis and many of these patients are children. These families with sick children have been stressed and traumatised for an average of five years. Some are then told that there is either no diagnosis (SWAN—syndrome without a name), or that there is a diagnosis but that no treatment exists. The best case is a diagnosis and a treatment. However, with the current appraisal process, the treatment might be delayed significantly compared to other developed economies or my fear is that some may never reach the market if an agreement cannot be reached with the NHS. Furthermore, a company may decide to prioritise supply to countries that don't insist on the low prices demanded by the NHS. The UK is already a tough market and it is getting tougher. The situation where a family has to

CDMOs On the Rise

KEVIN COOK
—
CEO, Sterling Pharmaceutical Solutions

STEVE BAGSHAW
—
CEO, FUJIFILM Diosynth

The UK's contract development and manufacturing market has seen healthy growth in recent years, with Big Pharma increasingly outsourcing all but its core functions and looking more to reliable, well-regulated markets such as the UK.

As Kevin Cook, CEO of Sterling Pharmaceutical Solutions, an API manufacturer based in England's North-East, explains, "roughly ten years ago there was a shift to Asia to solve financial problems and resolve API manufacturing issues. We now observe a reverse trend of manufacturing returning to the West." Cook continues, "Certain projects will never return to the West, nonetheless, where there is a degree of complexity and hazard, Sterling in particular is well placed to add value… We now see strong growth in the CDMO space, particularly within emerging pharma."

Steve Bagshaw of FUJIFILM Diosynth Biotechnologies, a CDMO which works with both small biotechs and Big Pharma, perceives that the market dynamics are shifting: "In the last few years, we have seen changes to the CDMO model, which FDB has fully embraced," he exclaims. "There is definitively a focus on creating long-term partnerships with the companies that we work with."

IAN SHOTT
—
CEO and executive chairman, Arcinova

Ian Shott of fellow CDMO Arcinova articulates the enduring value of companies which focus on small-molecule development in an environment where advanced therapies dominate the headlines. "Today, advanced therapies are in a way more 'sexy' than small molecule medicines," he notes. "However, many so-called biotech and emerging pharmaceutical companies focus on the development of small molecule treatments and small molecules still dominate the sales portfolios of all the major global pharmaceutical companies."

In terms of what British-based CDMOs can offer, Cook points to "Assurance of supply and reliability." He continues, "From a compliance point of view, we operate a simple approach: safety, quality, and quantity. If we cannot perform the operation safely, we will not accept the project, and there is an excellent framework within the UK to do things safely."

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go through the extreme stress of non-diagnosis to the relief of a diagnosis and a suitable existing treatment to then learn that it is not yet available in the UK, is just not acceptable for a top five global economy, considering its science base to be a global leader."

O'Regan does, however, see signs of positive change in terms of the authorities' attitudes to rare diseases. "NICE and NHSE responded favorably to our request to sit around the table and decide on a workable solution in the interests of patients," he notes. "The fruit of these discussions was a common agreement on how to move forward. The critical issue now is to prevent any clock stoppages along the way. I am, however, genuinely optimistic about how everything is panning out. We are witnessing an unprecedented degree of flexibility being shown by the authorities and that, in itself, appears to herald a new dawn."

Dugdale is, though, less optimistic, gloomily opining that "the challenge we encounter in the UK is that often the focus is on cost reduction and not innovation and not a free choice for healthcare professionals to utilise all treatments for the benefit of their patients. Recently, in Ireland whilst assessing Haemophilia treatments a large proportion of the criteria considered for reimbursement were clinical outcomes, but in the UK 85 percent of criteria for the Haemophilia A tender process were based on cost alone and no weighting existed at all for innovation or patient outcomes. Therefore, at this time, the majority of the people in the UK living with haemophilia A continue to be treated with conventional factor replacement products that have not changed significantly for 20 years."

GENERICS: THE RACE TO THE BOTTOM?

The UK has the highest percentage of generics penetration in Europe, at 86 percent. However, this does not naturally make the British market a playground for

THOMAS BOERR
managing director, Aurobindo

generics companies; indeed, as Tim de Gavre, country head of Sandoz, sums up, the UK market can be categorized as, "Highest penetration, lowest prices, lots of competition." Otsuka's Stewart Pearce is even blunter: "Sometimes, the UK really feels like it is a race to the bottom once generics come in," he sighs.

Because of this 'race to the bottom' on pricing, many generics companies are attempting to diversify into higher margin areas in order to remain profitable. Ben Ellis of Lupin explains that, "We have about 30 products in our UK portfolio implying that we have reduced our product range significantly as we are trying to get away from 'vanilla generics,' where there is very little margin at all in the UK." Mylan's Jean-Yves Brault documents how, "Several generic companies remain pure generic players, others, like Mylan have ventured into diversification, and some have walked down the path even further. I see biosimilars as being tomorrow's big game changer and those companies that will count biosimilars within their portfolio will most likely benefit from it." de Gavre of Sandoz is equally certain on the importance of a diversified portfolio, opining that, for generics companies, "You really need a mixed portfolio which is what we've done at Sandoz – we have some generics, branded generics and biosimilars, and that's our edge."

As a counterpoint, Thomas Broerr, managing director UK and Ireland at Indian generics specialist Aurobindo, does not feel that pricing pressures for pure generics are too severe in the UK; arguing instead that the British market offers opportunities for all companies truly willing to compete on price. He proffers, "The high rate of genericization in the UK market means that brand loyalty in the generic sector is less impactful; the importance is, therefore, competitiveness and ensuring the possibility of supplying the market sustainably. For Aurobindo, the UK operates as a level-playing field in which our cost-leadership and vertically integrated structure are given the opportunity to shine. Pricing is not necessarily aggressive if you take into consideration all aspects of a market structure before entry." Broerr continues, "The authorities in this market are not here to talk about economics; they are here to talk about the sustainability of supply, data integrity, quality and avoiding fortified medicines; this is the real qualitative spectrum of this market. Aurobindo plays to the rules and will continue to supply at the correct price point."

TOP 15 PHARMA COMPANIES IN THE UK

TOTAL MARKET (INCLUDING OTC), MOVING ANNUAL TOTAL (MARCH 2018)

	COMPANY	MARKET SHARE
1	PFIZER	8.2%
2	NOVARTIS	6%
3	GLAXOSMITHKLINE	5.3%
4	MERCK & CO	5.2%
5	BAYER	4.6%
6	ROCHE	4.5%
7	ABBVIE	4.5%
8	JOHNSON & JOHNSON	4.3%
9	SANOFI	3.9%
10	GILEAD SCIENCES	3.1%
11	ASTRAZENECA	3%
12	BRISTOL-MYERS SQUIBB	2.6%
13	BOEHRINGER INGELHEIM	2.3%
14	MUNDIPHARMA INTERNATIONAL	2.3%
15	BIOGEN	2.2%

IMS Health & Quintiles are now IQVIA™

Source: IQVIA

SURVIVAL STRATEGIES

This backdrop of slow uptake of innovation and difficult pricing structures has pushed companies to develop a wide mix of country-specific strategies. As Haseeb Ahmad of Novartis astutely notes, "This is a market where you need to be able to transform and perform at the same time. It takes individuals that can master agility and organizations with the ability to pivot rapidly to succeed here."

For Otsuka, this means sagacious product selection. "Otsuka has a smart strategy: it will never bring to market a 'me too' product," explains Stewart Pearce. "Aligned with our global mission of truly improving healthcare, we focus on complex products in areas of high unmet medical needs. By bringing products through our pipeline that are truly innovative and very specific, you have of course better chances of success," he states.

Lundbeck has chosen to focus on second and third-line treatments, rather than the crowded first-line treatment market. Thomas Bo Bjorn Klee, managing director UK & Ireland, clarifies: "I looked at our market potential and the challenges we faced. For example, in depression, first line treatments are now mostly generic and so we are looking at entering the market with either second and third line treatments. Similarly, generics are dominating the first line treatment of schizophrenia. Our biggest challenge was to translate our global strategy – showing the essence of the new Lundbeck – into a local strategy; one that focuses on offering second and third line options that make a difference to patients while responding to the financial pressures within the NHS."

Other companies have adopted even more unconventional business models. Clinigen, in the words of its CEO Shaun Chilton, "expands and extends the true value of a pharma or biotech partner's product's lifecycle. Our uniqueness stems from our ability to manage different commercial and access situations for our partners. Whether these companies want to retain rights but improve access, divest or license their products to us, we find a solution nonetheless. We see it as our responsibility to ethically manage access to difficult to procure medicines, mitigating the risk of counterfeit medicines entering a company's supply chain and thus ensuring that the health and safety of patients are not compromised."

