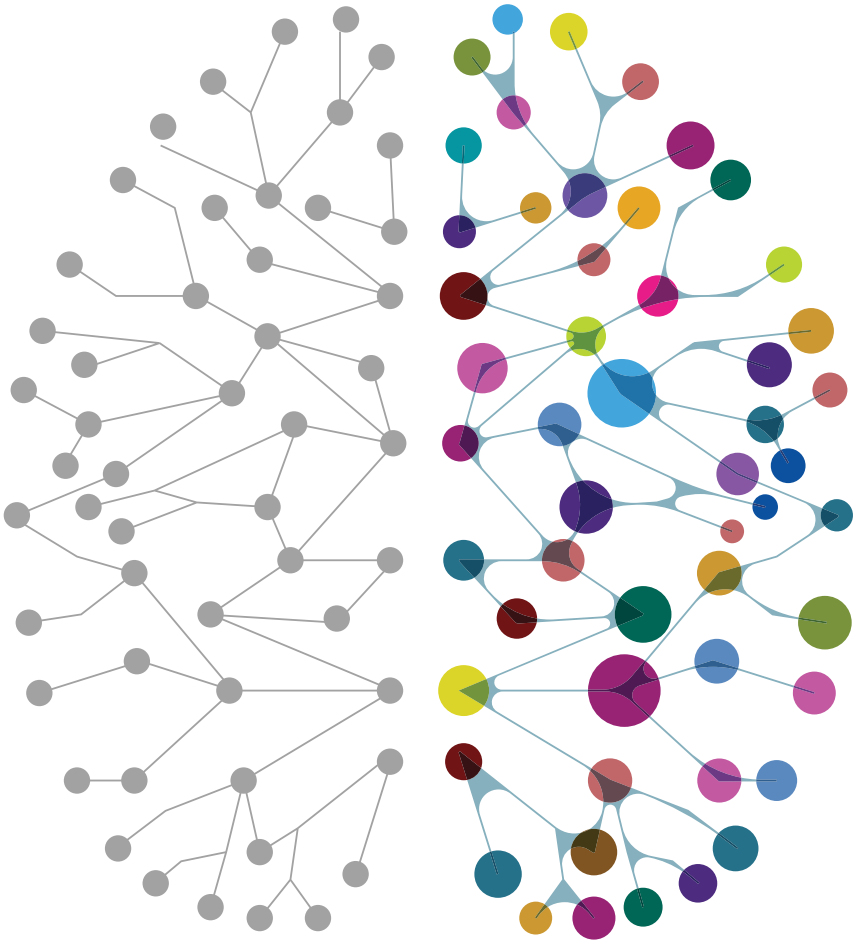
NewStatesman

Innovation in healthcare

Improved medicines, technologies and patient care

James O'Shaughnessy / Andrew Dillon / John Bell / Tony Young / Aisling Burnand



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British patients belong at the front of the queue

The United Kingdom is a leading force in medical innovation, with a strong, proud history of research excellence and cross-sector collaboration. However, uptake of new medicines in the NHS can be too slow: something I am determined to tackle in my role as health minister.

In November we announced a major step in doing just that, with a new fast-track route into the NHS aimed at providing British patients with the latest "breakthrough" medicines and technologies at a significantly faster rate, getting cutting-edge products for conditions such as cancer, dementia and diabetes from the lab to the bedside where they belong.

From April 2018, the Accelerated Access Pathway will allow selected products with the greatest transformative potential to become available up to four years earlier. The evaluation and financial approvals negotiation period will be reduced, allowing the NHS to purchase them sooner. A Strategic Commercial Unit is being created to negotiate cost-effective deals, making sure life sciences firms deliver taxpayer value.

As a nation, we are facing developments which will undoubtedly have an effect on our life sciences industry; further collaboration between industry and healthcare practitioners will be crucial to navigating this period of change. That is why these measures will guarantee future collaboration between the life sciences sector and the NHS post-Brexit, so that medical innovation can continue to thrive in Britain, benefiting the economy and generating jobs and skills.

This is a critical time to take stock of our strengths and weaknesses when it comes to accessing innovation. As always, the first priority for government is patients, and delivering the highest level of care. I greatly look forward to working with individuals and groups across UK healthcare to uphold and build on the UK's position as a life sciences innovator and leading force in medical progression, so that British patients are at the front of the queue for life-changing innovations.

James O'Shaughnessy is Parliamentary Under Secretary of State for Health

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Driving innovation through negotiation

Supporting innovation at the intersection of industry, government and the NHS is a challenging but rewarding pursuit, explains Andrew Dillon, chief executive of the National Institute for Health and Care Excellence

Operating at the interfaces between science, health and social care policy, patient and carer expectations, professional autonomy and industrial policy, all set in the broader context of the resources available to the health and care system, NICE has a rather sensitive task.

The relationship we have with the life sciences industry must align with both the government's policies for the sector and the capacity of the NHS to absorb and pay for innovation in a sustainable way.

By making recommendations on new and existing products, and supporting their adoption and optimisation in use, we know that we have an immediate impact on companies' commercial prospects, in this country and internationally. It is in the nature of what we do that there will always be a tension between our evaluations and companies' ambitions for their products. However, we aim to make this tension constructive and always oriented towards the best outcome for patients while ensuring value for money for the taxpayer.

We regularly discuss and exchange views with industry on how we should go about evaluating their products, keeping pace with emerging new technologies. In 2016 we published a report on the assessment and appraisal of regenerative medicines and cell therapies. This report attracted international interest and is considered a ground-breaking contribution to understanding the issues and challenges around the evaluation, pricing and reimbursement of complex advanced therapies.

Through our Scientific Advice Programme and the Office for Market Access, we have created new opportunities for dialogue beyond the processes of our guidance development programmes. By engaging in these ways, we have been able to inform companies' offers to the NHS and develop long-term, constructive relationships with them. Our experience in face-to-face meetings with around 500 individual medical technology companies demonstrates that there is a high level of demand for this kind of engagement in the medtech sector, as well as in pharma.

As the NHS becomes more sophisticated in its approach to adopting

We help companies to understand patients' needs

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new health technologies, our role in evaluating and making recommendations is providing opportunities for us to work with companies, to help them better understand what patients need and what the NHS wants to invest in. And we are developing capacity and expertise to help companies and the NHS engage successfully, through data-driven commercial access arrangements which make medicines more affordable for the NHS. This is enabling expensive treatments for very rare conditions to be adopted by the NHS. And it is being used in the new Cancer Drugs Fund for which, so far, ten new indications have been recommended for use, using processes designed in conjunction with patient groups, the NHS and the industry.

We want to reduce the risk for companies introducing products to the UK market by helping them focus their value proposition on the most compelling data. We can work with companies and the NHS to design and manage novel evidence generation processes and new data-driven funding models for fast-track approval and reimbursement which provide benefits to patients and make the best use of NHS resources. Building on the international value of a positive NICE appraisal, we want to extend our support for companies by increasing the visibility and accessibility of the Office for Market Access and Scientific Advice Programme abroad. And we want to support the UK in developing a world-leading approach to using data to track outcomes and manage early access to new technologies.

The changes we are making to our processes are integral to the vision we have for improving patient access to medicines, working with the life sciences sector and helping to safeguard NHS finances. Having clear, flexible approaches to evaluation reduces uncertainty for companies doing business in the UK. Through collaboration with NHS England we can help manage the introduction of costly treatments to the system. Also, through horizon scanning systems for new pharmaceuticals and, in the future medical devices, we can ensure timely identification and evaluation of the most effective health innovations, incentivising companies to plan early UK launches.

