FUTURE OF HEALTHCARE

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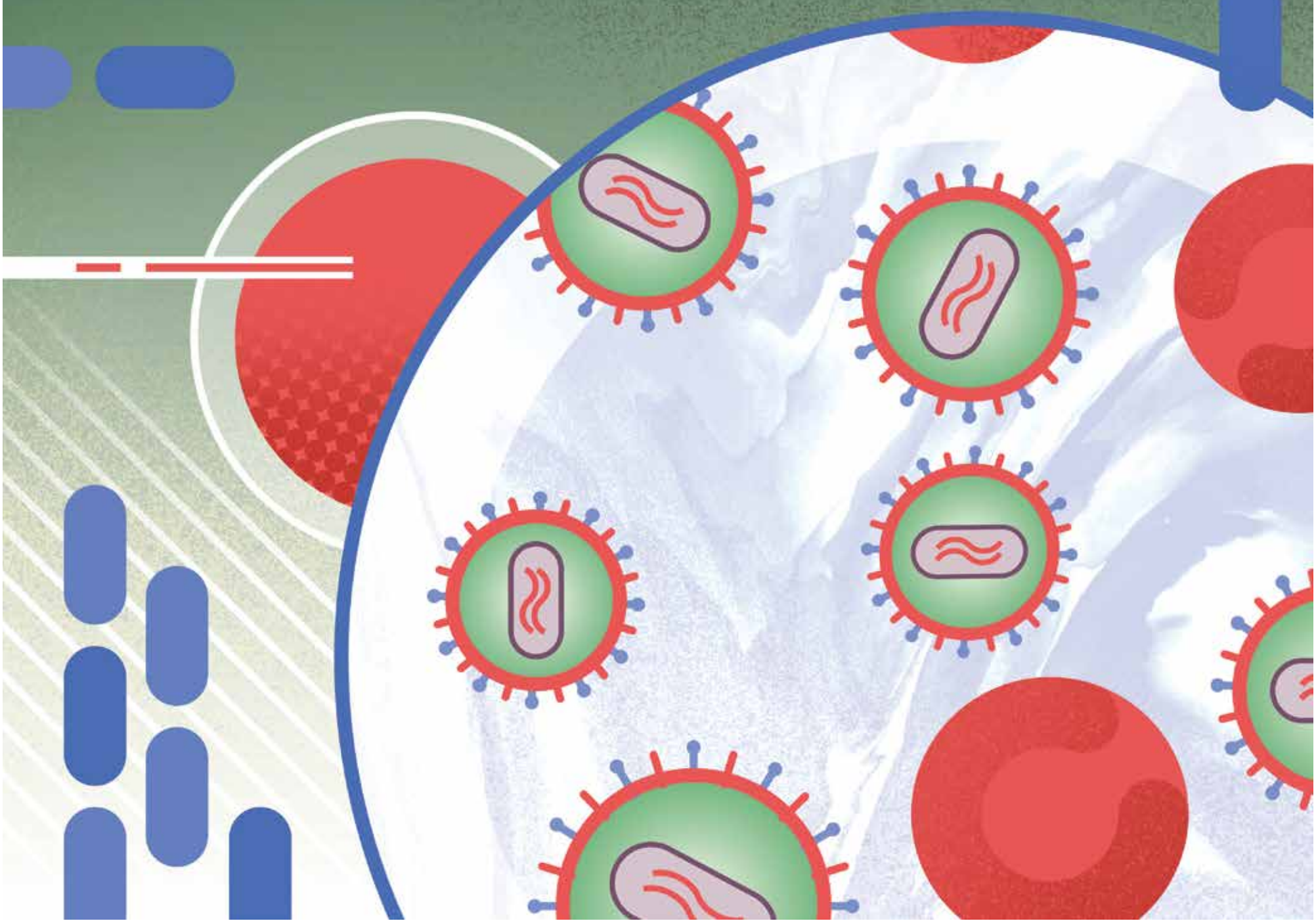

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Gerry Bolger, CNIO, Imperial College Healthcare NHS Trust

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OVERVIEW

UK life sciences can revive healthcare

As the NHS continues to creak under spending constraints and growing demand, the allied life sciences sector may provide some relief for the government and UK economy

DANNY BUCKLAND

The UK's economic reputation was forged by the industrial revolution two centuries distant and, given the uncertainty of Brexit, it is easy to lapse into laments about bygone glories. But questing minds and the relentless pursuit of solutions are propelling a fresh revolution that, although not wreathed in furnace steam and belching fumes, is delivering global success.

The life sciences sector, covering pharmaceutical and clinical innovation and pioneering technology, is providing sinew to the economy and hope for patients who want to enjoy their now longer life expectancy free from debilitating conditions.

The sector pumps £60 billion into the UK economy and supports around 420,000 jobs directly and in supply chains, according to government figures. It is unashamedly described as "one of the jewels in the crown" of the UK economy.

"We have four of the top six universities for clinical, pre-clinical and medical research, and three of the top ten medical schools in the world which is very impressive," says Karen Taylor, research director of the Centre for Health Solutions with analysts Deloitte. "The combination of academia, life sciences and healthcare creates an energy, and is attractive to investment.

"The sector is showing resilience and investment gives the government confidence it can remain an important element of the economy."

The investment figures have been charging upwards – the quoted value of the sector rose from £40 billion in 2015 to nearly £400 billion this year, according to figures from the London Stock Exchange in January – and Brexit has, so far, not put the brakes on.

Ms Taylor believes the seeds for current growth were sewn in David Cameron's Conservative administration and have continued to flourish with tax incentives, development strategies and catalyst funds.

"2017 is predicted as being another strong year," she says. "The attraction of our universities will not diminish. A combination of an innovative and vibrant life sciences sector brings wealth to the country not just in terms of employment and investment, but also in improving the health of the nation."

The government's appetite for life sciences seems unadulterated by Brexit as chancellor Philip Hammond's Autumn Statement, delivered five months after the landmark vote, featured a £2-billion provision for research and innovation which favoured life sciences.