THOMAS BO BJORN KLEE
managing director UK & Ireland, Lundbeck

Bristol Labs, which has grown into one of the UK's leading generics manufacturers since its foundation in the late 1990s, has focused on bolstering its productivity to ensure success. Tembalath Ramachandran, the firm's founder and chairman notes that "When you are going head-to-head with low labor cost countries such as China or India, and wages in the UK market are on

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BRISTOL LABORATORIES

TEMBALATH RAMACHANDRAN
chairman and managing director, Bristol Laboratories

average 10 times more expensive, it is essential to absorb that difference in operating costs through much higher productivity. That comes about partly through doing our research and coming up with an optimum selection of products. We have to be very attentive in our initial identification of which molecules to run with. Beyond that, our great track record on productivity hinges upon the excellence of our manufacturing equipment and our streamlined, rationalized operating procedures."

Ramachandran continues, "We have invested substantially in developing our Luton site into a state-of-the-art, MHRA-approved facility that is highly automatized. This has entailed installing the best possible machinery for pharma manufacturing which in turn enables us to produce a great many types of tablets, capsules, and sachets. Moreover, our high-speed packaging machines markedly reduce turnaround time and generate greater efficiency in the working style of the staff. Much emphasis is also given over to the training of the personnel and to automation. You have to make the sure the operator or technician has effectively understood the process and has the wherewithal and resourcefulness to be able to optimize it even more when the opportunity arises."

Furthermore, Bristol Labs has been able to make significant savings in its supply chain. Ramachandran reveals that, "Over the years, we have managed to gain such a credible reputation for reliability and responsibility that our raw materials, including APIs from China, come on credit by which I mean without the need for a bank guarantee or letter of credit. That, in turn, has enabled us to be financially self-sustaining and not to have to resort to external capital."

Swiss-headquartered gastroenterology specialist, Tillotts Pharma, has built its success in the UK on a perspicacious in-licensing strategy. Jeremy Thorpe, the company's managing director points out that "The UK is full of such opportunities, and Tillotts is very interested in products that other companies might look to divest whether this is on national, regional or global scale. A big pharma company may lose interest in a legacy product as it approaches the end of its patent life even though it may continue to address patient need, or may simply find that a GI product does not fit in their broader portfolio anymore, so they lose interest and ignore the brand. We are, as a globally acting company, interested in taking on these products particularly those with projected annual UK sales in excess of four million GBP."

JEREMY THORPE
managing director, Tillotts Pharma

Thorpe also highlights that not only is Tillotts offering products at a lower price than its Big Pharma competitors, but also outdoing them in terms of added support. He says, "The NHS was already cash-strapped in 2012, and we aligned ourselves with the new NHS strategic requirements, providing Octasa 400mg tablets as a high-quality lower-priced alternative to Asacol 400mg tablets. From total annual sales of GBP 230,000 in our first year in 2012, we took Octasa 400mg tablets to GBP 4.75 million in 2013. I believe this was because we had the most interesting value proposition to the system both in terms of financial savings and through a real passion for supporting patients with IBD."

He continues, "This coincided with a new EMA ruling that aimed to reduce the use of a potentially harmful component from the coating of many solid tablets, and that both Asacol and Octasa contained. Ahead of the curve, Tillotts had already been researching and found a replacement for the potentially harmful component. Now we had—because of our proactive approach—a differentiating factor in the formulation as well as the price, this helped to show that we cared about our patients and that we are innovators in IBD. Today, we are market leader in the UK with Octasa 400mg and 800mg tablets combined in terms of tablets dispensed, although Asacol is still ahead of us in terms of turnover. Seeing sales grow is the reward for doing a good job, and the volume of dispensed tablets leads us to believe we are now the trusted choice for our customers."

THE BREXIT EFFECT

The word on everybody's lips right now is naturally the topic of the UK's impeding withdrawal from the European Union and how Brexit might impact both existing local market dynamics and the country's lofty

ambitions to consolidate its position as one of the world's great life sciences powerhouses.

First and foremost, many MNCs are concerned about the possible implications of any regulatory de-alignment with EU norms and what this might practically mean for product launch timelines and approval frameworks. Sanofi's leadership, for example, are quick to point out that Britain may lose its appeal as a first-tier product launch destination as a result of the additional bureaucracy that the compilation of bespoke dossiers would entail. "Were the UK to end up requiring a separate regulatory submission, the market will automatically sequence behind America and the EU for product launches in much the same way as we see for other mature markets that possess their own distinctive regulatory frameworks such as Canada, Australia and Switzerland... this means market entry for new products will likely occur later than in the past with the result that patients will have to wait longer," bemoans Sanofi's chairman of the Brexit committee and UK market managing director, Hugo Fry.

Tim de Gavre, country head of Sandoz, very much concurs. "Even with a robust and professional market like Switzerland, for example, just having an additional layer of bureaucracy slows down the process and delays how they launch. For some of our biosimilars, they are now close to six to 12 months behind the UK," he warns.

Others are uncertain about the possible logistical complexities around having two parallel jurisdictions. "Many people do not appreciate that so many products come through the EU regulatory process and products manufactured outside the EU are tested and quality released in EU laboratories. It is not clear what is going to happen going forward and whether these activities need to happen in the UK specifically or in any EU member state which is currently the case. This leaves companies like ours having to try and second guess a hard or soft Brexit and put in contingency plans to cover a broad range of eventualities," asserts Lupin's Ben Ellis.

"If we have a 'Hard Brexit' I anticipate that changes will be necessary as the regulatory status of products in the UK will change. Marketing authorisations held in Europe will have to be transferred to the UK, and visa-versa, batch release will have to be conducted in the UK and there will be VAT implications as the customs status will change, there may also be delays at customs clearance and disincentives to supply the UK," confides Tillott's Jeremy Thorpe.

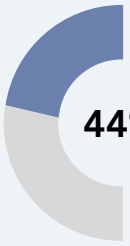
In most cases, however, insiders are tending to downplay the risk of widespread disruption. "It's important to maintain a good dose of perspective and realism. Unlike other industries, there are no tariffs on medicines. Moreover situation is much more complex for industries such as automotive or aerospace where supply chains are much more integrated. Though Brexit will, no doubt, thrown up some annoying, minor little challenges, I foresee nothing that the pharma companies can't competently handle," predicts KPMG's Chris Stirling.

Bristol Labs' founder, Tembalath Ramachandran, echoes this sentiment. "Companies like ours won't be any weaker after Brexit, but clearly we will have to adapt to certain changes. For example, we used to employ a lot of East European workmen in our factories and but are witnessing that

UK ATTRACTIVENESS TO GLOBAL PHARMA POST-BREXIT

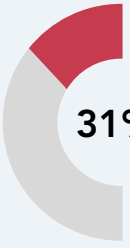
Between February and March 2018 an IQVIA survey of global pharmaceutical industry board level executives revealed ongoing uncertainty that the LSIS will be sufficient to address the historic challenges of access to new medicines in the NHS and the impact of Brexit negotiations on the UK life sciences marketplace.

Believe that Brexit has impacted on the attractiveness of the UK pharma market



Believe that Brexit makes the UK market less attractive for product launches

Of those who consider the UK less attractive for product launches see it as a later launch market



Suggest their clinical trial activity in the UK may decrease post Brexit

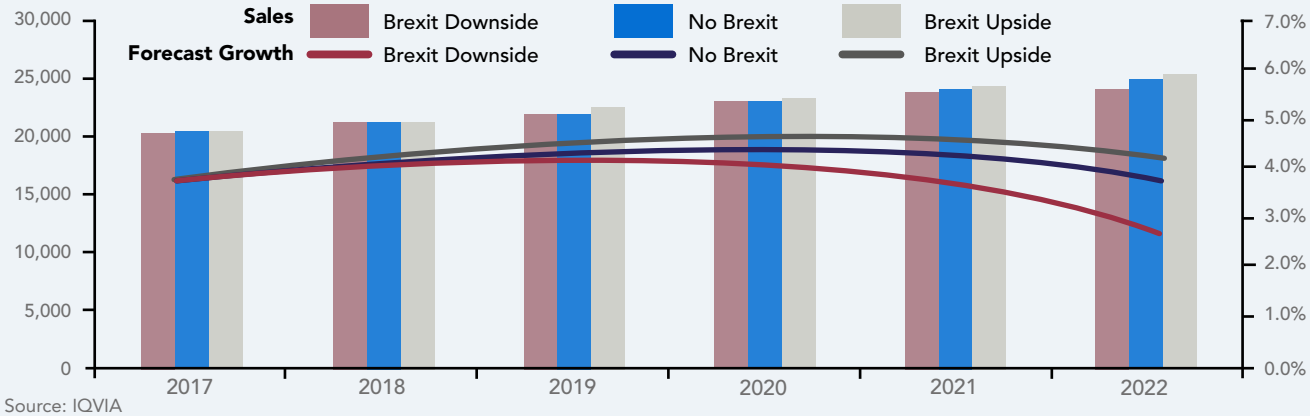
Source: IQVIA

IMS Health & Quintiles are now IQVIA™

UK TOTAL MARKET SALES AND FORECAST GROWTH 2017–2022

IQVIA analysis shows that there is still much uncertainty about the nature and impact of any new UK-EU relationship. In the analysis there are a number of possible changes that may impact on pharmaceutical sales within the five-year forecast period. These include measures to accelerate access to new medicines, the UK macroeconomic outlook, delays to new product launches and post-Brexit trade agreements.