NICE's contribution to a successful relationship between the NHS and the life sciences industry will involve:

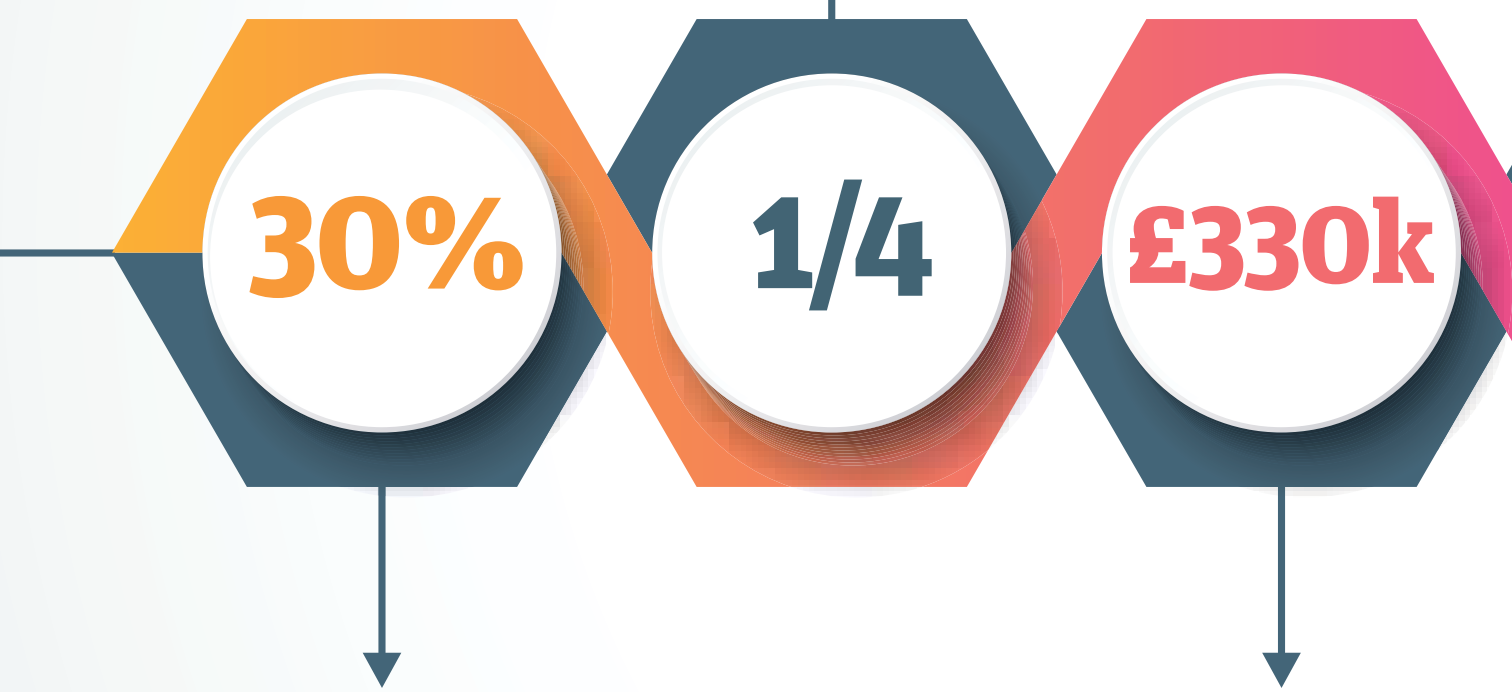
- Supporting companies to develop great product value propositions, increasing opportunity by working with them to focus their value proposition on the most compelling data.
- Helping to position the UK as a premier global life sciences destination and contributing to UK economic growth, with clear, predictable approaches to evaluating new products, reducing uncertainty and time-to-market for companies operating in the UK.
- Engineering effective collaboration between companies and NHS England to help manage financially challenging products into the NHS.
- Supporting the adoption and optimisation of effective and cost-effective new technologies, to drive the uptake of recommended products.
- Working with companies and the NHS to design and manage novel evidence generation processes and new data-driven funding models for fast-track approval and reimbursement of cost-effective technologies.

Our vision for a thriving relationship between the industry regulators and the NHS is for an environment which enables and promotes adaptive, integrated regulatory approval, followed by the fast, data-driven evaluation, reimbursement and adoption of compelling, affordable value propositions.

NICE has the global reputation and the expertise to help realise this vision. For nearly 20 years we have been at the heart of the debate around innovation, capacity and access. Through our own work, the continued willingness of the system to work together, and supported by government policy, we believe the UK can be a first rank global life sciences destination providing significant benefits for patients and the UK as a whole.

BY THE NUMBERS

The UK pharmaceutical industry



A quarter of the world's top 100 prescription medicines were developed in the UK.

Three of the ten most innovative companies in PWC's 2017 Global Innovation Study were pharmaceuticals.

Each employee in pharmaceutical manufacturing adds £330,000 in GVA to the economy, the highest of any technology sector.

More than 23,000 people are employed in pharmaceutical R&D in the UK. More than 70,000 people are employed by the sector in the UK overall.

23k

£11.4m

The pharmaceutical industry invests £11.4m per day in research and development.

A quarter of all industry spending on R&D in the UK takes place in pharmaceuticals.

25%

The author of the life sciences industrial strategy, John Bell, talks about channelling innovation into UK healthcare, and how to overcome challenges to the NHS

"We have made a life sciences roadmap"

John Bell is regius professor of medicine at Oxford University. He was formerly president of The Academy of Medical Sciences and founded the Wellcome Trust Centre for Human Genetics

Have you been pleased with the response to the life sciences industrial strategy?
It's been pretty uniformly positive from both industry and government so I think it's an interesting roadmap that we can now begin to follow.

Industry is frustrated by the rate of medicine uptake, would you agree that there is a problem with this in Britain?
Yes, I think there's a fair criticism of the NHS. It is quite slow to adopt innovation in all its forms - drugs, but also devices and new technologies.

Can increased cooperation between industry and healthcare speed up this process?
Yes, there's lots of ways to think about how you can improve the uptake. The accelerated access process that was announced last Friday is a good example, with Sir Andrew Witty chairing the partnership board. I think that's going to have an effect on bringing new innovations more effectively into the healthcare system. Other forms of collaboration between the healthcare system and industry may also help this quite a bit. For example, the Genomics England project, which was a collaboration between a large DNA sequencing company and the NHS, has now led to the transformation of genomic surfaces across the NHS. So there are a number of ways that this can happen, and we just need to use more of them more efficiently.

Do the NICE funding models need to be overhauled, or can they be adapted?
No, I think they can be adapted. The principles are absolutely right. If we're going to have a limited amount of resource to spend on healthcare then we want to make sure it gets spent in ways that are the most cost-effective. It's a model that lots of countries are now beginning to adopt. I think there are some areas where NICE could improve on its performance, and one is the speed at which they can produce opinions, but I would say adaption rather than a full overhaul.

How important is life sciences innovation, and technology, going to be for the future of healthcare?
I think it's going to be fundamentally important, so all major geographies are

having a terrible time finding the necessary resource to fund healthcare in the presence of a substantial demographic change and an epidemic of chronic disease. You're going to need innovation that makes it easier and more efficient to look after people; you need innovation that gives you better outcomes; you need innovation that allows you to take stuff that you currently do out of the system so that you end up with decommissioned activities, making space for new activity. You need all those things if you're ever going to make the numbers add up in healthcare systems.

"Innovating in an extremely stressed NHS is difficult"

Do you think institutions such as the NHS are equipped for a revolution in health technology?

In some ways the NHS can be hugely innovative. It's the first healthcare system in the world to have adopted state-of-the-art genomic technology for people with rare diseases and I have no doubt will be the first to adopt it for cancer. But that was done outside the healthcare system – with a lot of help from the NHS – but I think the problem of trying to innovate in the context of a hugely stressed healthcare environment within the NHS is really hard because people don't have the bandwidth to really spend time properly evaluating new interventions and testing them out to see whether you can actually change care pathways.

Who owns NHS data?

I thought it was the patients! Well, it should be, it is their data so I think that's probably the right answer.

Why is the input of SMEs important in the life sciences sector?

Well innovating in big companies is really hard. Much of the drugs innovation you see coming through from big companies started in small companies and then got taken into big companies for development and commercialisation. Small companies are the essence of the life sciences innovative culture and as a result they're really crucially important. A vibrant SME sector is essential if you're going to have a successful life sciences industrial strategy.

Would you call Britain a life sciences leader?

I'd say it's a life sciences leader. I think by almost every metric the US is the dominant force in life sciences globally. In terms of academic output on a per capita basis we do pretty well against almost everybody; we do pretty well in terms of the number of small companies; we do pretty well in terms of the innovation associated with areas like genomics where we're clearly the global leader. But, we don't win universally. Despite the fact that antibodies were invented in Cambridge in the UK, we were amongst the slowest to develop new biological therapies and amongst the slowest to adopt them into the healthcare system. It's competitive but there are areas where we haven't done that well.

Is its life sciences international position under threat from Brexit?

There are clearly challenges but I'm much more relaxed that we're going to end

up in a good place, and we'll continue to be competitive in the context of almost any Brexit scenario in my view. The quality of the underpinning science is likely to remain extremely high and I think it should be possible to retain a pretty globally competitive commercial environment if we think hard about how to do it.

Would you favour a transition period over a no-deal scenario?

What I hear from the industry is that they are keen on having a transitional view.

The two things that the industry, both medtech and pharma, want protected is some coherent regulatory environment, not necessarily as part of the EMA (European Medicines Agency) but at least in alignment with the EMA or another major international regulator.

The second thing is the migration of highly skilled people. I think both those issues are fixable and should be ok.

You highlighted the skills gap in the strategy; do you think it constitutes a threat to the life sciences industry in Britain?