Tom Werner / Getty Images

The sector also received star billing in the *Great Repeal Bill: White Paper*, published last month, which outlines 12 negotiating objectives for exiting the European Union, including making the UK "one of the best places in the world for science and innovation". Significantly, this goal comes with a "desire to continue to collaborate with Europe on scientific initiatives".

The financial imperative of a strong life sciences strand to the economy is matched by the need to address the nation's future health needs, characterised by a creaking National Health Service in search of £20 billion in service savings by 2020 and the population growth of over-65s who are more vulnerable to co-morbidities.

Population modelling is cloaked in dire warnings for the NHS as, by 2039, the over-65s are expected to represent 23 per cent of the population or 17.5 million people, according to the Office for National Statistics. About one in twelve of the population will be aged 80 or over by then.

More treatment needs for longer is not exactly bright mood music for an institution struggling to cope with its role of seeing one million patients every 36 hours.

But Sarah Haywood, chief executive of the influential MedCity UK, the political-private-academic collaboration that promotes life sciences in London and the South East, says: "There are questions and challenges, but there is great positivity about the future. We also have a very entrepreneurial culture with lots of companies setting up with passion and ambition in healthcare."

However, she cautions that access to the global talent, which is a prime element of the nation's academic and innovative attraction, needs to be carefully managed as the UK untangles itself from its EU connections.

Brexit is not the sole disruptive influence in life sciences as the big beasts of the pharmaceutical industry have seen return on innovation investment steadily drop from 10.1 per cent in 2001 to 3.7 per cent in 2016, according to research by Deloitte. Many are restructuring their business models as they grapple with tighter regulations and financial squeezes as well as shrinking profits, claim analysts PwC.

The Association of the British Pharmaceutical Industry has also warned that the biggest drug companies could abandon the UK if treatments continued to be rationed in a cash-strapped NHS. Its president Lisa Anson, who is also head of Astra Zeneca UK, called on the government to be ambitious to ensure the NHS had world-class status.

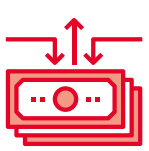
Huge advances in novel drugs and the promise of immunotherapy and gene therapy are causes for celebration, but these triumphs are stalked by the towering burden of non-communicable diseases (NCDs) and the financial constraints of healthcare systems.

The World Health Organization reported last month that NCDs, such as cardiovascular disease, cancers, respiratory diseases and diabetes, kill 32 million people worldwide annually.

The great hope is that devices, monitors and systems driven by artificial intelligence can energise diagnostic and preventative measures so the ruinous surge of NCDs can be arrested.

Public policy research centre the Rand Corporation recently published a paper on financial incentives for individuals and communities to promote better health, underscoring the view that exciting developments in healthcare will be handcuffed to some fundamental changes in how the public behaves.

The healthcare landscape is dynamic, and the big challenge is how society and government embrace innovation and remodel the future of health.



£60bn
estimated contribution of the life sciences sector to the UK economy

Office for Life Sciences

420k
jobs supported by the sector directly and indirectly through its supply chains

3.7%
return on innovation investment for big pharmaceutical companies in 2016, down from 10.1 per cent in 2001

Deloitte

NHS AND DATA

Sharing data is a matter of digital trust

Used ethically, NHS patient data has the potential to improve healthcare and save lives

dchinthamb/Shutterstock

Google's AI subsidiary DeepMind Health was given access to five years' worth of patient data for 1.6 million people by the Royal Free NHS Foundation Trust

JOANNA GOODMAN

Instances of identifiable NHS patient information being shared without explicit consent have raised concerns about data access and privacy.

The Information Commissioner's Office and the National Data Guardian for Health and Care are investigating the transfer of five years' worth of patient data for 1.6 million people between the Royal Free London NHS Foundation Trust and Google artificial intelligence (AI) subsidiary DeepMind Health. While the intent behind the data-sharing agreement was altruistic, a recent academic paper described it as controversial and inexcusable.

The paper, by Cambridge University academic Julia Powles and *New Scientist* journalist Hal Hodson, claims that the terms of the partnership are misleading. Although the data was used to create Streams, a smartphone app that helps clinicians manage acute kidney injury (AKI), the agreement allowed for broader collection of unrelated patient data. Central to the agreement is the definition of "direct care" which carries "implied consent" to data-sharing.

Another key consideration is data value, in terms of bringing advances in healthcare that benefit individual patients and the wider community, and potential commercial benefits.

In this respect, the Royal Free deal is not unique. DeepMind Health is working with several NHS hospitals, including Imperial College, Moorfields and University College London Hospitals.

Nor is DeepMind the only technology company working with the NHS. IBM Watson is working with Alder Hey Children's NHS Foundation Trust and a further 90 companies are using or proposing to use AI to support diagnostics and patient care. All these projects involve private companies accessing and utilising patient data.

Research into public attitudes about health data shows that people are generally happy for their data to be used for research, but become uncomfortable if a commercial organisation is involved.

A survey by the Wellcome Trust and Ipsos MORI found people were largely unaware of how their health data is already being used, and that the greatest objections arose around the possibility of insurance and marketing companies accessing personal data.

And much of the concern about DeepMind's involvement with the NHS relates to its association with Google, notwithstanding DeepMind founder Mustafa Suleyman's assurances. "The data that we access from the NHS will never be connected or associated in any way whatsoever with any Google data," he told the *BMJ*.

These concerns were reflected in the recommendations by national data guardian Dame Fiona Caldicott, in a letter to the health secretary Jeremy Hunt, which included proposals for a new consent model for data-sharing in the NHS and social care. "There needs to be a much more extensive dialogue with the public about how their information will be used, and the benefits of data-sharing for their own care, for the health and social care system and for research," she wrote.

Last month, Wellcome launched Understanding Patient Data, an independent patient data taskforce and website, to provide information about how and why patient data is used.

The initiative is led by Nicola Perrin, head of policy at the Wellcome Trust. "New data-driven technologies have the potential to transform healthcare," she says. "The Royal Free's Streams app has alerted clinicians to 11 patients a day who were at risk of AKI and is saving nurses two hours a day. But the NHS will only be able to make the most of the opportunities new technologies offer to improve healthcare if the public has confidence in how data is used."