In an upside scenario the free movement of pharmaceuticals will be maintained, and EU exhaustion of rights will continue to apply, i.e. parallel trade will continue. Under a possible downside scenario, there is a risk that under a new agreement additional trade barriers and tariffs could restrict, and increase the cost, of pharmaceutical trade. In the downside scenario the UK regulatory pathway would diverge post-Brexit. This, together with the UK's tough pricing and market access, would lead to the country becoming less commercially attractive for the pharmaceutical industry and delay entry of new product launches.



Source: IQVIA

DIFFERENT BREXITS; DIFFERENT IMPACTS ON PHARMA

	EEA member (Norwegian option)	Free Trade Agreement (FTA)	Bilateral Agreement (Swiss option)	No access agreement (WTO/MFN)
Situation	The UK remains part of the EEA and keeps the four freedoms of people, capital, goods and services	The UK negotiates a Free Trade Agreement (FTA) with the EU	The UK enters into a bilateral integration treaty with the EU	The UK does not establish any new trade agreements withthe EU
Potential implications	The UK would need to contribute to the EU budget and comply with EU social, employment and product regulation	Tariff-free trade between the UK and the EU	The UK would have access to some areas of the Single Market, at the cost of adopting the relevant EU regulations	Only WTO terms apply – UK goods and services would be treated in the same ways as those of third countries
Impact on pharma companies	This scenario would allow the UK to retain access to the EU market and participate in trials. EU authorised medical products would have to be nationally authorised in the UK. Alternatively the UK may wish to enact legislation which gives automatic effect to EU marketing authorisation decisions.	**Depending on what agreement is reached. The UK may want to negotiate as complete market access as possible. Depending on the concessions demanded by the EU, extensive market access may be feasible or not.**	The UK would need to approve medicines and grant clinical trial authorisations etc., separately from the EU (and the EEA). The UK could recognise the quality of pharmaceuticals manufactured in the EU and vice versa, thus ensuring quicker market access.	This scenario presumes a complete separation of the UK systems for pharmaceutical regulation from that of the EU. Under a Most Favoured Nation (MFN) status, a 0% tariff would apply to the UK on pharmaceuticals. However, there could be tariff implications for component parts and broader goods used. There could be scope to agree mutual recognition of GMP inspections and certifications, subject to negotiations and the willingness of the EU.

These scenarios are the most likely, however a number of variations could be negotiated

Source: PwC, 'Brexit Monitor: The Impact on Pharma & Life Sciences'

SHAUN CHILTON
CEO, Clinigen Group

particular talent pool drying up in the wake of the Brexit decision so will have to source affordable staff from elsewhere in the future," he reflects.

Roche's Richard Erwin is equally serene. "From a business point of view, we have to accept the Brexit decision and work to make the most of it. The impact on Roche is likely to be limited. We manufacture in Switzerland and the US exclusively, so we are already importing our products from a third country with very high-quality standards. Our role in the UK consists in ensuring we have continuous supply and we are confident that, by working closely with government, this can be achieved," he laughs.

Clinigen's Shaun Clinton is also sanguine on the country's future prospects, noting that, "irrespective of what is going on around Brexit, the UK is still a fantastic source of innovation and talent and a great base for building successful international companies."

Nor do British-based biotechs appear particularly flummoxed. "It is possible for biotech companies to be pragmatic about upheavals such as Brexit, by our very nature we are constantly going through change. In order to survive, we have to embrace such change.," confesses TC BioPharm's Michael Leek.

> **IT IS IN THE INTERESTS OF THE EU TO ENSURE THE UK REMAINS INTEGRATED AS FAR AS POSSIBLE TO THE EUROPEAN LIFE SCIENCES ECO-SYSTEM**
>
> — **Mike Thompson** ABPI

Meanwhile the government has been at pains to reassure the industry that any disturbance will be kept to a minimum and that stability will be the name of the game. Any member of the scientific community fretting about being cut off form EU research funding can also rest easy from the news that the UK government will match or better any available grants.

Equally confidence building is the reality that Europeans and Brits alike have strong motives to continue to align closely. "Quite frankly, fracturing the European life sciences industry as a result of Brexit would be damaging to the industry across Europe. That's why it is in the interests of the EU to ensure the UK remains integrated as far as possible to the European life sciences eco-system, which would also be in the best interest of European patients," reasons ABPI chief executive Mike Thompson.

That is certainly what many established pharma companies are advocating and expecting. "Under the best-case scenario, nothing really changes except the address of the EMA to Amsterdam. Our hope is very much that the current tight knit relationship between the MHRA and EMA can survive intact. The UK has, after all, contributed so very much to the design of regulatory reform and health technology assessment (HTA) mechanisms Personally, I can't imagine the UK losing its prowess in life sciences anytime soon. The UK will remain a fantastic arena for understanding genomics and undertaking early drug discovery," forecasts Biogen's Terry O'Regan.

SPYING THE OPPORTUNITIES

Moreover an increasing number of actors are now starting to identify likely opportunities for the post-Brexit period. "Especially bearing in mind that we are a nimble and agile player with rapid reaction speeds, we calculate that Brexit can help us create a better commercial environment for inward investment from the government and for commercial return," reveals Eisai's Gary Hendler.

Others speak of Brexit as injecting a certain level of momentum and energy into the industry. "What is making the UK particularly relevant right now is the pressure it is under to really think about its future. This reality combined with the need for the NHS to transform generates a impetus that forces creativity and prepares the ground for innovation to thrive," enthusiastically asserts Pfizer's Erik Nordkamp.

Novartis' Haseeb Ahmad detects a similar sort of vibe where opportunities are there for the taking. "Juan Manuel Fangio, one of the best racing drivers of all time, once explained his superior win ratio with the words: when I see an incident up ahead, while all the other drivers take their foot off the gas, I put the foot to the floor because I view that as my opportunity to lead. Well, I tend to look at Brexit in a similar way," he recounts. "This could be an excellent chance to take British life sciences global!"

A COMMON HERITAGE

One might think a republican confederation in the middle of Europe has little in common with a constitutional monarchy on an island off the European mainland.

Appearances, however, can be deceiving: Switzerland and the UK are longstanding and firm partners whose common heritage of political and economic liberty forms the basis for successful co-operation in many fields.

> **SWITZERLAND AND THE UK ARE LONGSTANDING AND FIRM PARTNERS**

Take our shared history of championing scientific research. Switzerland consistently tops the Global Innovation Index, often closely followed by the UK. Innovation, this shows, is a key driver for both our knowledge economies. Such innovation is underpinned by world-class education: all European universities ranking in the global top ten are found in the UK and Switzerland. The Leiden Ranking shows that the top 15 universities in Europe producing the largest share of the 10 percent of most cited papers are all British and Swiss, too.

The biotech sector is an eminent example of a field where this research excellence translates to economic growth, as evidenced by the quality of patents for biotechnology:

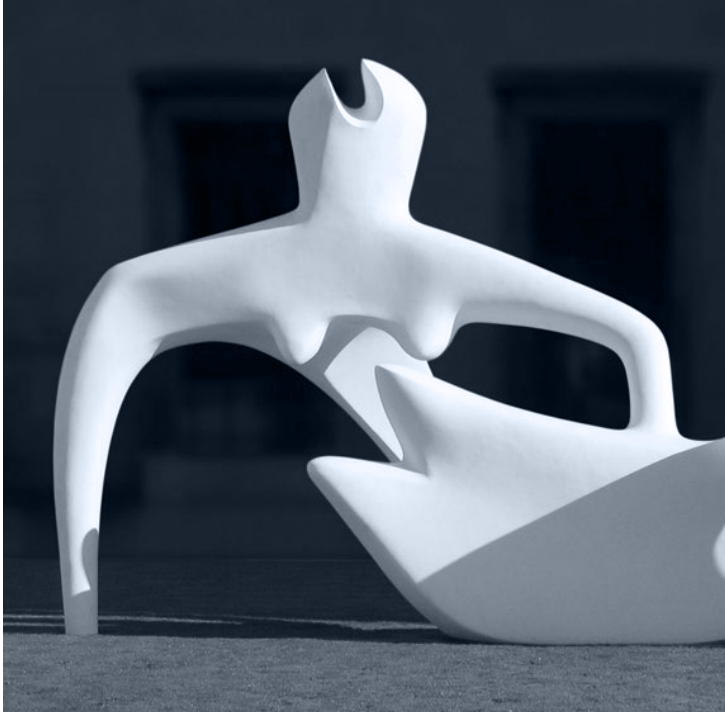
Switzerland and the UK rank second and third globally among countries of origin for world-class biotech patents. It should therefore be no surprise that the UK is Switzerland's third-most important partner in the Life Sciences sector.