Well I think the skills gap is a threat, but it's a soluble threat because there's lots of smart people who can be trained and brought up to speed. At one level we're quite good at it because we've got five of the top 20 universities on the planet, but then there's a whole other set of skills which might not come out of institutions that we've got to worker harder at deriving. If we're going to fix the productivity issue, which is clearly a big issue for everybody, then we're going to have to have a workforce which is trained and skilled up in a very different way than we've historically done. One of the problems is that if you want an R&D (research and development)-based economy, and to be clear our R&D expenditure is well below the top quartile, then, as I said in my report, we need to try and get to the top quartile. You're not going to get there unless you have industries that do R&D, which means you've got to have skilled people to do that. As soon as you get industries that are R&D-intensive, like most of the life sciences, your productivity figures are going to change dramatically and it will look a lot better, so these things are all tied up with each other.

"I'm anxious to implement the strategy"

Are you strategy recommendations designed for implementation as soon as possible?

Yes. What we were trying to do was lay out a roadmap, so I'm very anxious to get on and start implementing. I hope I'll have a sector deal before Christmas which people can have a look at.

I put together what was essentially the industry ask for an industrial strategy which was agreed in principle by government, although not formally. To be honest I'm not really looking for a formal response from government, I'm waiting for people to say "this looks like it's a good way forward ... let's roll up our sleeves and do it together and see if we can generate some economic growth."

I think we'll have some announcements in the next six months which are pretty interesting, and they're showing a major uptake in the UK sector which, given all the uncertainty out there at the moment, is very good news for everybody.

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When innovation is adopted, life sciences flourish

For the NHS to thrive it must keep pace with advances in medical science, explains Lisa Anson, president of the Association of the British Pharmaceutical Industry (ABPI)

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Bringing medicines to life

It's my ambition for the UK to be the best place in the world to research, develop and launch medicines. This isn't an unattainable vision, it's a conversation I have with colleagues in global pharmaceutical companies every day.

Not only is this a reality, I believe it's a necessity if we truly want to transform the NHS into a service that delivers world-class healthcare for all patients.

The UK is already punching way above its weight in the world of pharmaceutical science and I am proud to lead an industry that plays a pivotal role in improving global health and helping people live longer, more productive lives.

As science progresses we are now managing and eradicating diseases that routinely killed thousands of people a few decades ago.

Medical advances help the NHS save nearly 10,000 more lives a year from heart attacks than 20 years ago, avoid millions of emergency admissions for asthma, have doubled the cancer survival rate over 40 years, helped transform HIV/ AIDS into a chronic, manageable condition and cure hepatitis C in just 12 weeks.

Advanced, personalised therapies – immunotherapy and cell and gene therapies – are pushing us closer to cures and treatments for even harder-to-treat diseases. The industry's medicines pipeline is as exciting now as it has ever been. Globally, our companies are developing over 7,000 potential new medicines for conditions like heart disease, diabetes, mental illness and rare genetic conditions, often affecting the youngest patients.

As our industry increases its pace of development, the NHS faces two great challenges; an ageing population, and with it the increased burden of chronic disease, and major funding difficulties.

We share the ambition of the Health Secretary to put UK patients at the front of the queue for new medicines and the Life Sciences Industrial Strategy is a glimpse of how we can achieve this. First, by helping the NHS to capitalise on its unique strengths and expertise in using health data, I believe it can become the go-to partner for global companies for medicines and vaccines research and development.

Greater Manchester is pioneering this approach, where a more collaborative relationship between industry and the NHS is delivering cost savings and better patient outcomes through "real time" clinical trials for patients with chronic obstructive pulmonary disease (COPD).

Approving new medicines reaps benefits

Secondly, there is a promise of economic and health benefits for everyone if we can address the UK's challenges with adopting new medicines. If we want the NHS to keep pace with medical advances, we must find new ways of working in order to transform services, make the NHS a global hub for clinical research and foster an environment to allow the NHS to offer game-changing treatments to patients.

We stand at a critical juncture: if we want a thriving life sciences sector, a future-ready NHS and a flourishing economy, we must work with the NHS to adopt innovation and address these challenges. As we negotiate to leave the EU, making the choice to invest in our future is more important than ever.

How collaboration between the NHS and the pharmaceutical industry can improve patient care

Recent trials of collaborative working models offer hope for the future of the NHS, writes **Nick Bruce**, director, value, access and policy at Amgen

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As the National Health Service in England approaches its 70th birthday, the pressures it faces are arguably greater than at any time since its creation. A growing and ageing population with increasingly complex health needs is placing the service under significant financial and operational pressure. This is before we consider funding new treatments that offer the prospect of patients living longer and healthier lives. Despite planned year-on-year increases in the NHS budget, the service estimates that it will face an annual funding gap of around £20bn by 2020.

The NHS Five Year Forward View, published in October 2014, recognised these challenges and set out a vision for how the NHS needs to evolve. It placed emphasis on improving prevention and public health and developing new approaches to delivering healthcare by breaking down the barriers that exist between hospitals and community settings. The ambition is for a more collaborative and integrated approach to the delivery of healthcare with more services provided closer to where patients live.

Amgen – a worldwide leader in biotechnology – believes that the pharmaceutical industry can play an important role in supporting the NHS to respond to these unprecedented challenges. According to John Kearney, Managing Director for Amgen UK and Ireland: "We believe that the government, NHS and the life sciences industry have a collective responsibility to work collaboratively to improve patient care and health outcomes. This view has been reinforced by the growing appetite from local NHS organisations to work with us on this shared agenda".

The Cancer Vanguard was established in the NHS to pilot and roll out new ways of delivering cancer care in order to improve diagnosis and detection,

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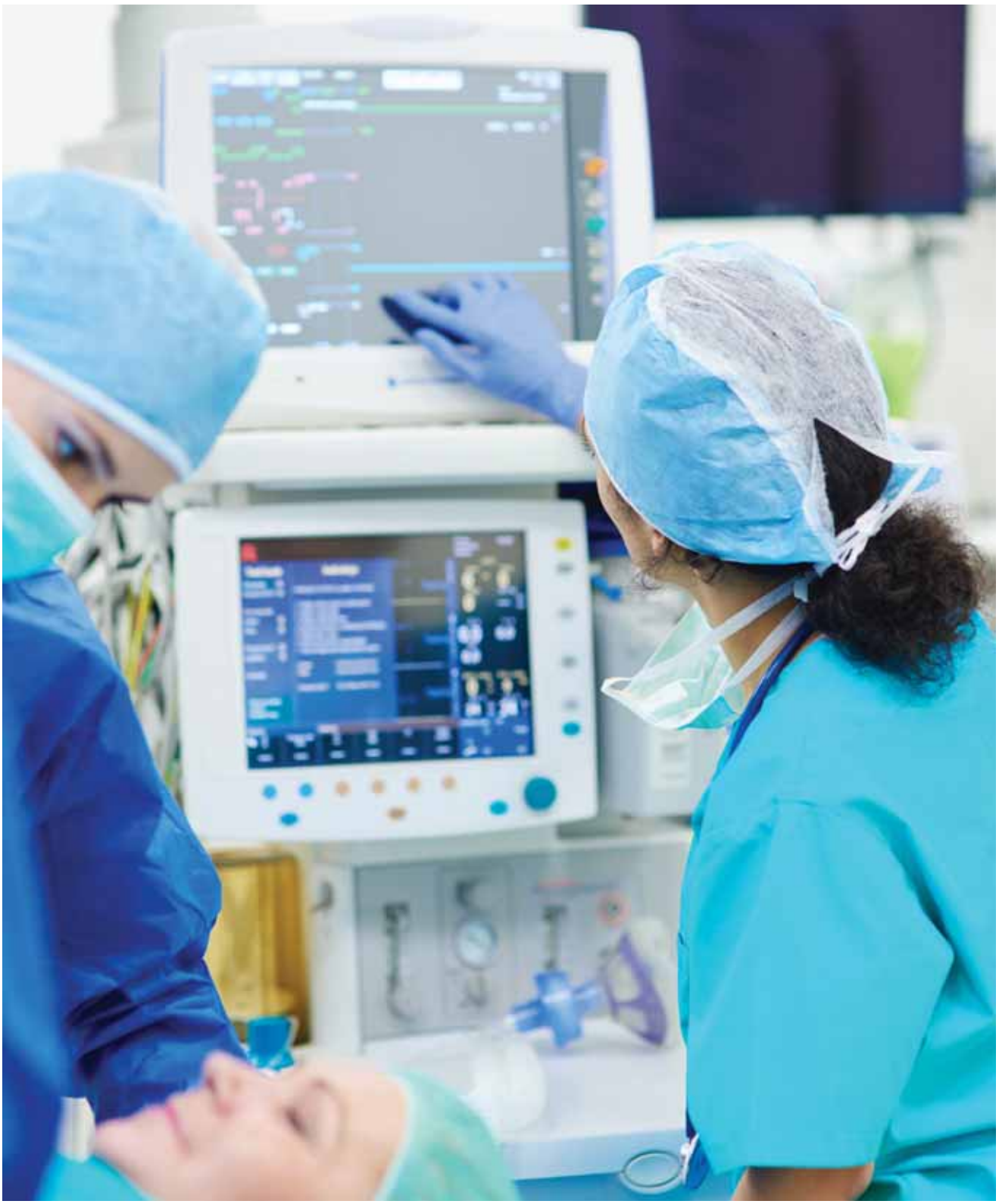

Care can be delivered closer to home

patient outcomes and experience of care as well as reducing variations in treatment. Spearheaded by leading cancer hospitals in London and Greater Manchester, the aim of the Cancer Vanguard is to develop transformational healthcare services that can be replicated nationally.