To maintain patients' trust, the NHS needs to ensure they understand any use of their data beyond their own direct care. This also means establishing public confidence in partner organisations. "The DeepMind-Royal Free case is a reminder of how important it is to get the right governance frameworks in place when developing these partnerships, to ensure everyone can have confidence that data is being appropriately protected," adds Ms Perrin.

The AXA PPP Health Tech & You Awards was dominated by tools predicated on leveraging patient data. And there was a sharp focus on patient information and consent. Winner of the Health & Care Professional's Choice Award, uMotif, is a platform that captures patient-generated health data for NHS, academic and corporate research projects.

> The NHS will only be able to make the most of the opportunities new technologies offer to improve healthcare if the public has confidence in how data is used

"Patients volunteer their data because they want to make a difference," says founder and chief executive Bruce Hellman. "They know their data is used only for ethically approved projects, and that they can choose which research to participate in and which data to share."

At DeepMind, Mr Suleyman is introducing the Verifiable Data Audit, a mechanism to enable partner hospitals to check in real time how their data is being processed.

Establishing trust means respecting the value and ownership of patient data, rather than its economic implications. Ms Perrin highlights "the economic value to UK plc" as a contributory factor to the spectacular failure of the NHS care.data initiative.

She says: "NHS Digital explicitly states that it does not charge for data. We need to have better conversations about the value of the data to the NHS, the role of companies and technology providers. Until the benefits are more clearly understood, there is probably a risk of damaging public confidence even further by talking about commercial value and patient data in the same breath."

There is general recognition that NHS patient data can be used to improve healthcare and save lives. The underlying issue is trust. We need to be able to trust our healthcare providers to use patient data in a way that benefits the population's health while respecting patient confidentiality and data privacy.

COMMERCIAL FEATURE

Partnering in the nation's health

The National Health Service is under growing pressure as the demand for new and effective treatments, services and solutions increases

SANOFI

The UK's population is ageing. Medical advances mean people are living longer. When the National Health Service was created, life expectancy was 13 years less than it is today. Vaccines now play a vital role in preventing death and disability. Heart attacks no longer take the lives of as many people. Even cancer is not the death sentence it once was.

But this progress has come at a cost. People are living longer with a growing number of long-term chronic conditions such as diabetes, heart disease and dementia. The average 65 year old costs the NHS 2.5 times more than the average 30 year old. An 85 year old costs more than five times as much. The cost to the NHS therefore continues to rise.

HUGO FRY
GENERAL MANAGER FOR THE UK, AND GENERAL MANAGER OF SANOFI PASTEUR FOR THE UK AND IRELAND

IMPROVING THE HEALTH OF THE NATION TODAY

"At Sanofi, we have deliberately established ourselves as a truly diversified healthcare company. We accompany people on their full healthcare journey from birth through to old age, contributing wherever we can make a difference," says Hugo Fry, general manager for the UK, and general manager of Sanofi Pasteur for the UK and Ireland.

"Through our five distinctive but complementary global business units, we support those living with chronic diseases such as diabetes and cardiovascular disease, innovate in specialty care conditions including multiple sclerosis and rare diseases, prevent death and disability through vaccination, and empower millions to take charge of their own wellbeing with effective self-care solutions."

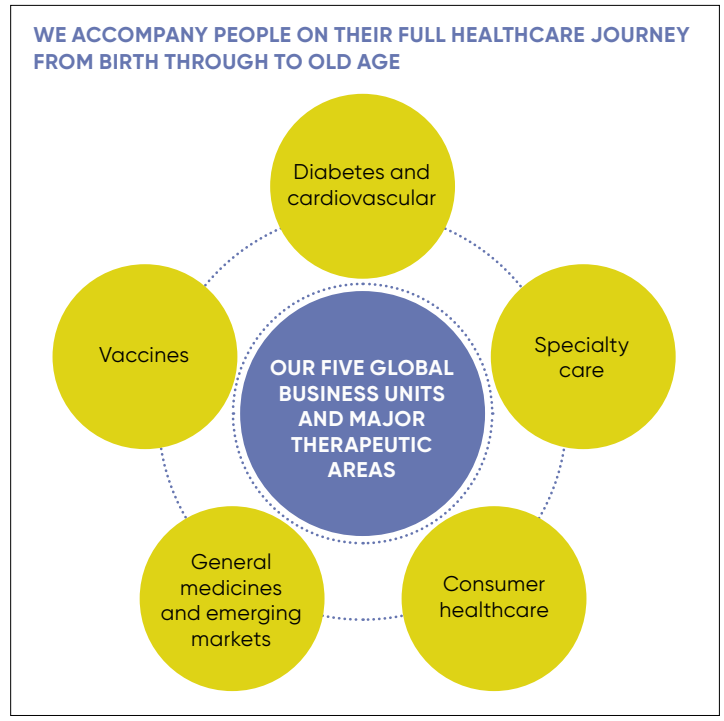
In complex, resource-constrained times, Sanofi supports the NHS in reaching their healthcare goals. We strive to add value on top of innovation to deliver effective and affordable prevention and treatment accompanied by the highest quality of value-added services and solutions.

Sanofi tackles health challenges collaboratively in the UK. We work in partnership with the NHS. We have a number of joint-working projects up and running. Another eight are in development, all aimed at improving quality of care for people living with diabetes and cardiovascular diseases.

We actively partner with patient and professional groups to support the prevention and treatment of diseases that significantly impact the wellbeing of the population and the UK healthcare system. We develop not only the treatments, but also the services and solutions that accompany them.

In multiple sclerosis, for example, we supply a personalised one-to-one support programme and home delivery that complements existing care provided by the NHS. We protect the health of the nation by working to increase vaccine coverage rates among at-risk populations through access to educational resources and tools such as vaccination reminders.

We are also committed to further enable self-care and reduce the burden on healthcare services. We provide access to sharps bins, demonstration materials, and online self-management tools to equip and empower people to manage their own condition effectively.



SHAPING TOMORROW'S HEALTH

Medicine is constantly evolving. Extraordinary advances have been made in fighting disease and extending life, but we need to innovate continually to bring effective life-enhancing medicines and devices to the UK.