As the UK forges its new position outside the European Union, there are more parallels than ever between our two countries – and, going forward, we would do well to affirm and develop our common strengths together.

Alexandre Fasel
AMBASSADOR OF SWITZERLAND TO THE UNITED KINGDOM

> **THERE ARE MORE PARALLELS THAN EVER BETWEEN OUR TWO COUNTRIES**

110 YEARS OF INVESTMENT



Richard Erwin, general manager of Roche Products Ltd, discusses the future of personalized healthcare, the scope of Roche's operations in the UK, its portfolio strategy, and the areas in which the UK can lead globally.

Richard Erwin
ROCHE

HCLS: Roche is a pioneer in personalised healthcare. How do you see this new approach to patient treatment evolve in the future?

RICHARD ERWIN (RE): Roche is the first company to start on the journey towards targeted medicines. We remained committed to identifying new solutions for patient treatment and positive outcomes. Our vision for the future is that every cancer patient will have their tumour genetically profiled. This will allow for more accurately-tailored treatment and clinical decision-making. For example, if it can be predicted a patient will show no response to chemotherapy, we can avoid exposing them to unnecessary toxicity.

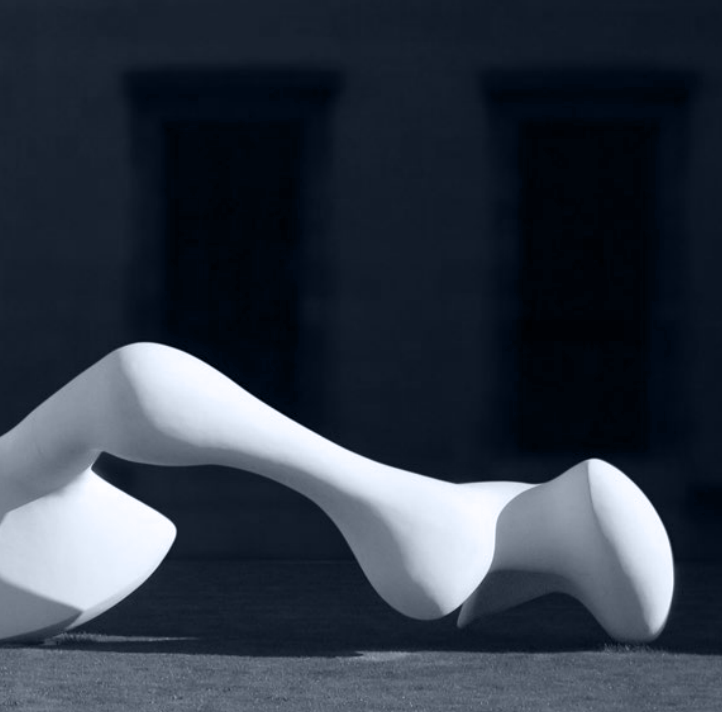
Through our acquisition of Foundation Medicine Inc. (FMI), we are in a leading position when it comes to building up the next generation of personalised medicines. FMI is really the world leader in its field, an FDA-approved and endorsed system. It all boils down to helping physicians make better decisions. Within the next five years, there will probably be a recommendation based on genetic sequencing for every tumour. Through FMI, our focus is on paediatric and rare cancers, as well as CUP (cancer with unknown precedent), especially in lung cancer. CUP is extremely difficult to treat as the origin of the tumour is unknown. However, if the makeup of the tumour can be profiled, it can be treated, by Roche products or those of our competitors.

The next step in personalised medicine is big data management. What we need is regulatory-quality real world data. The only company in the world able to deliver such data today is Flatiron, which is why Roche acquired it earlier this year. Roche has a dream for the future, linking all cancer centres globally through data. We strongly believe this will be the key to achieving the best patient outcomes. It will be revolutionary; even the need for clinical trials could diminish, as physicians will have tools that will allow them to know precisely which treatments patients will respond to.

> **THE NEXT STEP IN PERSONALISED MEDICINE IS BIG DATA MANAGEMENT. WHAT WE NEED IS REGULATORY-QUALITY REAL WORLD DATA**

HCLS: What is the scope of Roche's operations in the UK?

RE: On our site in Hertfordshire, Roche hosts four key functions. Our Early Research and Development function is responsible for Roche compounds in very early translational research. A small group of people from Genentech Early Research, as well as our Pharma Development business, deal with later stage development for compounds from both Roche Genentech and our Japanese partner Chugai. Finally, we have business units dealing with clinical trials, access and uptake of our medicines.



Roche has been investing in the UK for 110 years and will continue to do so. It's one of our global Roche centres where we have early research and development activity. Our most recent figures from 2016 showed that we contributed £1.1bn to UK GDP, supporting more than 18,000 jobs, and registered more industry-sponsored clinical trials than any other company.

My mission is to therefore to drive patient access and uptake. Roche measures its success according to the proportion of UK patients our drugs are reaching and improving health outcomes.

HCLS: Within Roche's portfolio, three of its major cancer drugs will be coming off patent soon and are about to face biosimilar competition. At the same time, Roche boasts a very rich pipeline with about 15 molecules in late stage development. What will be next in your UK portfolio strategy?

RE: The patent cliff we are facing did not take us by surprise and we have thought carefully about it. We took the decision not to compete in the biosimilar space, as we're a company focused on innovation.

In the UK, we will be extremely busy over the next two years launching seven to eight new products. We are innovating in multiple therapy areas including multiple sclerosis lung cancer and haemophilia, hoping patients in the UK will be able to benefit from new treatments this year. In oncology, we recently obtained an additional license in HER2-positive early breast cancer and hope to navigate it through reimbursement later this year. One of our new cancer immunotherapies is also looking at approval across several indications.

Therefore, while a significant part of our revenues is at risk through biosimilar competition, we are in an incredible position to meet this challenge. Thanks to our pipeline, no company is better placed than Roche to adapt to the changing environment. It's worth stating that so far in 2018, all eight of the submissions we made to NICE and NHS England were successful, so we have had a fantastic start.

HCLS: Do you have any examples of where the UK has shown it can find solutions?

RE: There are few areas, perhaps in generic and biosimilar uptake, where the UK excels when compared internationally. But I think we have to ask ourselves: are those the only areas we want the UK to succeed in? Do we not care about the areas of medical breakthrough and real innovation?

Slow access can often lead to poor uptake. Therefore, when we collectively try to improve access, especially early access, we will start to see uptake and outcomes improving for patients.

Nevertheless, I think we should take the time to recognise success when things have worked well. The Cancer Drug Fund is one such example, and NICE now often assesses oncology drugs in parallel with the regulatory approval process, which speeds up the whole procedure. One focus of industry should now be to push for such models to be considered for other therapy areas.

One can see vast differences between disease areas. If you consider lung or colorectal cancer, outcomes are below where they should be, but the UK has improved outcomes in breast cancer from a below average level to one in the top quartile. Of course, this is not down to medicines alone but also the result of co-ordination and commitment across institutions, from screening to surgery. We do see a will and an intent from stakeholders, from government to physician groups, for the UK to be a global leader in life sciences. This recognition is the first step in the right direction for the UK's incredible potential to unfold.

> **"WE DO SEE A WILL AND AN INTENT FROM STAKEHOLDERS, FROM GOVERNMENT TO PHYSICIAN GROUPS, FOR THE UK TO BE A GLOBAL LEADER IN LIFE SCIENCES**

EYEING UP SUCCESS

The UK ophthalmology market – the third largest in Europe – is a different beast to those of its European counterparts, prompting affiliates of enterprising international mid-caps Santen and Théa to adopt disruptive strategies in what can be an awkward and unorthodox business environment.

Théa's Philip Lewis Williams explains that, "the British marketplace in eye care differs markedly from that of France in that the functions of optometry and ophthalmology are split ... If you experience a minor problem with your eyes in France you will likely visit one of the country's 8,000 ophthalmologists and it is relatively easy to secure an appointment. In Britain, however, there are only 1,250 ophthalmologists who will be busy dealing with more serious issues and the waiting times will be considerable." Craig Wallace of Santen concurs, noting that, "In the UK, if you have an ophthalmologic condition, your first port of call will either be the GP, or you might go to an optician or a pharmacist. A patient will only see a specialist ophthalmologist if he or she is referred to one."

Professor David Garway-Heath, a specialist in glaucoma at Moorfield's Eye Hospital offers a counterpoint, noting that "although it has very few ophthalmologists per capita, the UK has 14,000 optometrists, academic eye care specialists. Some take the opportunity to go through subspecialist training, taking them to the level of practitioners in glaucoma care. In the UK, they act as a partner in care, whereas in most European countries they are seen as competition to the ophthalmologists."