As part of its programme, the Cancer Vanguard is aiming to improve access to chemotherapy and other medications used in treating patients with cancer. Many of these modern treatments can be used outside of hospital, enabling new services to be developed closer to where patients live.

As Mr Kearney explains "When appropriate, providing treatments closer to patients' own homes – or even at their homes – may be more convenient and improve their treatment experience. It can be positive for their family and carers as well. Patients can be relieved of the burden of potentially long journeys, waiting times in hospital and the need to delegate some of their personal commitments like work or childcare to others. They can also be spared the costs of travel to and from outpatient appointments". The latter can be significant, with Macmillan Cancer Support estimating that patients treated for cancer spend on average £170 per month on travel.

The National Cancer Survivorship Initiative (NCSI), a partnership between the Department of Health in England, NHS Improvement and Macmillan Cancer Support, has proposed a 'risk stratified' approach to care planning. Patients who are regarded as high risk would continue to be managed by specialist teams, those at low risk are supported to self-manage, while those at moderate risk have their care shared between hospital and community based organisations. One of the key principles highlighted by the NCSI is the need for a shift from a 'one size fits all' approach to a personalised approach based on a holistic assessment of each individual patient's needs, risks and preferences. As a general rule decisions on starting a course of

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treatment will continue to be taken by cancer specialists and the treatment is usually initiated in hospital before transferring to a community-based service with the patient and their carers fully involved in making an informed choice.

As part of its 'Pharma Challenge' initiative, the Cancer Vanguard invited pharmaceutical partners to submit innovative proposals that would quickly deliver an improved patient experience while increasing the effective use of NHS resources. A cross-functional and multi-agency panel that included chief pharmacists, hospital medical staff, local NHS leaders and patient representatives evaluated the proposals.

Amgen was selected by the Cancer Vanguard to work with University College London Hospital NHS Foundation Trust (UCLH) to look at the out of hospital administration of an injectable medication used to help prevent serious bone problems in

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The "one size fits all" model does not suit everyone

patients with advanced breast cancer or other solid tumours who have developed bone metastases. This injection is commonly given to patients in hospital chemotherapy units even after patients have completed their chemotherapy treatment.

The project explored how out-of-hospital treatment allows patient care to be delivered closer to where a patient lives building on the principles of enhancing patient choice and improving treatment experience. These new services may also reduce pressure within hospital departments where cancer care is currently provided.

The project tested the efficiency of a range of out of hospital services that have the potential to be replicated at other NHS locations. The services included: primary care-led administration; a community outreach model; specialist nurse administration at home; home administration under the responsibility of a healthcare professional, and district nurse-led administration.

Project success relied on an experienced team of multi-disciplinary professionals, guided by specialist input from the NHS. This was fundamental to exploring how different healthcare providers can work together collectively towards an agreed common goal.

UCLH pharmacist Pinkie Chambers, who co-chairs the chemotherapy expert reference group for North Central and East London and West Essex, said: "Throughout this process, we have found that being able to overcome some of the system-wide barriers to implementing new models of care is crucial to our success in improving the delivery of cancer medicines to patients. We are excited to be working with Amgen to potentially bring the administration of medication closer to patients' homes where appropriate."

A simulation model was a key component. The model developed using insight and data from London and Manchester allows health commissioners and hospitals across the country to understand how medicines can be administered in the best way possible for patients and the NHS.

An Options Appraisal Document describes the out-of-hospital possibilities that have been considered. This includes practicalities, financial and workload implications for health managers locally to decide the suitability of each option for their own local service. Insights from the hospitals that have introduced new services are also provided in the form of case study reports, which include information on barriers to implementation and lessons learned. Patient feedback has been very positive with convenience and reduced travel and costs a common theme in those that favour out-of-hospital options.

The simulation and supporting materials have been made available to healthcare managers across England. As Dr Robert Urquhart, Head of Pharmacy and Divisional Clinical Director at UCLH reports: "This novel partnership between the NHS and the pharmaceutical industry has the potential to both improve patient outcomes and experience, whilst potentially saving the NHS money. Combining the first-hand experience and expertise of both the NHS and industry has been crucial to delivering a valuable outcome.

"The simulation model for out-of-hospital delivery will facilitate others in developing their own ways of delivering cancer medicines closer to home, for patients that wish to participate."

As Mr Kearney concludes: "It is clear that the NHS challenge of improving patient care and health outcomes at a time when the demands on the service are only going to increase is not going to go away anytime soon. A collaborative approach between government, the NHS and the life sciences sector gives us the best chance of navigating these challenges and it will take leadership from all of us to make this a reality."

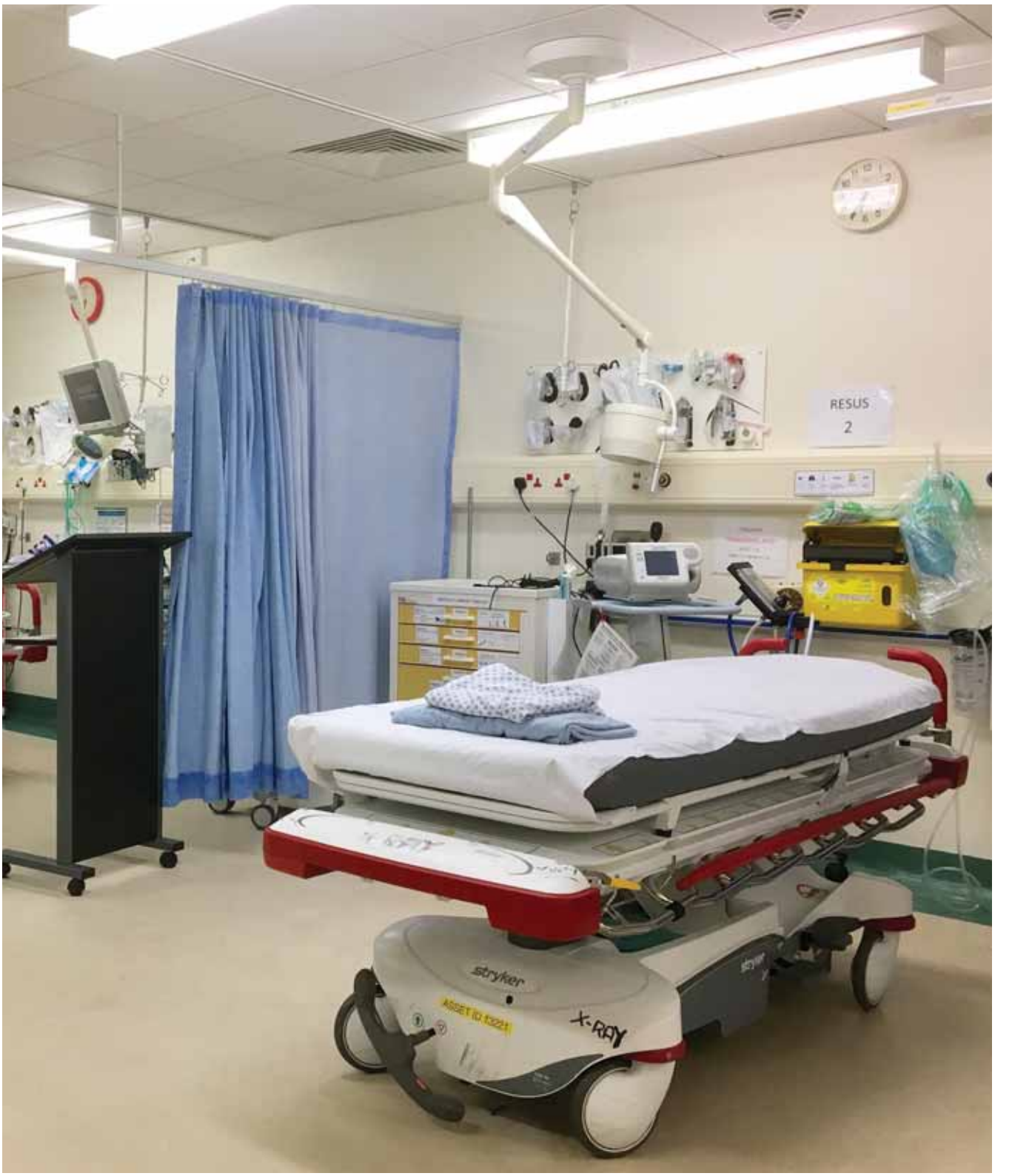
For more information, please visit www.amgen.co.uk