Sanofi is committed to sustaining our innovation in research and development, expanding our pipeline in leadership categories including diabetes and rare diseases, and rebuilding a competitive position in oncology. Our pipeline contains 43 pharmaceutical new molecular entities, excluding life-cycle management, and vaccine candidates in clinical development of which 12 are in phase III or have been submitted to the regulatory authorities for approval.

In the UK, we have more than 2,000 people involved in clinical trials, and worldwide Sanofi invests €5 billion every year, rising to €6 billion by 2020, to develop and identify new innovative treatments to meet the needs of people across the globe.

We view our scientific partnerships and the launch of new treatments as critical. We have therefore strengthened the efficiency of our industrial resources. Regardless of where our treatments are manufactured, our industrial network provides both healthcare professionals and patients with the highest quality and maximum safety.

INVESTING IN PEOPLE AND COMMUNITIES

Our dedication to make a real difference to the lives of people every day is fundamental to how we operate our business. In 2015, we had 280 corporate social responsibility initiatives, benefiting more than 300 million people worldwide. We contribute to initiatives with groups such as the World Health Organization, and organisations supported by the Bill and Melinda Gates Foundation such as the Global Alliance for Vaccines and Immunisation. In the UK and Ireland, we have multiple corporate charity partnerships to provide a platform to drive positive change in communities.

We commit to diversity, inclusion and professional development of our employees. We see this as fundamental to delivering the best for the people whose lives we touch. Efforts around talent management and retention have been recognised by Investors in People and the UK is rated a top employer by the Top Employer Institute for providing exceptional conditions for employees and developing talent.

Mr Fry concludes: "Sanofi is a partner in improving the nation's health. We are dedicated to empowering people to live life to the fullest and engaging with our healthcare stakeholders to deliver real value beyond our medicines."

For more information please visit www.sanofi.co.uk

ABOUT US

Sanofi is a global healthcare leader committed to the discovery, development and distribution of therapeutic solutions focused on the needs of the people we treat. Improving access to healthcare and providing the best support to you through a full continuum of care – from prevention to treatment – guide our actions day by day. In the context of a changing world, we are all facing greater health challenges. We strive to transform scientific innovations into therapeutic solutions that make a difference to your daily life wherever you live and enable you to enjoy a healthier life. Sanofi is organised into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare.

SAGB.SA.17.04.0495 Date of Prep: April 2017

What is the true price of good health?

With notable examples of price hikes, there is a public perception that drug companies attempt to rip off the NHS

DANNY BUCKLAND

Survival rates for cancer have doubled over the last 40 years and there are enough bright, "golden ages" of medical advances to blind even the most sceptical.

Molecular mechanisms that baffled and confounded for a generation are now being picked apart by genetic code-crackers with regular success while "breakthroughs" have almost acquired cliché status.

There is great promise from generics and biosimilars, copies of standard and biologic pharmaceuticals, which lower costs of treatment regimes across a spectrum of conditions. Every day we take a step closer to personalised medicine where therapies can be tailored to individuals.

But, despite these triumphs, there is a perception that pharmaceutical salvation is being charged at too high a price.

The National Institute for Health and Care Excellence (NICE), the government agency that evaluates drugs for use in the National Health Service, has rejected treatments for breast and lung cancer, multiple myeloma, multiple sclerosis and pancreatic cancer over the last year alone on cost grounds.

NICE applies a strict formula that calibrates the number of good health quality years gained against price when judging if a drug should be made available on the NHS. Its litany of refusals sparks outrage from charities and patient populations, but it also lasers attention on to pharmaceutical company balance sheets.

They are an easy target and US President Donald Trump used the first press conference of his administration in January to promise that drug prices would be slashed to save millions of dollars. In a further blow to pharma, approved drugs can now be stalled for up to three years if the NHS deems them too expensive, costing more than £20 million in the first three years, potentially forcing companies to abandon the UK as a market.

The atmosphere is further darkened by the government's consumer watchdog, the Competitions and Markets Authority (CMA), investigating huge price hikes in some drugs.

It issued a record £90-million fine against drug giants Pfizer and distributers Flynn Pharma for allegedly charging excessive prices to the NHS for the anti-epilepsy drug phenytoin, the price of which rocketed from £2.83 for a 100mg pack to £67.50 after it was debranded. GSK picked up a £44.9 million fine for allegedly manipulating the market to minimise the impact of generic copies on its £90-million-a-year blockbuster anti-depressant Seroxat. Both cases are being appealed.

> There is a perception that pharmaceutical salvation is being charged at too high a price

The Department of Health is promoting a new Bill enhancing government powers to act on excessive price hikes on unbranded drugs. A spokesman says: "No pharmaceutical company should exploit the NHS. We are working closely with the CMA on unwarranted price rises of unbranded generic medicines and, where companies have breached competition law, we will seek damages and invest that money in the NHS."

This legislation is trained, principally, on the generic and biosimilars market where rival companies create copies of branded medicines and start selling them when the original patent expires, usually after 20 years.

The practice relies on competing firms and hard-bargaining high street pharmacies to keep prices down. The British Generic Manufacturers Association (BGMA), which represents 90 per cent of companies that produce one billion prescription items annually, believes the competition has seen some named drug costs drop by up to 95 per cent and a notional £13 billion saving for the NHS on branded drugs.

"There is a benefit in saving money in itself, but this competition also increases access to medicines," says Warwick Smith, BGMA director. "There was a study when the statin Simvastatin came off patent which showed that the price dropped by 95 per cent with the introduction of generics while the use of all statins increased. The result was more people were being treated for a lower overall cost."

Generics and biosimilars suppliers have freedom of pricing on most drugs, but the government can step in to stabilise the market in some cases and these powers will strengthen with the new legislation.

"The system works well with the pharmacists as effectively the government's gatekeeper, but if the price goes down too much the manufacturer will not sell. It is a flexible supply-and-demand system that drives low prices," says Mr Smith. "Data shows we are in the top three countries in Europe for low prices, with average charges in Europe around 3.5 times more than the UK.

"But we need a mechanism for drugs where there are no competing suppliers. We would never defend putting the price up for no good reason. We exist to drive access for patients, but we are commercial companies and we need a return and prices at a sustainable level that will allow us to keep putting these products into the market."