PHILIP LEWIS WILLIAMS
managing director UK and Ireland, Théa

The successful navigation of a market so unlike others in Europe has required Théa to enact a root-to-branch shake-up of its operations. Lewis Williams exclaims: "We had to try to be superior in every task that we undertook. That started with our sales representatives and ensuring that they properly understood the subject matter and were not overly pushy. We also placed a lot of early emphasis on getting ourselves known in local academic circles." Lewis Williams also recalls that, "we embraced a rather disruptive business model in which we targeted high street opticians and independent optometry outlets in much the same way that cosmetic companies like Chanel sell their beauty products."

> **THE BRITISH MARKETPLACE IN EYE CARE DIFFERS MARKEDLY FROM THAT OF FRANCE**
> — **Philip Lewis Williams** THEA

The UK strategy of Santen – only present in the country since 2014 – has prioritized inter-stakeholder collaboration to help redesign a healthcare system more conducive to eye health and create a patient population more receptive to ophthalmological products. Wallace stresses that, "In some parts of the UK, we are already collaborating with the NHS to begin the process of redesigning the system, striving to find ways to modify pathways." He continues, "We aim to avoid referring people with mild conditions to hospitals, but therefore need GPs, optometrists and pharmacists to be more confident in assessing conditions. In the case of a severe dry eye conditions, however, we need to work towards an accelerated pathway to the specialised ophthalmologist. This is exciting as these projects are transformative and clearly demonstrate our commitment to improving eye health in the UK."

DAVID GARWAY-HEATH
Moorfields Eye Hospital

CATAPULTING INNOVATION FORWARD

Keith Thompson, CEO of the Cell & Gene Therapy Catapult, one of a number of Catapult institutions in the UK designed to help commercialize innovation research, introduces the Catapult concept, funding model, Brexit and the future for gene therapies.

Keith Thompson
CELL AND GENE THERAPY CATAPULT

HCLS: Could you please explain the Catapult concept?

KEITH THOMPSON (KT): The whole Catapult idea came out of work done through the late 2000s. When the coalition government got in in 2010, they undertook a number of measures. Number one, they maintained the science budget, when everything else was being cut. Secondly, on the basis of the issued reports, they asked the question which has been asked over and over again in the UK which is, "Why are we so good at inventing things but failing to fully exploit those discoveries?" And that is a very complex question. I think the UK is good at making its inventions stick. Nevertheless, a gap was identified which is the intermediary technology institute – the Catapult, in-between industry and academia that would help accelerate innovation.

HCLS: How would you characterize the Catapult funding model?

KT: The Catapult funding model is sometimes called "a third, a third, a third." The initial third is all about establishing the technological capability, refreshing it and growing it so that it can then be accessed through collaborative R&D or commercially by companies. That whole idea of leveraging an investment through these other mechanisms really works, and I think this is one of the underlying and key parts of the infrastructure. It allows the Catapults to be industry-led which is very different to other technology innovation models that exist. There are innovation research organizations in other countries, but most of them are in some way attached to a university and much more academically-led. Here, we are industry-led.

> "[GENE THERAPY] IS BEYOND "UP AND COMING", IT IS HERE TODAY WITH APPROVALS HAPPENING NOW

HCLS: As drug development is becoming increasingly global, what do you see as the effect of Brexit on your endeavours and Britain's place of being a leader in cell and gene therapy?

KT: Cell and gene therapy has been nurtured in clinical research rather than university science, and there are several good groups across the UK. A huge concentration is in London, but there are centres scattered all the way up the UK to Edinburgh and Glasgow. I think that once you get past Brexit, all the fundamentals are here: the good science, the clinical research, the excellent regulatory environment, and an industrial strategy from government which has put its money where its mouth is and supports the translational research.

HCLS: What is the future for gene therapies?

KT: This whole sector – cell and gene therapy – is seen as the "up and coming" area in life sciences. But it is beyond "up and coming", it is here today with approvals happening now. Gene therapies, and gene modified cell therapies for certain blood cancers are here and they are going to be moving forward into the hospital environment now. We have a big initiative with Innovate UK to establish specialist treatment centers for advanced therapies across the country.

THE SKILLS TO PAY THE BILLS

The UK country managers of some of the biggest global pharma companies explain what it takes to manage in the UK market.

Erik Nordkamp, the Dutch national serving as managing director of Pfizer UK and newly-appointed president of the ABPI, likens managing a UK affiliate to "being a managing director on stilts." Nordkamp elaborates, "Everything is on a bigger scale: influencing operations and complexity. And while it is an honor to lead the organization in this changing time and play an active role in the industry, resilience is much needed. In the UK, you have to deal with challenges and learn to prioritize under pressure."

Haseeb Ahmad, country president of Novartis UK and vice president of the ABPI, has a shared history with Nordkamp, with both men having previously been assigned to positions in Greece. He foregrounds the importance of adaptability for those managing UK affiliates, noting that "This is a market where you need to be able to transform and perform at the same time. More than anywhere, I see this holding truth in the UK. Hence, it takes individuals that can master agility and organizations with the ability to pivot rapidly to succeed here."

Ahmad's ability to lead his team to success in a difficult market environment has seemingly caught the eye of Novartis top brass. Speaking after a visit to the UK in July 2018, global CEO Vas Narasimhan exclaimed, "I'm proud of my colleagues in the UK, who are demonstrating a passion for delivering outstanding health innovation to UK patients, despite complex circumstances. This is underpinned by collaboration and strong partnerships with the National Health Service which I was inspired to learn more about."

With many never having worked outside of their home nation, is there a danger that UK country managers of large international pharma companies are too UK-centric and unaware of global developments? Laurent Abuaf, the French national and country president of AstraZeneca certainly thinks so. He declares that, "The UK is known to have a tendency to be self-centric. My experience of working in other countries enables me to see things differently; to see opportunities and challenges you might miss by not having the element of comparison. For instance, the UK is one of the worst countries in Europe in cancer outcomes and respiratory deaths, but it has on the other hand made great progress in cardiovascular outcomes."

Lars Bruening of Bayer moved to the UK as CEO UK and Ireland in 2017, having previously held responsibility for global market access at the company's headquarters in Berlin. On the task of becoming a country manager in a market as complex as the UK, Bruening exclaims, "It is challenging but also exciting at the same time. I have always followed roads on different geographic levels, both regional and global, in my career. I see tremendous value for a manager to have those different perspectives. To me, it was a very logical move to join the UK, which is a thriving market and organization, with the added management challenge of Brexit."

However, the impending exit of Britain from the EU – which looms over all aspects of the country's life science industry – seems to have precipitated a wave of new appointees, as companies scramble to find the right personalities and skillsets to manage them through turbulent times. Sanofi's Hugo Fry, himself only in position since 2017, posits, "I am part of the ABPI board, and we noticed there that there has been a huge turnover [of general managers] even since I arrived 15 months ago. I think some of it has to do with understanding that Brexit is going to change some things and you need a particular profile to be able to manage and lead through that."

For Fry, the typical UK country manager of the future will be a long-term appointee, well-versed in

the intricacies of the British market. He exclaims, "I have heard that there was a phase where the UK was very much a training ground for people on big upward trajectories, and the turnover became high, especially for American companies. Now people are coming back to the understanding that you need people for the long-term, because this market is complicated, it does require a lot of effort, and there is such a large corporate, external affairs function here because of the nature of the market. You need to build those relationships and commit to them longer term."

ERIK NORDKAMP
Pfizer

"[managing a UK affiliate] is like being a managing director on stilts"

HASEEB AHMAD
Novartis

"This is a market where you need to be able to transform and perform at the same time"

LARS BRUENING
Bayer

"It is challenging but also exciting at the same time"

LAURENT ABUAF
AstraZeneca

"The UK is known to have a tendency to be self-centric"

HUGO FRY
Sanofi

"Brexit is going to change some things and you need a particular profile to be able to manage and lead through that"

THE FUTURE OF CELL THERAPY

After 30 years in the cell therapy space, Dr Michael Leek founded TC BioPharm in Scotland. Within four years the company has forged major partnership deals and advanced its CAR T therapies towards the clinic. Dr Leek explains the added-value of TCB's science, its business model moving forward and the future of regenerative therapies.

Michael Leek
TC BIOPHARM

HCLS: **What is the added-value of TCB's science?**
MICHAEL LEEK (ML): While most companies in the CAR T field work with Alpha Beta Cells, we started with Gamma Deltas.

Alpha Betas constitute part of the adaptive (or memory-driven) immune system, while Gamma Deltas are more innate, and programmed to 'always be ready for a fight'. Historically, they have been considered hard to expand in culture, so many CAR T companies focussed on Alpha Beta Cells. At TCB however, we developed a system to routinely produce Gamma Deltas by the billion.

The advantage of working with Gamma Deltas is they are already programmed to attack cancer and cells infected with a virus. Moreover, they only become activated to kill in presence of cells which have become 'stressed' by transformation or infection – these stressed cells produce a unique signal isopentenyl pyrophosphate (IPP) not expressed on healthy cells. CAR T therapies based on Alpha Beta technology are controversial as they may provoke adverse responses by destroying healthy cells. Gamma Delta's CAR Ts can't target healthy cells as the IPP 'killing switch' is not triggered – so we have a healthy, next generation CAR T approach.