Professor Tony Young, national clinical lead for Innovation NHS England, lays out a vision for a future NHS that embraces technology, harnessing the power of innovation to benefit patients and professionals alike

Innovation will unlock the NHS for future generations

Almost 70 years ago the UK embarked on one of the most ambitious social innovations of the modern era: the delivery of universal healthcare to its population through a National Health Service. Since then our core values may not have changed but the clinical and social challenges we face have. Demands on the system and costs are rising, due in part to a population living longer than ever before with an increasing number of chronic diseases. There is also an increasing expectation of what healthcare can deliver from the public, patients and professionals.

Paradoxically, front-line medicine is arguably under more pressure now than it has ever been, but is also providing higher quality care with better outcomes than ever before. When the NHS was founded there was good reason to design a system around acute conditions and hospital care. Cancer, heart disease, stroke and infectious diseases had such a major impact on the population that average life expectancy was only 65 years. Since then significant medical advances have been made in chemo-radiotherapy and pharmacology, together with the introduction of coronary stents, thrombolysis, clot extraction and vaccination, that average life expectancy for UK citizens is now over 80 years. However, in the 21st century our healthcare system now has to contend with chronic long-term conditions and complex clinical pathways that could not have been envisaged in 1948. Indeed, we now spend around 70 per cent of the NHS budget on the management of chronic disease such as diabetes, chronic obstructive airway diseases and



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Technology is heralding a healthcare revolution

heart disease.

Many countries are grappling with how best to deal with these issues and deliver the often quoted triple aims of better health, better care, delivered at a lower cost and higher quality. Seemingly insurmountable problems warrant reflection on how nations have overcome them in the past. The words of Abraham Lincoln to Congress in December 1862 ring true now for the challenges we face in healthcare:

"The dogmas of the quiet past, are inadequate to the stormy present. The occasion is piled high with difficulty, and we must rise with the occasion. As our case is new, so we must think anew, and act anew. We must disenthrall ourselves, and then we shall save our country."

To address these major healthcare challenges the NHS published its 5 Year Forward View (5YFV) 3 years ago. This identified three key areas that needed to be addressed:

1. A health and wellbeing gap
2. A care and quality gap
3. A funding gap

The 5YFV sets out a vision that includes a radical upgrade in prevention, new models of care and an efficiency and investment programme. Innovation is at the heart of delivering this transformative vision. It acknowledges that we not only have to "do things better" but also "do better things".

In addition to the changes set out in the 5YFV we recognise that the world around us is changing. The latest developments in genomics, advanced technology, data analytics, digital health, machine learning, artificial intelligence, ultra-connectivity and social networking are heralding a new era in healthcare that could be described as a personalised, democratised healthcare revolution. Increasingly patients and citizens will be empowered with the knowledge and technology to manage their health and doctors, traditionally seen as the gatekeepers to healthcare, are likely to become system navigators and advisors.

The combination of profound medical challenges and technological advances are setting the pace. Innovation has an influential role to play in addressing these challenges and delivering a healthcare system that is both true to the founding principles of the NHS and fit for the future. We need to embrace new evidence-based technology and the potential benefits it can offer our patients. We have to innovate and do it at scale, but how can that be achieved? Furthermore, how can proven innovations be adopted into best practice and taken up across the whole healthcare system rapidly?

How the NHS is delivering on innovation

The key is to develop a culture in which innovation can be rapidly adopted and spread across the system. If we get that right, the transformation we need will follow. Solutions are to be found in the intellectual capital of those people who work in the healthcare system and the patients and citizens that use it. We need a culture that empowers them to help make that change happen. Many of the building blocks that will help form the foundation of a healthcare innovation culture are already in place in the NHS.

Sometimes being the largest, longest established healthcare system in history can be perceived as a daunting place to innovate. The NHS in England serves a population of 54 million people, with an annual budget of approximately £110bn. It is the fifth largest employer in the world with 1.4 million employees, deals with one million patients every 36 hours and sees 75 million out-patients and 15 million in-patients per year. Therefore, the NHS is in fact the best place on the planet to innovate in healthcare at scale.

Emerging innovation themes

There are a number of transformative and innovative opportunities within our reach. The rapid progress in artificial intelligence and advanced technology has the potential to assist patients, citizens and professionals to transform the way care is delivered and new areas such as autonomous robotic surgery will

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start to emerge. 5G mobile networks are going to radically upgrade data transfer speeds. Not only will this allow technologies like driverless cars to realise their potential, but in healthcare rapid, reliable monitoring of patients and connection to their care provider whereever they are is likely to allow more and more care to be delivered closer to the patients' home. These advances will empower healthcare professionals rather than replace them, unshackling them from many administrative and repetitive tasks, freeing them up to spend more time caring for and advising their patients.

Patients and professionals hold the future solutions

The area of big data also offers huge potential. In the UK, we have one of the jewels in the world's crown: the NHS data set. The task in hand is to combine this with the great strides we are making in genomics with the 100,000 genome project to deliver benefits to our population. Getting this right will truly allow us to become the first country to offer personalised medicine to its whole population. There are concerns in some countries that genome screening could allow the potential for genetic discrimination. However, the power of the pooled risk model that the NHS offers would act as a safeguard and provides another reason why it is the healthcare system of choice in delivering personalised medicine.

By bringing new thinking and action and supporting our frontline clinical staff to adopt and spread innovation we can rise to the challenge and help transform and safeguard the NHS to deliver high quality care for generations to come.

Collaboration can improve outcomes for patients

Haseeb Ahmad, managing director of Novartis, makes the case for abandoning old roles, and uniting industry and the NHS to improve healthcare overall

In most professions and industries, collaboration is recognised as the key to success. In healthcare, various parts of the care process are provided by different organisations to produce the final product – a first-class patient experience. At Novartis, we believe that greater collaboration is the key to a world-class healthcare system that puts UK patients at the centre of their care.

Historically, a vendor-supplier relationship has existed between industry and bodies such as the NHS, Department of Health, and the wider government. We supply medicines and they purchase them. I believe that it is crucial to rewire this relationship, to foster interaction and shared thinking, for the long-term benefit of patients.

Our country faces a perfect storm that could have an unprecedented impact on health in the UK. The combination of an ageing population and a subsequent reduction in taxpayers (people of working age), and now the uncertainty of Brexit, provide us with an opportunity to come together as an industry, and develop solutions to navigate the unsettling period to come.

Novartis engages in a number of collaborative projects with the NHS; these projects seek to add value at every stage of the care process, from prevention to intervention, in an effort to address key challenges faced by doctors, nurses, managers, and ultimately to improve the overall experience for patients. Our focus is improving patient care through rapid diagnosis, accelerated access, and outcomes-based payment models. These initiatives have resulted in reducing the level of patient referrals back into the healthcare system, realigning funding so that CCGs pay for appropriately treated patients, and greater secondary care integration.

Looking at the bigger picture, the UK lags behind its peer group when it comes to new medicine uptake. A person in

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France or Germany is almost five times more likely to gain access to any newly developed medicine. Patients in the UK should not have to wait to access the latest innovations that could improve and extend their lives. Early uptake and a strong flow of new treatments into the system have huge value implications for national health. Innovative medicines are being produced all the time that can save money, time, and resources for the NHS, but they are not being utilised.

Novartis welcomes the Five Year Forward View, and the Life Sciences Strategy, which places patients squarely at the centre of its recommendations. However, the devil is in the detail, and we would embrace the opportunity to work with the NHS and government to put together an implementation plan to ensure we attain these goals. Novartis is hungry for a conversation that looks to be positively disruptive, reimagining models of care, funding channels, and the process by which we interact.

The basis to effective collaboration is aligning long-term aims, and, above all, transparency. It comes back to rewiring that entrenched relationship, and redefining the roles of supplier and purchaser to move forward. Novartis always approaches a collaborative project with the experience of NHS staff as our starting point, considering their concerns first and foremost.