It is easy to be seduced into thinking that the stratospheric returns for some blockbuster drugs – the top three generated $18 billion sales in 2016 – means pharma companies are drowning in prof-


Spencer Platt/Getty Images

Pfizer and Flynn Pharma were fined £90 million collectively for allegedly charging the NHS excessive prices for phenytoin

its, but for every successful drug there is a $1-billion bill and nine out of ten drugs fail to make it to market.

"Society almost banks medical successes and treats them like they've always been there," says Dr Virginia Acha, executive director of research, medical and innovation at the Association of British Pharmaceutical Industry (ABPI), which represents companies that supply more than 80 per cent of all medicines used by the NHS.

"My father had polio as a child; how many people now have childhood polio? My son is 20 and has no memory of anyone having mumps. Over time, these innovations become part of normal health and the bar continues to be raised. The bigger question for society is what do you expect from healthcare of the future?"

David Watson, the ABPI's director of pricing and the Pharmaceutical Price Regulation Scheme, the voluntary arrangement aimed at ensuring fair prices and a safe and effective drug supply, says: "Industry struggles to communicate the value of medicines. There are some new medicines that are very expensive, but they end up being used in a small patient population with complex conditions, while you have widely used medicines that were expensive 20 years ago but are now much cheaper.

"The bigger picture is that we are at risk of demonising the price of medicines. The UK spends relatively little on healthcare compared to some countries and, within that, a bit less than some other countries on medicines. We are not massively generous. It was recently said that we spend more on gin in the UK than we spend on cancer drugs."

Steve Arlington, director of the Pistoia Alliance, a global, not-for-profit organisation of life science companies, technology and service providers, publishers, and academic groups, believes drug-pricing strategy in the UK needs radical restructuring.

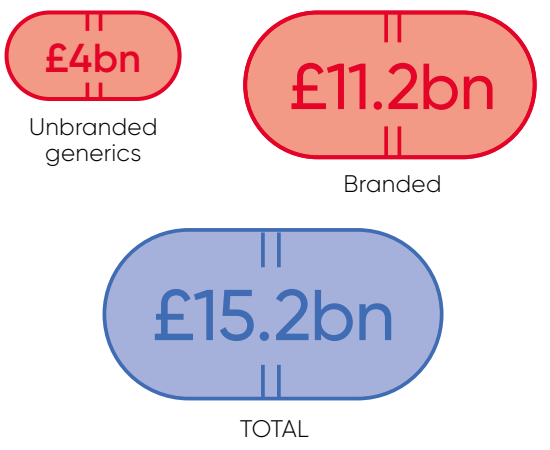
"The British public are being done a disservice as we are no longer able to have access to top-quality life-extending drugs because of the parameters applied by NICE," he says.

The nation's reputation as a medical powerhouse is being eroded and important clinical trials are being lost to other countries as patients in the UK are not on gold-standard treatments which are needed for trials for newer, even better drugs, he claims.

"We are losing ground and are no longer approving drugs in the NHS so when global pharma companies launch new drugs, the UK does not come into the dictionary," Mr Arlington concludes, calling for greater collaboration between industry, government and regulators. "At the moment, we have an adversarial set-up which is actually driving up costs and not serving the public well."

NHS ENGLAND'S SPENDING ON MEDICINES

FOR THE FINANCIAL YEAR 2015 TO 2016



Department of Health 2016

> We have an adversarial set-up which is actually driving up costs and not serving the public well

PRESCRIPTION DRUGS OUTLOOK

Worldwide sales of prescription drugs are set for strong growth over the next half-decade and most of this growth will be driven by the prospects for a raft of new products coming on the market. However, strong competition from generics, the loss of sales following patent expiration and the constant uncertainty over drug approvals puts these forecasts at risk

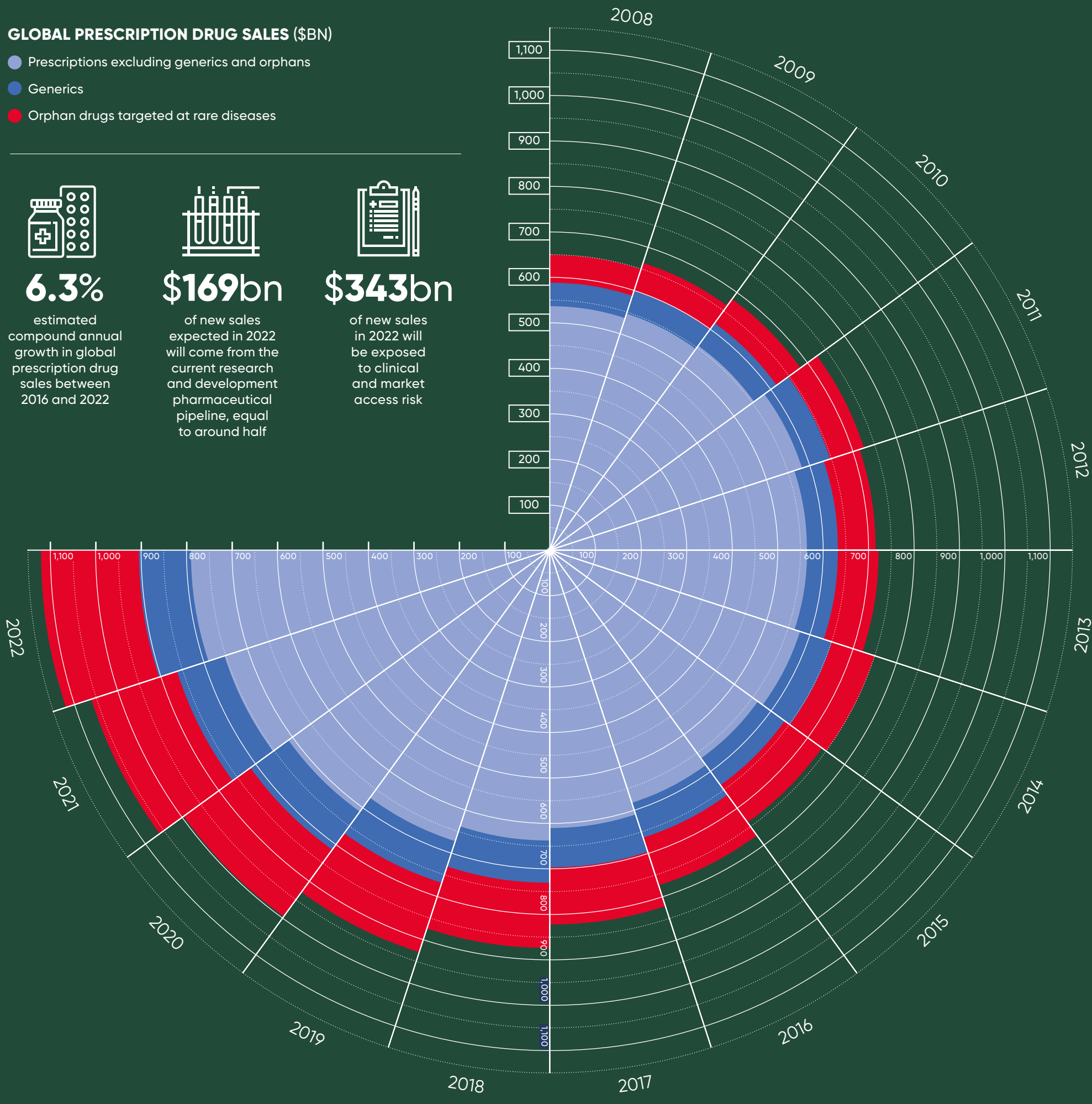
GLOBAL PRESCRIPTION DRUG SALES ($BN)