HCLS: **What will the business model be moving forward?**
(ML): We are great at producing clinical-grade efficacious cell therapies and treating patients with these products. We don't have sales andmarketing infrastructure at the moment and will continue to partner with companies such as bluebird bio and Nipro with much of our CAR T platform. Nonetheless, when it comes to certain orphan indications, we may consider commercialising treatments ourselves in-house.

> **THE SCOTTISH DEMOGRAPHIC PRESENTS US WITH A LONG, DISTINGUISHED HISTORY IN CELL THERAPY.**

HCLS: **Do you consider with CAR T and regenerative therapies there is a race around being first to market - or is there space for everyone?**
(ML): In cutting-edge business, there is always a kind of race, we are all competing for similar cash and clinical resources. However, the field we operate in is very broad, I consider that if you have developed an efficacious, cost-effective therapy, there will be market space for it.

HCLS: **Where do you see regenerative medicine heading?**
(ML): The Scottish demographic presents us with a long, distinguished history in cell therapy. Angela Scott who contributed to creation of Dolly the Sheep in 1996 is our co-founder and COO. Cell therapies were just starting back then – right now I suspect every company in the space will be developing an allogeneic 'pharmaceuticalised' treatment – for sure this is the future of cell therapy.

SCOTTISH INNOVATION

Some of the UK's most radical and experimental healthcare initiatives have been taking place not in the much vaunted 'Golden Triangle' of London, Oxford and Cambridge in the South of England, but further north in Scotland.

Terry O'Regan, vice president and managing director UK and Ireland at Biogen, outlines how Scotland is ahead of the game in terms of patient access to innovation, noting that "When it comes to upstream activities Britain stands out as being excellent in drug discovery and translational medicine. However, when it comes to the downstream tasks of medicines assessment and access to new innovative medicines, we lag behind Europe. With respect to the latter functions, the Scottish Medicines Consortium has a different approach. They have introduced a new system specifically designed for the assessment of ultra-orphan and orphan therapies, which also brings patient and clinician views to the heart of the process.

Furthermore, they are reinvesting funds received from the pharma industry Pharmaceutical Price Regulation Scheme (PPRS) rebate to fund new innovative medicines through its Medicines Fund. It reflects the direction of travel for existing process and demonstrates the need for new approaches as the landscape continues to evolve."

Julia Brown, portfolio director strategy and sectors at Scottish Enterprise, Scotland's investment agency is keen to highlight the opportunities for clinical research in Scotland. She points out that "for a life sciences company, there is the access to our outstanding universities and the quality of research within. Their sheer number of top-notch academic bodies in Scotland has been key to attracting pharmaceutical companies to come and seek out non-clinical research collaborations and projects, as well as clinical research partnerships."

The welcoming Scottish infrastructure is also much appreciated by many industry actors. "Since the beginning, we have been strongly supported by the Scottish Investment Bank who provided several million pounds in equity-based investment. More recently a couple of large Scottish Enterprise grants provided additional research and clinical support. As a regional development agency SE have proven to be our guardian angel on more than one occasion," recalls Michael Leek of Scottish cell therapy specialist, TC Biopharm.

Dave Tudor, chair of the Scottish Life Sciences Industry Leadership Group is similarly upbeat on Scotland's life sciences potential. He posits that, "In Scotland, we have a very rich company start-up and SME scene with a significant number of the life sciences companies very active in creating new and innovative products and services. We see this as a significant opportunity in the Life Sciences growth ambition. Turning this innovation wave into sustained economic benefit will be a major priority for the Industry Leadership Group. The underlying growth rate for this sector in Scotland was 6% between 2010-2014. At this steady rate, we would have been able to get the total turnover of Scottish life sciences companies to GBP 6.5 billion by 2024. However, we have raised our ambition based on this innovation pipeline and have set ourselves the challenge to reach GBP eight billion in that same time period."

DAVE TUDOR
chair, Scottish Life Sciences Industry Leadership Group

JULIA BROWN
portfolio director strategy and sectors, Scottish Enterprise

Moreover, the clinical trials environment is sufficiently mature. "We have a long history of patients being very interested in participating in clinical research in this country and possess great systems in place to enable efficient clinical research projects, such as the NHS Research Scotland portal we created as a single point of access. Through it, we guarantee a centralised system that can quickly assess the feasibility of a study, something CROs have been very especially delighted with. The establishment of Pfizer's Inspire site or the repeated work Quintiles has conducted in Scotland are just some illustrations of Scotland's clear attractiveness," voices Scottish Enterprise's Brown.

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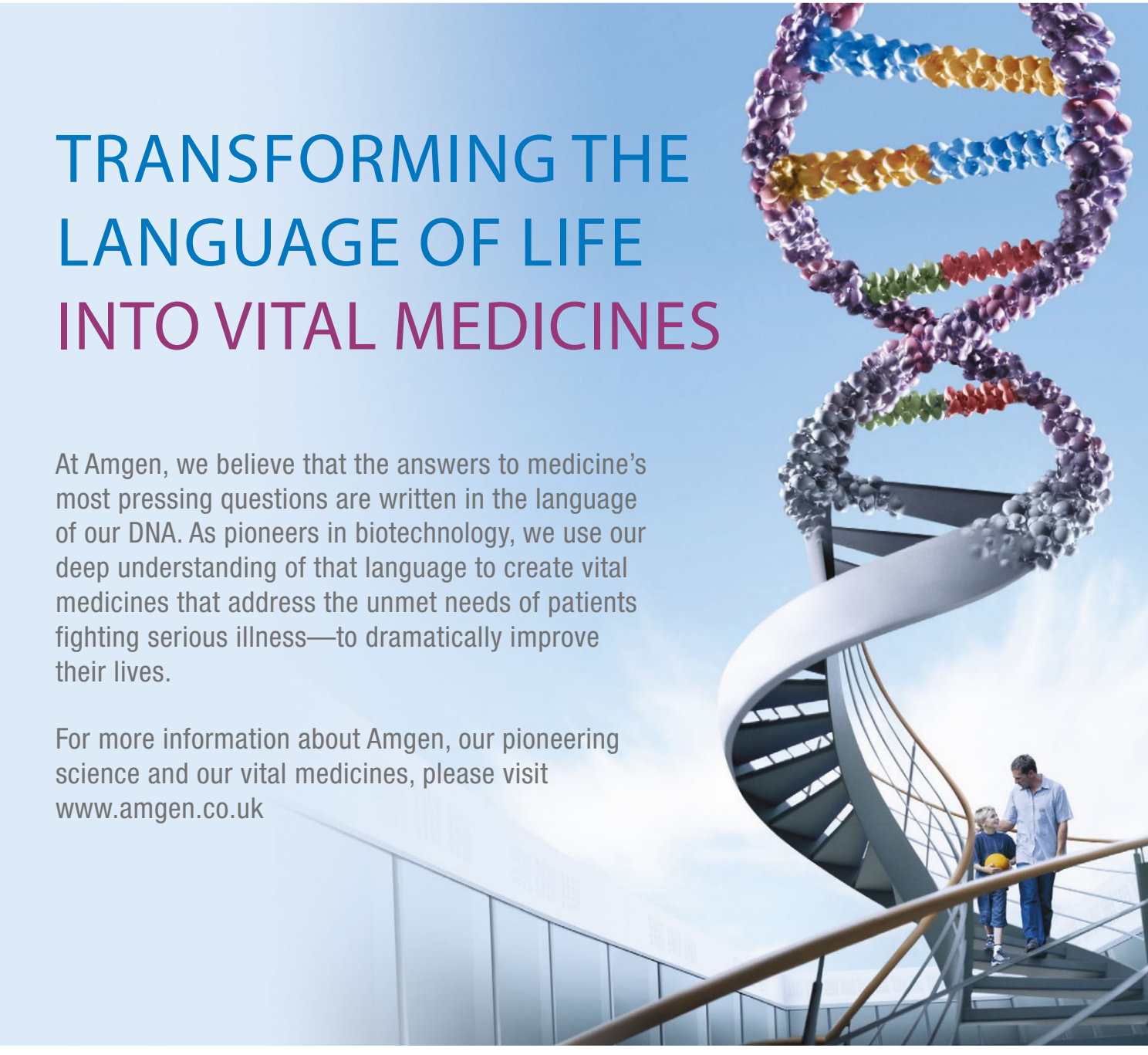

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COMPANY PROFILE

UK COMMITMENT PAYING OFF

For French mid-cap Ipsen, the UK is one of three global hubs, with manufacturing in Wales, large-scale R&D activities near Oxford as well as UK Commercial Operations and global functions including HR, Tech Ops and Commercial Operations in Slough, near London. With ten percent annual growth to reach GBP 80 million (USD 106 million) in 2017 and comparable results expected for 2018, the cross-functionality of Ipsen's UK footprint appears to be paying dividends.