The UK is one of the world's biggest economies – I'm sure that all UK healthcare professionals are united in wishing to see a healthcare system that reflects this stature. In order to think outside the box, and find innovative solutions for the NHS, it will take a handful of forward-thinking companies and leaders in healthcare to step out, come together, and demonstrate how it can be done. Novartis relishes the chance to be part of that leading pack.

Novartis is a healthcare company which strives to change the practice of medicine.

COLLABORATION

A doctor's view

Dr Raj Thakkar, general practitioner, primary care cardiology lead for Oxford Academic Health Science Network, collaborated with Novartis on the Cardiac Champions Project, a post-graduate diploma in cardiology

"When partnering with industry, it is essential all parties involved have clear boundaries when it comes to conflict of interest guidelines. With the correct governance structures in place, I see no reason why partnerships shouldn't be created to improve clinical outcomes. In the case of my own Cardiac Champions programme, if it will improve outcomes in heart failure, and reduce rates of stroke and coronary disease, it seems counter-intuitive not to collaborate. Historically, there has been a nervousness in the public sector about partnering with industry. This, I believe, has started to change, especially in the last couple of years. Like any other healthcare professional, I want to see real outcomes, an improvement in quality of life, a better experience for patients, an improved sustainable health economy, relief for social services, and to get these I'm interested in doing things differently, as long as I work within the rules. If we don't move care upstream and get ahead of the curve, we're not going to survive as a health economy. We need to enable better prevention, earlier diagnosis, and optimise care 24/7. Supporting continuous improvement and innovative system-wide sustainable change is essential. If partnering with industry helps to achieve that, then we should do so, for the greater good of the population.

I hope that this successful partnership will pave the way for more partnership with industry."

Reimbursing medicines in a new age of innovation

The UK is slow to adopt advances in medical science, writes **Jennifer Lee**, director of health economics, market access & advocacy at Janssen UK, but it's possible to learn from other countries

Over the last decade, advances in biology and bioinformatics have revolutionised drug discovery. At companies like Janssen, this has led to the development of pioneering new medicines that target diseases more precisely than ever before.

Our research and development model continues to evolve as we respond to advances such as large genome sequencing and artificial intelligence. We collaborate with experts from a range of scientific disciplines in pursuit of the next breakthrough, and the future for medicines development is bright.

Despite these positive advances in science and our network of partnerships, many groundbreaking medicines do not reach UK patients quickly enough – if at all. The UK reimbursement process can be lengthy and often dwells on the lack of comparative evidence supporting pioneering new products compared to existing, often long-studied standards of care. As a result, the Office for Life Sciences recognises a "low and slow" uptake of innovative medicines that undoubtedly affects patient outcomes in the UK. For example, the UK's five-year cancer survival rates are lower than most other European countries, which have been quicker to adopt new medicines and dedicate more healthcare expenditure per capita.

For many years, the National Institute for Health and Care Excellence (NICE) has been regarded as a world leader in assessing the clinical value and cost effectiveness of new drugs. However, its methodology has remained largely the same since its inception nearly 20 years ago. During this time, regulatory bodies such as the European Medicines Agency have modernised their evaluation processes, enabling them to give the go-ahead for new medicines, where there are significant unmet needs based upon early clinical trial data.

This has created a significant barrier for patients hoping to access new

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medicines, as NICE considers these types of datasets to be immature or incomplete. In short, regulators are saying "yes" whilst health technology appraisers are saying "no".

This, coupled with NHS financial pressures, presents a growing concern for patients.

In a drive to find £30 billion in savings by 2020, measures introduced in April by NHS England and NICE restrict spend on new medicines to the degree that even when NICE deem a medicine to be cost-effective, NHS England can now choose not to adopt it. As such patients must wait even longer to access new medicines, while the NHS works out if and how it can pay for these treatments.

This is despite an existing agreement – the Pharmaceutical Price Regulation Scheme (PPRS) – through which the UK medicines bill is already capped and pharmaceutical companies rebate the NHS if the cap is exceeded. Under this agreement the industry has already rebated over £1.9bn.

Importantly, there is currently no other area in the NHS that is subject to the same rigorous cost-effectiveness analysis than medicines (with the exception of a few medical devices and diagnostics). Targeting medicines that have been recommended as cost-effective by NICE – particularly in areas of high unmet need such as cancer – is simply not the answer when there is room to make so many other efficiencies in the system.

Janssen and our parent company Johnson & Johnson, have worked in partnership with healthcare systems around the world for many years, continually seeking to improve the way we deliver products in collaboration with regulators and governments.

This includes developing flexible payment schemes that support accelerated access to medicines, whilst encouraging up-to-date methods to assess their value.

Many of today's medicines – and many more in research and development – are likely to be effective for multiple diseases, known as indications. In each of these different indications, the medicine will have a different impact and therefore a different value, but the current assessment system in the UK isn't set up with this in mind. This must be resolved so that agreements can be reached for treatments that work across different patient populations, which is ultimately one of the main reasons behind delays to the introduction of new medicines in the UK.

Firstly, there is an urgent need to introduce more flexible, multiple-indication pricing if we are to overcome the issues patients experience with accessing new treatments in the UK. This must be central to the Pharmaceutical Price Regulation Scheme (PPRS) that is set to commence at the start of 2019.

The need has already been recognised in other European countries where they have kept up with the pace of change. For example, in Italy, patient-level, indication-specific data are collected for new drugs in registries maintained by AIFA (the Italian medicines agency), allowing health authorities to track every medicine that they pay for, per indication. Essentially, they're tracking patient outcomes per drug, per disease and using this to implement flexible pricing schemes with pharmaceutical companies. This allows the Italian healthcare system to spend its budget more efficiently.

The recent Life Sciences Industrial Strategy published in August recognised the need for change if the UK is to remain an attractive place to invest in research and development, and the Accelerated Access Review highlighted the need for faster access to new treatments.

Our goal now is to work closely with NICE, the NHS and the Department of Health to help solve the affordability challenge facing the UK healthcare system. With the backdrop of Brexit and an economic downturn, there has never been a better time.

The patient's view

Roger Brown, chair of Waldenstrom's Macroglobulinemia UK (WMUK)

"As a lucky survivor of a rare blood cancer, whose many friends diagnosed at the same time have died, I naturally ask why our survival rates are lower than other EU countries, when we have many of the world's top specialists. The answer is simple: adoption of new and effective treatments doctors can use is slow, and we spend substantially less on treatment per patient. NICE and NHS England increasingly seem more concerned about financial impacts than effectiveness or quality of life for patients. Applying a further layer of budget rationing of drugs will make our situation even worse and seems uniquely applied to this area of NHS expenditure".

Understanding the value of in vitro diagnostics

In vitro diagnostics can improve the accuracy and cost-efficiency of NHS treatments during challenging times, writes **Doris-Ann Williams**, chief executive of BIVDA

The UK's population is growing and it is growing older. But vastly improved length of life, one of the great successes of the last century, is set to provide some of the great trials of this one. The NHS is undoubtedly one of the UK's prized assets, but faced with more people and tighter budgets, delivering the world-class care it is known for becomes more of a challenge. Managing budgets effectively is a more desirable path than cutting certain expenditures entirely; and in vitro diagnostics (IVDs) represent an opportunity to break up bureaucracy, streamline decisions and most importantly, improve primary care.

IVDs are non-invasive tests used on biological samples from a person (for example blood, urine or tissues) to consider symptoms and determine the status of that person's health. IVDs provide useful information on how the body is functioning; they are used for diagnosis, screening, assessing predispositions and therapeutic monitoring of diseases such as diabetes. Innovations in IVDs have been a key element in cutting costs in healthcare systems by making treatment more precise and efficient. At such a pressurised time for the NHS, however, even more needs to be done.

There are three main types of IVDS: clinical laboratory testing, point of care testing and self-testing. It is thought that around 70 per cent of clinical decisions are informed by IVDs. They are a crucial factor in the NHS frontline and a fundamental part of almost every patient pathway.

If used effectively, IVDs can help to reduce or avoid hospital referrals – because they can get to the correct diagnosis quicker – and to support patients to look after their own health. A more accurate diagnosis can also reduce risk of unnecessary prescriptions of antibiotics. If general practitioners use IVDs in instances, for example,

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where a patient may be showing symptoms of deep vein thrombosis, then a simple test can rule out this diagnosis for many people. The cost of this test is less than one tenth than that of a hospital referral, signifying a clear business case for the use of the IVD. As resources are freed up for use elsewhere in the NHS, a healthier population directly correlates to a more productive one, supporting wider economic growth.