- Prescriptions excluding generics and orphans
- Generics
- Orphan drugs targeted at rare diseases

6.3%
estimated compound annual growth in global prescription drug sales between 2016 and 2022

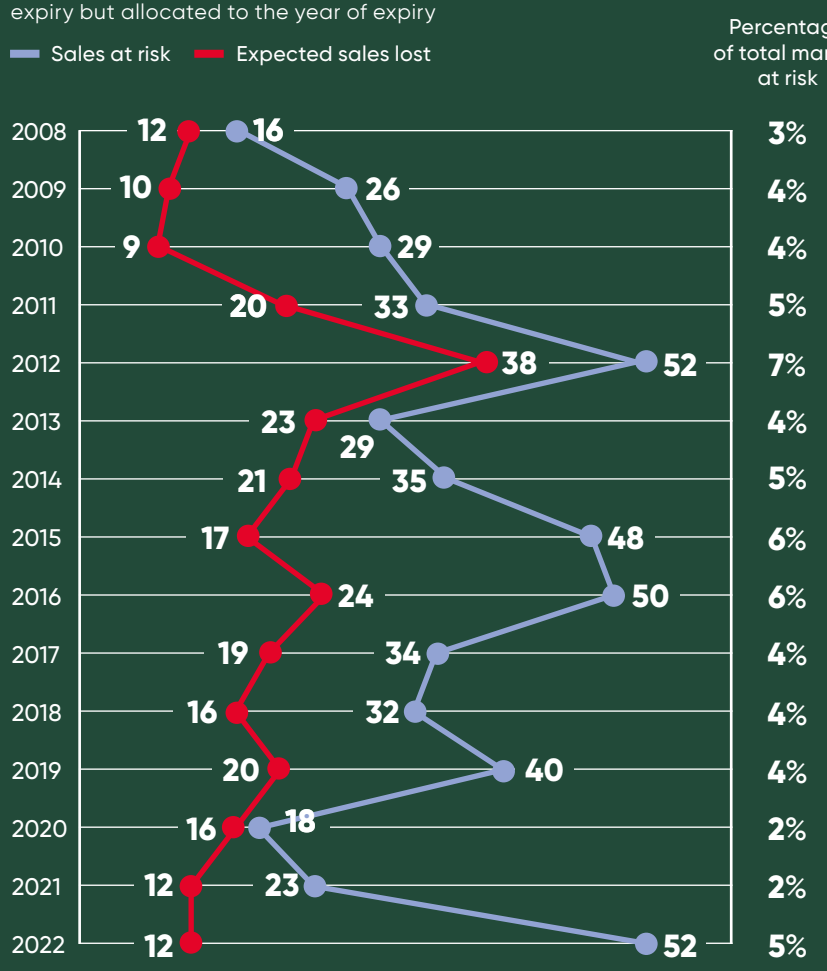
$169bn
of new sales expected in 2022 will come from the current research and development pharmaceutical pipeline, equal to around half