In 2017, Ipsen announced a GBP 22 million (USD 29 million) investment into its manufacturing facility in Wrexham, Wales; a significant show of faith in the UK as a manufacturing hub, given the uncertainties of Brexit. Ewan McDowall, the company's general manager of operations from July 2014 to June 2018, proudly states that, "We currently have 340 people working in North Wales and are the biggest pharmaceutical employer in the area, and that number is to grow to around 600 with the new investment."

> **"WHILE UNCERTAINTIES RESULTING FROM BREXIT ARE INEVITABLE, THE UK IS AND WILL REMAIN AN IMPORTANT CORPORATE HUB**
>
> — **Ewan McDowall** IPSEN

McDowall explains the importance of the Wrexham site thusly: "As the facility produces medicines for our neuroscience franchise, it is a very specialised business area and we want to ensure we continue to invest in it to maintain accessibility to treatment for patients." He continues, "While uncertainties resulting from Brexit are inevitable, the UK is and will remain an important corporate hub, continuing to be incredibly important for Ipsen in the future. In the last 12 months, we have recruited 15 percent more people, many in senior and global positions based at our Slough office. With a strong and growing presence in the UK, we are preparing for all eventualities, including a hard Brexit. That is the most prudent assumption and we are focusing on two priorities: avoiding any disruptions in patient supply, and supporting our people working in the UK."

EWAN MCDOWAL
general manager, Ipsen UK & Ireland (July 2014-June 2018)

While R&D is also a key element of Ipsen's UK activities, McDowall is keen to highlight the synergies between the company's various in-country activities. He posits, "We work in collaboration with our manufacturing and R&D sites through a cross-functional UK management forum which brings together site leaders across the UK, reflecting our values as One Ipsen. This allows us to share expertise and move forward together, whether the subject at hand relates to something internal or is linked to external stakeholders."

Looking to the future, McDowall foregrounds the importance of human resources in ensuring that Ipsen UK enjoys continued success. "For me, it all comes down to people," he opines. "How can we retain and attract the best people in the industry, reaching within the life science space, but also beyond those rooted solely in pharmaceuticals? In the last four years, we have set a high bar in terms of the talent joining Ipsen, seeking to make this one of the 'best places to work'." He continues, "I believe we are able to attract great talent because at Ipsen, you are empowered, and you can make a difference very quickly. Patient-centricity is one dimension, but we are in a very dynamic and exciting phase and have an attractive proposition for our employees. This chimes with the profile of the people we look for: employees willing to take accountability and move fast."

A UNIQUE PROPOSITION

Ian Shott, co-founder and CEO of Arcinova, tells the story of how he established a speciality CMO on an historic site and discloses his plans to revolutionise small molecule manufacturing through a combination of continuous process manufacturing and bio-transformation.

Ian Shott
ARCINOVA

HCLS: Can you outline for us the state at which Arcinova is today, we hear you have been experiencing tremendous growth since inception?

IAN SHOTT (IS): In our first year of business we had a revenue of GBP four million, increasing this to GBP 7.5 million in year two. This year we aim for GBP 12 million and will hence have at least doubled revenue every 18 months since inception. Our target is to reach GBP 45 million in 2022, with about 300 employees.

I am very proud of how far we have come within these first 30 months of the Arcinova business, especially when it comes to talent. We have been able to hire great minds from various companies, which added to the fantastic team we inherited, and we will continue to scout. At Arcinova, we are very focused on values and encourage our 100 employees to uphold them at all times.

HCLS: How did you come to set up Arcinova and what made the legacy site from Sanofi and Covance in Alnwick a good target for a takeover?

IS: Like many things in my life I would describe this as a fortunate accident! My business partner Paul Ryan and I set up a specialist investment and advisory firm - Shott Trinova - focused on established SMEs with high growth potential in chemicals, materials, industrial biotech, pharma and medical technology sectors. We were also advising large pharmaceutical corporations on their strategy, and at the time were involved with Sanofi who were wishing to exit their manufacturing facility at Newcastle upon Tyne and wanted to leave a positive legacy.

We thus set up a plan for them, intending to change the site into a business park. We were successful in selling the project to the local government and small businesses in the region, and everyone was aligned to the concept. In 2014-2015, we created the plan and settled on Discovery Park—the company that took over Pfizer's Sandwich site—to establish the science park.

At the same time, Covance were trying to sell their Alnwick site. Just like Sanofi, they wanted to leave a positive legacy. However, there was a real risk that a sale would not happen, people would lose their jobs and the site would be demolished. We were asked to come up with an alternative. Rapidly, we reviewed their Information Memorandum and found that, with an annual compound growth of 25 percent and halving the workforce to 55, the business would lose GBP seven million over three years. This was not exactly compelling for a sale.

Therefore, we took a different approach and decided to chop off the vivarium activity and the bulk of the toxicology businesses on the site and downsize across the remaining units while adding something new. In short, we decided on a fundamentally different strategy. I thought the facilities were very well designed and in excellent condition, and a that there was a lot of world class talent on site.

We saw the opportunity to create something truly unique in the world: combining the manufacture of active drug substance with pre-formulation and formulation knowledge to design new pathways and processes to manufacture pioneer drugs. Our focus is the Pharmaceutical Development pipeline where we help our customers enter phase I and phase II clinical trials, primarily servicing the emerging pharma segment, while serving the big pharma segment with a range of specific and differentiated technologies.

While nothing was premeditated, I have spent four decades in the pharmaceutical industry in manufacturing in various geographies and felt I had the right network to accelerate the growth of such an endeavour. So, we did it. We let go of 62 people diminishing the workforce to 50 but then over the last 18 months have hired 50 people with the necessary skills for our new business model. Within 12 months, 57 of the 62 we had to let go, had found a new job elsewhere, were retraining for other career opportunities, undertaking charity work or had decided to retire.

“

WE SAW THE OPPORTUNITY TO CREATE SOMETHING TRULY UNIQUE IN THE WORLD: COMBINING THE MANUFACTURE OF ACTIVE DRUG SUBSTANCE WITH PRE-FORMULATION AND FORMULATION KNOWLEDGE TO DESIGN NEW PATHWAYS AND PROCESSES TO MANUFACTURE PIONEER DRUGS.

HCLS: **Arcinova was initially set up as a CRDO, but we understand you wish to transform it into a CDMO.**

IS: After spending 25 years looking at how pharmaceuticals are made, my major assertion was that active drug substance has been manufactured according to a process flowsheet that is 450 years old, in 99 percent of all sites globally. Organic synthesis chemists work in laboratories and have been trained to believe that heat and mass transfer is terrible and that they therefore need to slow the process down. However, this has side reactions, decomposition occurs, and, at the end of a batch reaction, you have many impurities.

In parallel and historically, the industry has always been very siloed and conservative. The discovery chemist does not care about the production process and passes on his research to the development chemist. When coming into contact with the regulator, the development chemist has to consider each step of production and try to optimise the yield. In order to do this, he often has to change the solvent and thus make the process even longer and more complex as purification and solvent recovery is needed after each new step. The plants hence become huge, but the reaction vessels themselves are limited in number and represent a small proportion of the total facility and hence capital and operating costs. The costs are no longer concentrated on the drug making itself but are driven by the issues surrounding the overall process.

HCLS: **What is your overall vision?**

IS: My vision is to come up with a completely new methodology for manufacturing medicines and to employ on the one hand continuous technology and process and not continuous flow, and on the other hand industrial biotechnology and synthetic biology to engineer biocatalysts that are stereospecific. Indeed, two molecules can be chemically identical but physically different. In new treatments, the physical shape of the molecule (the chirality) is critical for success to be able to target the right molecular switches in the human body. With conventional chemistry you obtain molecules that present a mixture of shapes: the same drug chemical can in different physical forms behighly effective in one form and highly destructive in another form such as witnessed with Thalidomide.

Separation processes are often difficult because of boiling points, solubility etc. being very similar and this adds further process complexity to resolve. By using biological organisms for drug production, we can reduce the number of stages of chemistry needed and improve the precision of the manufacture to the desired end.

THE JAPANESE CONNECTION

Japanese firms have tended to penetrate European markets late in the day, having traditionally focused on their home nation and the more lucrative US market. However, those that have taken the plunge into Europe have frequently selected the UK as their regional headquarters and launchpad for operations across the continent.

For Stewart Pearce, managing director of Otsuka UK and Ireland, the UK's regulatory rigor makes it an extremely important market for the global group. He posits, "to Otsuka, Europe is in many ways a test bed for success in Asia. Europe has some of the toughest markets globally and within that mix, the UK holds the undisputed position of the toughest single market. Our way to look at this as a group is that, if you can make it in the UK, you can make it anywhere!"