Research and Development (R&D) by the IVD industry has led to the creation of many new and innovative IVDs across a wide range of disease areas. But the industry still faces a glass ceiling when it comes to the uptake and diffusion of IVDs within the NHS. This is in part down to budget silos. The current budget for testing and general pathology in the NHS is separated from the rest of the budget for a medical pathway. This can be a disincentive for the introduction of cost-saving and potentially life-saving new tests because while the on-going costs are borne by the innovators, the savings don't accrue until further down the patient pathway. In general, the understanding of IVDs is lacking. As such, the NHS is too inflexible when it comes to adopting new IVD tests. In fact, uptake of new IVDs within the NHS typically takes about 10 years. Solutions are still thought of as pharmaceuticals and consideration is not given to how IVDs could be adopted to improve outcomes.

In fact, IVDs are well placed to deliver on many of key ambitions in the Five Year Forward View, including disease prevention, patient empowerment, implementing new models of care and driving efficiency savings. Consider, for example, that by 2025 it is expected that 5m people in the UK will have diabetes. IVDs are essential to diagnosing diabetics and then help them to manage their condition and enjoy quality of life. The best way of ensuring that a person is on top of their diabetes is by testing their blood sugar at regular intervals, particularly before meals. Self-monitoring can be a great way to help control blood sugar as it allows flexibility in lifestyle and treatment choices, as well as helping to monitor for symptoms of hypo or hyperglycaemia.

The current landscape facing the IVD sector is difficult. On the one hand, there is an increasing demand for tests; it is expected that there will be a 10 per cent annual increase in demand for blood and tissue tests over the next 10 years due to an ageing population and rising incidence of chronic disease. On the other, the final report of the Carter Review stated there was an opportunity for the NHS to save around £200m in the provision of pathology services. This is despite the fact that the NHS only spends about £800m annually on IVD products – less than 1 per cent of the total NHS budget. Recent research has found pathology services in the UK are struggling to cope with the increasing demand for samples to be tested, in part due to workforce shortfalls.

So, how are IVDs different? IVDs are tests used on samples taken from the human body to determine status of health unlike pharmaceuticals, which aim to treat or manage a condition or disease. An IVD has no physical contact with the body unlike medicines, designed to be absorbed and act systematically. For IVDs, innovation comes primarily from clinicians' insights, rather than laboratories.

Delivering benefits for patients and the NHS is at the heart of the IVD industry. However, it should be noted that the industry also makes a valuable contribution to the UK economy, employing more than 8,000 people, with annual sales of approximately £850m to the NHS and playing a significant role in UK exports; £1.1bn were exported in 2013.

Ultimately, the IVD industry is clear in its aim to grow benefits for the NHS, the UK economy and, of course, patients. We need to get as much care as possible out of hospitals and into communities. IVDs can help us to do that.

Collaboration is the key to innovation

The nation's health is a widely held responsibility, writes **Elena Tricca**, director, market access and government affairs, AstraZeneca UK, and it is best served by working together

I am amazed when I reflect on technological advances since the turn of the century. Most of us can probably remember our first mobile phone or using email for the first time, and now Google processes over 40,000 search queries every second.[1]

While gadgetry and connectivity have made a significant impact on our lives, I would argue that scientific innovations in the medical sector have been the most exciting. For example, our understanding of cancer has matured to such a degree that we are now able to pinpoint and exploit the vulnerabilities of cancer cells with targeted medicines. Significant progress has also been seen for people with other diseases, from hepatitis to HIV, and multiple sclerosis to macular degeneration.

Research in British laboratories and patient participation in clinical trials have made a significant contribution to this golden age of medical science. For example, at AstraZeneca we apply a precision medicine approach to select the right patients for treatments and have been able to significantly speed up the development process for new innovative medicines. Our ambitious genomics strategy, launched in April 2016, aims to analyse up to two million genomes by 2026. This will enable us to identify new targets for medicines and understand which patients are most likely to benefit from each one.

But while the UK life sciences industry is an incredibly stimulating place to be right now, the processes for making these medicines available to patients in the UK have been slow to adapt. As medicines development has changed and continues to evolve, the access system must have the capacity to respond positively to new technologies. In the same way that AstraZeneca is working with government to make the UK the best place in the world to discover and develop medicines, we also want to ensure these medicines can

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benefit patients in this country.

All healthcare systems face challenges, and rarely a week goes by when the NHS isn't in the headlines. But the truth is our nation's health is not the responsibility of any one person or organisation. We need to work together to ensure the system is hardwired to translate medical advances into improved patient outcomes. Patient access to new medicines in the UK is slower than in many comparable countries. The government's Life Sciences Indicators show that the uptake of medicines approved by NICE as cost-effective was just 18 per cent of the international average of other similar countries in the first year after launch.[2]

While it is extremely complex to directly correlate lower medicines access with poorer health outcomes, there are trends that suggest this. For example, the UK has one of the lowest uptake rates of new cancer medicines compared to the four largest European economies (Germany, France, Italy and Spain); the UK also has the highest mortality rate from cancer compared with these countries.[3] So while there are other factors at play, there is a case to be made for taking a good hard look at the current medicines access framework, and asking whether it's working for UK patients.

We need to seize opportunities for the future. We support the ambition in the recently published Life Sciences Industrial Strategy (LSIS) that the UK should be positioned in the top quartile of comparator countries for the speed of adoption and the overall uptake of new medicines by 2023.[4] We also support the proposals to improve patient access to new medicines while ensuring value of the health service and urge government to respond to them as a priority. We are ready to support this effort.

Unlocking innovation for patients

Once a medicine has been deemed cost-effective and is approved for use in the NHS, the next step is to ensure it is used in an optimal way to enable the highest standards of care and best outcomes for patients. This is very much easier said than done, with variations in access to NICE-approved medicines across the UK; however, there are many examples of local teams working in innovative ways to achieve this goal.

The pharmaceutical industry has supported some of this work through collaborative working. These are mutually beneficially partnerships where we pool skills and resources with the NHS to improve health outcomes in our areas of expertise. AstraZeneca has collaborated with the NHS on over 30 initiatives across the UK.

One current example is the Cardiovascular Partnership programme, created by AstraZeneca to provide clinical leadership and support to the NHS in addressing unwarranted variation in the non-ST elevated myocardial infarction (NSTEMI) pathway. With input from multiple stakeholders, including a consultant cardiologist with experience in service redesign, we have hosted a number of workshops with hospitals and have conducted an innovative analysis of hospital data enabling trusts to understand their patient journeys. As a result, participating trusts have made several changes, concentrating on reducing the time to intervention and length of hospital stay.

Partnerships can improve outcomes

In summary this initiative has provided value to the NHS and has supported a limited number of trusts due to capacity. We are now looking for support from the NHS to take the learnings forward, use the data and address system-wide improvement.

AstraZeneca and the pharmaceutical industry has expertise, resources and ideas for how the NHS can sustainably adopt new technologies and innovative medicines at scale. Equally, the NHS has huge potential to drive the life sciences industry to the benefit of the British economy – for example, by working in partnership to harness the power of medical data; delivering more clinical trials and research; and supporting the development and greater use of precision medicines and genomics. Collaboration is the key to unlocking the benefits of innovation for all.

For more information, please visit www.astrazeneca.co.uk and follow us on Twitter @AstraZenecaUK

1. Internet Live Stats, Oct 2017.
2. Office for Life Sciences. Life sciences competitiveness indicators, 2017.
3. The Swedish Institute for Health Economics. International Comparator report on patient access to cancer medicines in Europe revisited – A UK perspective.
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The transformative power of health data

Aisling Burnand, chief executive of the Association of Medical Research Charities, explains the potential data has to fundamentally innovate the health landscape

Last year, the government announced its intention to create an industrial strategy with "sector deals" across leading areas of industry. The UK's decision to exit the European Union was a driving factor in this new approach, with a refreshed need to ensure the UK can strengthen and maintain its competitive edge in those leading industrial areas.

The life sciences sector is one of those leading and highly productive sectors of the UK economy; last year it generated a turnover of £64bn. Medical research charities are a vital part of the UK life sciences ecosystem. Since 2008 charities have invested over £11bn in research in the UK to save and improve the lives of patients. Last year medical research charities invested over £1.6bn of research funding in the UK, funded the salaries of 17,000 researchers, and recruited 170,000 patients onto charity-funded trials. Medical research is also the leading cause the public choose to give their money to, with 8 million people donating last year.

As well as investing in research, charities play crucial roles as innovators, collaborators and risk-takers who open up early-stage research and spark further investment within the life sciences. In the last five years, charities have contributed to over 60 spin out companies and 300 medical products including drugs, medical devices and diagnostic tools. Partnerships and collaborations between charities, industry and others are leading new innovations for patients such as mini insulin pumps for people affected by diabetes, new treatments for burns, improved access to clinical trials and digital tools that use artificial intelligence to offer advice and information for those with arthritis.