$343bn
of new sales in 2022 will be exposed to clinical and market access risk

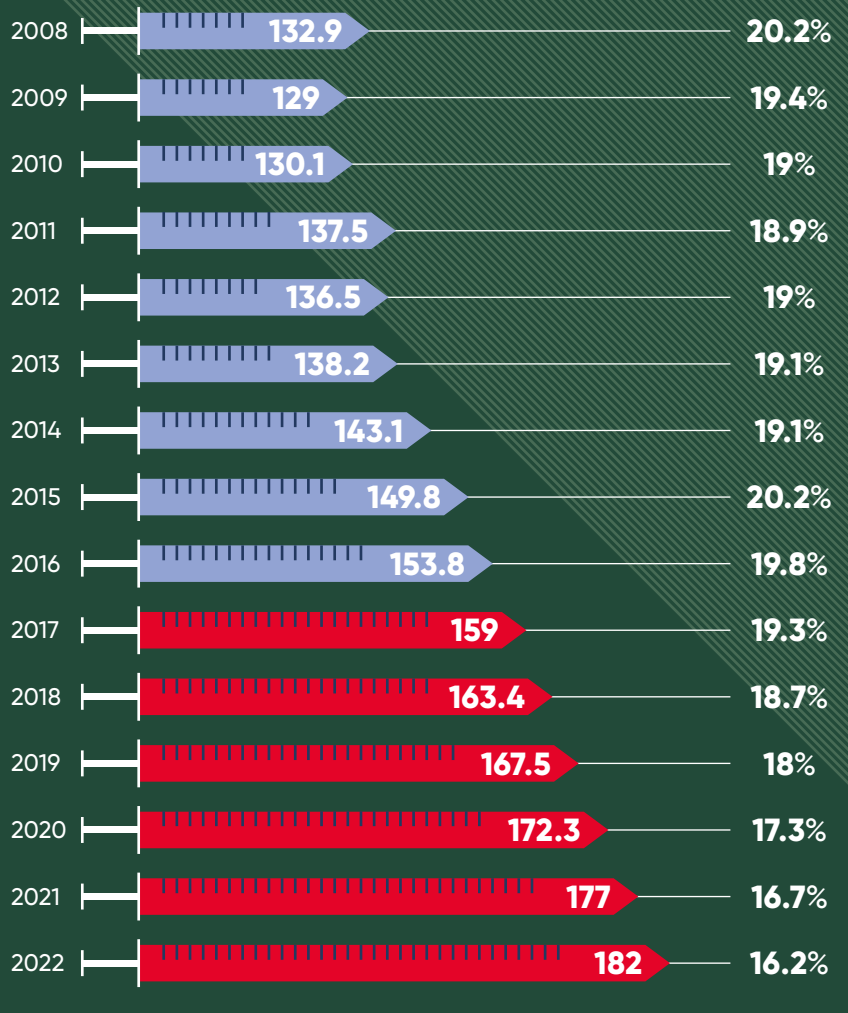


GLOBAL PRESCRIPTION DRUG SALES AT RISK FROM PATENT EXPIRATION ($BN)

Sales at risk represent product sales in the year prior to patent expiry but allocated to the year of expiry

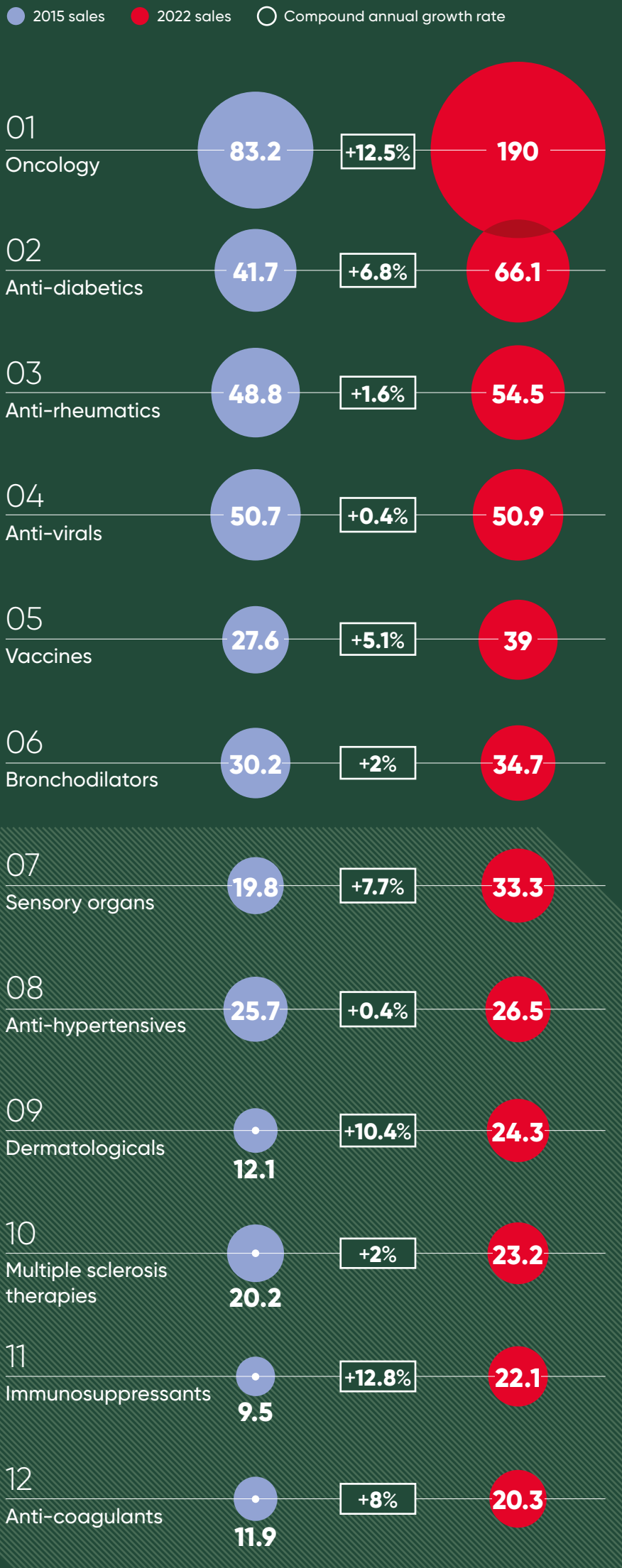


GLOBAL PHARMACEUTICAL RESEARCH AND DEVELOPMENT SPEND ($BN)



GLOBAL PRESCRIPTION AND OVER-THE-COUNTER DRUG SALES ($BN)*

COMPARING SALES IN 2015 AND 2022 BY CATEGORY



*Industry sales are based on the top 500 pharmaceutical and biotechnology companies

EvaluatePharma 2016

HIV AND PrEP

Call for preventative HIV drug on NHS

Taking antiretroviral drugs to prevent contracting HIV has greatly reduced infection, but so far success has been achieved by DIY campaigners

Justin Sullivan/Getty Images

GONZALO VIÑA

Rarely has the fight against disease been so dramatic and unexpected, but a DIY insurgency against HIV helped infection rates plummet in the British capital last year.

Two websites offering advice on PrEP – pre-exposure prophylaxis or the practice of taking antiretroviral drugs to prevent contracting HIV – has helped cut infections recorded at four London sexual health clinics by 40 per cent.

While the clinics themselves offered essential support in the effort, use of PrEP among the highest group at risk from infection – sexually active gay men – has increased dramatically over the last 18 months through word of mouth and thanks to social media.

"We have created a community out of hope and created a substantial shift in the way community healthcare has been provided," says Greg Owen, who runs the website *I Want PrEP Now*, which offers advice on how to buy the treatment. Mr Owen launched the site following a deluge of questions after posting on Facebook that he would be using PrEP.