> **"OUR WAY TO LOOK AT THIS AS A GROUP IS THAT, IF YOU CAN MAKE IT IN THE UK, YOU CAN MAKE IT ANYWHERE!**
>
> — **Stewart Pearce** OTSUKA

Jon Neal, Pearce's counterpart at Takeda – which has its European Center of Development in the UK – agrees, noting that, "the UK is a very strategic market for Takeda, not just for the quality of the infrastructure available, but also because of institutions like NICE, the UK's health technology assessment (HTA) vehicle. NICE is a thought leader globally and serves as a reference for many HTA bodies. Once we achieve a positive NICE approval, this step holds importance not just for the UK but Takeda globally, just as a negative response from NICE can have important ramifications for all our affiliates."

Eisai is another Japanese firm that has based regional management functions in the UK and, despite Brexit-based uncertainties, has no plans to relocate elsewhere. As Gary Hendler, the company's chairman and CEO for the EMEA region, explains, "We do not have any intention to relocate our EMEA headquarters out of the UK. As an investing Japanese company, we do not simply have a commercial hub here in the UK, we possess a research hub and a manufacturing facility. Although this makes us unique, it also presents assets we cannot simply move around on a whim. Our manufacturing plant in the UK is geared towards supplying one of our flagship products, lenvatinib mesylate. From the UK we will export it to Brazil, to China and elsewhere. We are hence well-positioned and the reasons to stay in the UK become straightforward."

Ophthalmology specialist Santen's UK affiliate has grown to be the firm's fifth highest grossing globally in just three years of operation. Craig Wallace, UK and Ireland general manager, is keen to highlight the historical linkages and synergies between the UK and Japan, pointing out that, "Japan and the UK have really strong connections, not just in terms of commerce. For example, when Japan left behind the period of the Samurai, and formed its first government, four of the key politicians that set up this first Japanese government, including the first prime minster, had studied together at UCL in London a few years earlier before returning to Japan to apply what they had learnt."

A POT PIONEER

Founded in 1998, GW Pharmaceuticals is a true pioneer in cannabinoid medicines and the only pharmaceutical company with a license to cultivate cannabis in the UK. Sativex, the world's first prescription medicine derived from the cannabis plant, has now been approved in multiple countries for the treatment of spasticity due to multiple sclerosis and Epidiolex (cannabidiol), the company's lead candidate for certain rare and severe early-onset, drug-resistant epilepsy syndromes, was approved by the US FDA in June 2018, marking the first cannabidiol approval in the world's largest pharmaceutical market.

When asked about the most significant moments in GW's history, Dr. Geoffrey Guy, the company's visionary founder and chairman since 1998, is decidedly circumspect. He proffers "I could give you the response Chairman Mao gave when asked about the French Revolution: "It's too early to tell."" Guy continues, "However, the first really significant moment for GW Pharmaceuticals was the granting of the license to grow cannabis in 1998. The second important moment was the approval of Sativex in the UK and Europe. Third of all was the initiation of the Epidiolex program which brought together much of the work that we had done on the beneficial properties of Cannabidiol (CBD)."

Always keen to distance itself from the more controversial realm of 'medical marijuana', GW has continuously branded itself as a regular pharmaceutical company which happens to use compounds from the cannabis plant. Guy feels that the UK has been more accepting of the concept than some of its peers; he points out that "Stigma was not a major issue in the UK. However, it is dependent on culture; there is significantly more stigma in Canada, the US and France whilst Spain is incredibly tolerant."

Though investors were initially skeptical of the concept, Guy notes that "When we put the company on NASDAQ five years ago, there was massive enthusiasm for what GW Pharmaceuticals was doing. While people were wary of cannabis, they became very aware that it was treating patients with severe conditions, where other medicines had either failed or had introduced serious side effects and developmental issues, particularly in children."

In terms of GW's future areas of research and development, Guy posits that "We intend to follow those signals that are indicative of cannabinoid benefit regarding homoeostasis, compensation and decompensation. We will probably focus on children for a long time; there will then make a leap towards much older people. Cannabinoids are especially orientated towards neural development. Cannabinoids create, guide, join and maintain neural development in the fetus. In the adult brain they further enhance plasticity and connectivity. They repair, replace and regenerate, particularly in neural tissue but also in cardiac tissue as well."

"WHILE PEOPLE WERE WARY OF CANNABIS, THEY BECAME VERY AWARE THAT IT WAS TREATING PATIENTS WITH SEVERE CONDITIONS, WHERE OTHER MEDICINES HAD EITHER FAILED OR HAD INTRODUCED SERIOUS SIDE EFFECTS AND DEVELOPMENTAL ISSUES

— **Geoffrey Guy** GW PHARMACEUTICALS

SHAPING THE HEALTHCARE OF TOMORROW

Angela McFarlane
market development director, IQVIA

IQVIA UK's vastly experienced market development director Angela McFarlane outlines the four unique features that differentiate Britain in the globally competitive life sciences industry.

THE 100,000-GENOME PROGRAMME

"The UK won the race to complete the genetic code of a human being – their genome – which led to the 100,000-Genome Programme. Our global leadership in genome sequencing is akin to a new industrial revolution, but in healthcare. This will be a revolution of an importance not seen since Victorian times. The NHS can link a whole lifetime of medical records with a person's genome data and can do this at scale. The fact it can do this on a large scale is unique."

THE LIFE SCIENCES INDUSTRIAL STRATEGY

"The Life Sciences Industrial Strategy (LSIS) places an emphasis on putting the UK in a world-leading position to take advantage of the health technology trends of the next 20 years and sets the objective that, by 2023, the UK should be in the top quartile of comparator countries for the speed of adoption and overall uptake of innovative, cost-effective science."

UK BIOTECH

"The UK's vibrant biotech industry is booming as the 2017 BIA report shows with record Private Equity Investment rising from GBP 665 million (USD 867 million) in 2016 in 67 UK companies to a record GBP 2.8 billion (USD 3.65 billion) in 2017 in the golden triangle of London, Oxford and Cambridge. IPOs doubled one-year post-Referendum to GBP 234 million (USD 305 million) - with cell and gene therapies attracting some of the biggest deals that year-building on the UK's leadership in genome sequencing."

REAL-WORLD EVIDENCE

"The UK is a global leader in real-world evidence (RWE). The LSIS will accelerate our existing global leadership in real-world data to spread the use of this relatively new science into practice across global research and evaluation systems, building on the UK's rich health data ecosystem."

RARE SUCCESS

Formed in 2015, listed UK start-up Amryt targets rare diseases with high unmet medical need. With one commercial asset on the market, a strong pipeline of development assets and a commercial infrastructure across the EMEA region already in place, the company is aiming to expand rapidly.

Rare diseases affect 350 million patients globally and, as Amryt's CEO Joe Wiley points out, "there are around 7,000 identified orphan diseases, but only some 500 or so approved drugs to treat them." He continues, "There is a long way still to go to develop drugs for all these indications. Therefore, regulatory incentives for companies like us to develop products for rare diseases are increasingly common and investment is encouraged."

Amryt's strategy revolves around gaining market access and reimbursement for these rare disease treatments. Wiley explains, "For the first time, patients have access to Lojuxta [Amryt's lead commercial asset – Ed.] in England through the NHS, while we also expect reimbursement announcements in other countries soon. In addition, we have also been highly successful in bringing together highly talented people: we assembled a strong commercial team and managed to ramp up our know-how in market access across Europe. It's a complex environment to navigate, but we have been successful despite the fledgling size of the company."

Looking globally, Wiley notes that "Amryt has already built a commercial infrastructure in Europe and the Middle East, which we can leverage. The first milestone was to become a commercial stage business through building our sales infrastructure and a distributor network. This should provide a powerful foundation from which to launch our future growth." He continues, "We generally access patients through key opinion leaders and, with that in mind, have been attentive to crafting a network of experts and opinion shapers across the globe. We have expanded our business recently in the Middle East and we identified lots of KOLs and a hospital in Saudi Arabia that attends to more patients than have been diagnosed in the whole of the UK. Therefore, the Middle East will be a really important future driver of our business."

Joe Wiley
CEO, AMRYT

> **"WE ARE VERY WELL POSITIONED TO CONTINUE TO BUILD AND SCALE AMRYT INTO A WORLD LEADER IN RARE AND ORPHAN DISEASES AND THE VALUATION WILL FOLLOW!**

Amryt can also lean on the expertise of Harry Stratford, the founder of Shire Pharmaceuticals, to guide their growth strategy. Wiley exclaims, "We are delighted to have Harry as our chairman. Having his experience is fantastic as he is a veteran of the pharmaceutical industry and a highly successful serial entrepreneur. I believe he sees in our team parallels to what he did when he developed his businesses. Our strategy is to acquire, develop and commercialize; this is where we are aligned with Harry as it was the pathway that Shire followed in its inception."

Listed on the stock market, Amryt's share price is still relatively low but Wiley is confident that this will soon change to mirror the growth of the company. He concludes, "It has taken some time for people to understand our business and to buy into what we are developing. Nevertheless, I am particularly proud that we managed to deliver on every promise we have made to date and more... We are very well positioned to continue to build and scale Amryt into a world leader in rare and orphan diseases and the valuation will follow!"

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