Key to these life-enhancing innovations is data. There is much more that the life sciences sector can continue to achieve for patients and the UK economy, and patient data is central in helping to unlock this.

Patient data: the power to save and improve lives, and drive the life sciences sector

In August, the Life Sciences Industrial Strategy was published. It was led by Sir John Bell, with representatives from

Patient data enables researchers to save lives

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across the life sciences sector – including pharmaceuticals, biotech, digital and charities. The strategy is the first step towards a life sciences "sector deal", putting forward recommendations that would retain the UK's world-leading position in the life sciences industry over the next five years.

At the heart of the strategy is maximising the potential of patient data for care and research. The transformative potential of patient data to advance medical research and improve patient care cannot be understated. The UK has a rich and unique health data source in the NHS, reflecting its cradle-to-grave service and the diversity of the UK's population. For researchers in the life sciences sector, working to better understand the causes of ill health, and develop possible treatments and cures, this is an incredible resource.

The responsible use of patient data has helped progress our understanding of disease and ill-health in many different ways. To name just a few examples of research funded by charities: a study using data from the UK Renal Registry and hospitals found a pattern of hospitalisation amongst kidney patients that led to new recommendations for clinical practice; in cystic fibrosis a registry of patient data led to the development and monitoring of essential new treatments; and a brand of hip implants was identified as having high failure rates through the collection and sharing of data.

Patient data ultimately enables researchers to save and improve lives, whilst also contributing to our nation's productivity and economic growth.

However, the current failure to record, link and share data across the NHS is jeopardising our ability to conduct world-class research and importantly the care and safety of patients. Progress on creating a truly digital and 21st century NHS has been far too slow and patient care and research has suffered as a result of this.

At a time of uncertainty for the UK and amidst increasing financial pressure on the NHS, taking forward the recommendations in the Life Sciences Industrial Strategy on patient data could help to ensure the UK remains a world leader in the life sciences and vitally improve care for patients. The recommendations include building further disease-specific data registries, ensuring data in the NHS is interoperable and can be joined-up across the country; and crucially that the government implements the National Data Guardian's recommendations on data security, consent and an opt-out.

Critical to all of this is ensuring that the public is well-informed, engaged and has confidence in the system that collects, stores, and links patient data. We want the public to understand the difference their data can make to research and to those suffering from ill-health; while also respecting concerns about privacy and data security, and ensuring that these concerns are taken seriously with appropriate safeguards put in place.

It is important to recognise that those affected by ill-health want to share their data for the purposes of research, provided their information is kept safely and securely. Research from the Brain Tumour Charity found that 97 per cent of brain tumour patients surveyed said they'd be happy to share their medical data to help improve brain tumour treatment and care.

Next comes the "sector deal"

The next step for the Life Sciences Industrial Strategy is the development of a "sector deal" – this will be negotiated with government, industry and others. We hope the "sector deal" will draw on all partners across the breadth of the life sciences sector – including medical research charities – to ensure that opportunities are seized and the ambition to deliver transformative outcomes for patients and UK life sciences is realised.

Small companies are fighting to innovate

Emma Chaffin, general manager of Shield Therapeutics UK and Republic of Ireland, explains the challenges faced by SMEs in the pharmaceutical industry

At Shield, we were very proud to launch our first product in the UK in 2016 just six years after we were established as a company. The UK launch was the first launch globally for Shield, which was initially for a narrow indication for a small group of patients. We are now looking to obtain a broad license which would mean our product would be available across Europe for a much larger number of patients. However, in the UK we will have to engage with multiple reimbursement processes before clinicians can prescribe for patients.

Shield is an independent SME and the UK pharmaceutical industry, although full of opportunity, can be a difficult environment, particularly for a small company. Recruitment and retention is a huge challenge for pharmaceutical SMEs, and a great deal of manpower is required to navigate the complex innovation access landscape. The British healthcare system is, by nature, highly decentralised. This is firstly as a result of being divided into four different countries. Within that, in England alone, there are over 200 hospital formularies to allow new drugs into hospitals, and 90 area prescribing committees to allow GPs to prescribe therapies, all of which have separate application processes and varying budgets.

Germany launched shortly after, which made for an interesting comparison. Unlike the UK, once the price and reimbursement was agreed at a national level, clinicians could prescribe the drug without further process. Within a year of launch, Germany has roughly three times the rate of patient access than the UK, despite the German launch coming three months later.

The UK spends just 9.9 per cent of its GDP on healthcare, with Italy being the only other G7 nation that spends less, and Britain lags in patient access to new drugs. The ABPI found that for every 100 patients in comparable countries that can access a new drug in its first year of launch, just 12 patients in the UK can do so.

Shield would like to see faster adoption of innovative medicines and a simplified adoption process, with more support for SMEs. We have heard positive noises from government in recent months, most notably the Accelerated Access Review (AAR), led by the Office for Life Sciences, which is designed to speed up adoption of innovative medicines.

Particularly encouraging is the commitment of £6m over the next three years to support SMEs in gathering the evidence required to develop and market innovative medicines. More generally, Shield welcomes the recommendation to remove the duplication of assessments, with an eye to establishing a standardised assessment that channels localised approval bodies into four key hubs . The current national health technology appraisal system adopted by independent agencies, such as NICE and the SMC (Scottish Medicine Consortium) are the most system supported methods of gaining reimbursement in the UK. However, unlike in Scotland, less than half of medicines are topic selected for a NICE appraisal, which has a significant impact on adoption of new medicines in England.

In line with the Life Science Strategy recommendations 2017 made by the life science industry, Shield encourages the further implementation of recommendations made in the AAR, particularly increasing the SME tax break threshold to higher than £5m to foster a level playing field between SMEs and the pharmaceutical giants that dominate.

Companies like Shield have so much to offer the life sciences sphere, but the challenges are great. We eagerly await the Autumn Budget, and other announcements, for signs of support.

Medical innovation in the face of Brexit

Insecurity around Britain's future threatens SME pharmaceutical innovation, explains Shield Therapeutics founder and chief executive Carl Sterritt

Shield Therapeutics is a born and bred British company; we are UK-founded, UK-based with UK products. I started the company in 2010 with a simple mission: to develop therapies for patients that will significantly improve their lives. Shield develops drugs that are likely to be used in a secondary care environment, for patients with diseases that cause specific conditions. We launched our first product in 2016 in the UK and Germany.

Despite our proud British roots, we are far from inward-looking, nor is the wider pharmaceutical industry. Healthcare innovation has no nationality – all the medical congresses and journals are international – so operating across borders is imperative, as is the need to engage with the varying national regulatory and commissioning environments. Between 2015-19 Shield will have invested around £100m across France, Germany, Italy, Spain and the United Kingdom (the EU5). Our own workforce represents this internationalism; we have employees who hail from Russia, the USA, France, Germany, Austria, Australia, and many more parts of the world.

Brexit presents a number of question marks that could prove very unsettling for the UK life sciences industry, and particularly SMEs within it. A number of points require urgent clarification to prevent any pre-emptive movement away from the British market, and stave off doubt over companies' future ability to invest in UK-based medical innovation.

The European Medicines Agency (EMA), a network which authorises marketing across all EU member states, is currently based in London; a testament to Britain's position as a leading medical force. If Brexit signifies a withdrawal from EU institutions it seems highly unlikely that the EMA can remain headquartered in London, and more generally that the UK can remain a member of the EMA at all. This could result in the UK becoming a secondary market; pharmaceutical companies will have to submit a separate application for the UK to the rest of the EU. This is currently the case for Switzerland, and results in a delay on patients gaining access to new medicines. Shield is eager to see productive negotiation with the EU that aims to prevent further complication of regulation, and retains alignment with the EMA.

As an SME, it is already a struggle to compete with the big pharmaceutical companies for highly skilled workers, so any harm to the UK healthcare sector's reputation as a great place to work will have an adverse effect on smaller companies. To this end, addressing the insecurity around free movement of people is imperative to the healthcare sector, as it is to all UK-based industries.

EU funding plays a significant role in the research and development of new drugs; therefore, securing continued access to bodies like the European Investment Bank and European Investment Fund is imperative. Similarly, free trade agreements that are existent between EU and non-EU states need to remain accessible, and the movement of medicines and pharmaceutical supplies across borders should be frictionless to mitigate delays that could prove very costly.

Shield is British and proud, but we cannot guarantee that the UK will continue to be our home without certain assurances. Without these, operating out of the UK may well become too difficult to justify, especially as a smaller company. Either way, it will become clear very soon just what is feasible for Shield, and for much of the sector.

NOVARTIS UK

Changing the practice of medicine

At Novartis, we harness the innovation power of science to address some of society's most challenging healthcare issues. We are passionate about discovering new ways to improve and extend people's lives.

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