Few now question the effectiveness of PrEP in reducing the spread of HIV. One of the most-commonly cited studies, known as PROUD, showed when it was published in *The Lancet* that PrEP helps prevent 17 out of every 20 HIV infections. And those who did contract the virus had failed to properly adhere to the treatment, suggesting the efficacy of PrEP is closer to 100 per cent.

The drug most commonly used in PrEP is Truvada, which prevents HIV cells from replicating. The branded drug developed by US pharmaceutical giant Gilead costs around £400 which has proven prohibitive for many as a private prescription and has been similarly unaffordable for mass rollout by the NHS.

Mr Owen's site, working with sexual health clinics such as 56 Dean Street in London's Soho, has helped verify the quality of cheaper generic copies of Truvada manufactured in India and other countries in the developing world. The monthly cost for the treatment has plunged to about £40. Mr Owen says he hopes soon to be making the treatment available for as little as £20 a month to the more than 18,000 people who use his site on a monthly basis.

> This is about preventing transmission, but the PrEP debate gets tainted with a special significance

Will Nutland, of the London School of Hygiene and Tropical Medicine, says the effort should be seen as part of a broader set of campaigns that promote early diagnosis, access to antiretroviral drugs for those who are HIV positive as well as PrEP use.

Still, even though cities such as San Francisco, where infections dropped 17 per cent in 2015 following its Getting to Zero campaign, something different has happened in London.

"I have worked on HIV for 25 years and what we have seen with PrEP has been a massive change that I have never seen before – it's completely unprecedented," says Dr Nutland, who founded the PrEP advice website *Prepster*.

He estimates that as any as 6,000 people, some now from other European cities, are being directed from Mr Owen's UK site to online pharmacies based overseas for PrEP.

Sheena McCormack, professor of clinical epidemiology at University College London, who led the PROUD trials, attributes the success in London to the opening of the Dean Street clinic in 2015 and the two websites that have helped make PrEP more commonplace.

17/20

HIV infections were prevented by PrEP in a 2015 study

PROUD 2015

"The endorsement of the clinic has been important, but the website is the one place people can go and be confident about the source of the drugs," she says.

But for all the successes, on average 17 people are diagnosed with HIV every day in the UK for whom PrEP is not available, according to the British HIV Association (BHIVA), a body representing those who work in HIV care.

Even Mr Owen concedes: "There is no way I can offer a wrap-around service for everyone. I love the website, but it is unsustainable in the long term."

Unlike the United States, France, Norway, Australia, Israel, Canada, Kenya and South Africa, the UK has yet fully to approve PrEP use.

NHS Scotland announced last month that it will offer PrEP, while NHS Wales has advised against, pending a large-scale study.

But the biggest and most contested decision on whether to provide Truvada or a generic copy as a prophylactic has yet to be taken by the NHS in England, which said it would make the treatment available after losing a High Court battle. It has promised to start a trial during the summer for 10,000 people.

Chloe Orkin, who chairs BHIVA and is a consultant physician at the Royal London Hospital, says the attitude of the NHS in England has been "very disappointing".

"We don't need another trial. The justification for this trial is not to see whether it works, but simply to see how they should implement using PrEP," she says.

The NHS fears that rolling out PrEP could end up costing between £10 million and £20 million a year, taking a significant chunk of its £25-million budget for new treatments against rare diseases.

Professor Orkin says decisions on which treatments are given priority are taken on grounds of effectiveness and value for money, and PrEP provides both.

"This is about preventing transmission, but the PrEP debate gets tainted with a special significance. But sex is a behaviour and we don't hold back on other forms of preventative treatments whether it's cervical screening or the pill," she says. "We have a real chance to change the course of this epidemic." ●

PROJECTED LIFETIME HEALTHCARE COSTS ASSOCIATED WITH HIV

Based on a study of 10,000 men aged 30 with HIV and a median life expectancy of 71.5 years

£360.8k
estimated mean lifetime cost of treating one person

68%
of these costs are attributed to antiretroviral drugs

£179k
estimated lifetime treatment cost if patented drugs are replaced by generic versions

OPINION COLUMN

‘The next government must have a clear strategy to grow the UK’s status as a world leader in innovation and access to medicines’

MIKE THOMPSON
Chief executive
Association of the British Pharmaceutical Industry

The men and women who work in the pharmaceutical industry make a positive contribution to millions of patients, every day, in every corner of the world. We help to change, improve and save lives.

With 7,000 medicines in the pipeline, we are in a golden era of medicine. Innovation in conditions such as cancer care, where the speed of the science has helped us to make strides in treating the disease, and advances in gene and cell therapies and immunotherapies have the potential to change healthcare globally. The UK is already at the forefront; a heavyweight in medicines discovery. Our academic and research institutions are among the best in the world.

Over the course of my career, I’ve seen medical advances transform HIV/Aids from a death sentence to a manageable, chronic condition and the advent of curative treatments for diseases such as hepatitis C, which can now be cured with just a 12-week course of pills. Our scientists spend their entire lives searching for ways to make our lives better. Some devote their careers to just one disease.

We have a unique opportunity do this by capitalising on the potential of the National Health Service. Through its large patient populations and vast networks of expertise, we can make the NHS the best place in the world to research, develop and use new medicines.

The use of real-world data is central to achieving better patient care through a more productive and efficient NHS. The pioneering Salford Lung Study, a groundbreaking collaboration between the University of Manchester Health Informatics, the NHS and GSK, used electronic health records to carry out clinical trials in near real time. Initial results suggest the data from the trials could transform our understanding of chronic obstructive pulmonary disease and how patients respond to treatments. These real-time clinical trials are key to understanding diseases in our population and will be vital in helping us develop the safe and effective treatments of the future.

But uptake of new treatments and technologies in the UK is slow in comparison with other developed countries. For every 100 patients who receive a new medicine in its first year of launch in comparable countries, including Germany, France, Canada, Australia and the United States, only 18 will get it in the UK.

Ahead of the general election, it is important that the next government have a clear strategy to secure and grow the UK’s status as a world leader in innovation and access to medicines.

Whoever is in power come June 8 must have a strategy to make NHS patient outcomes among the best in the world. This should start with a plan to increase healthcare investment to the G7 average of 11.3 per cent of GDP compared with the 9.9 per cent we currently spend. The best way to do this is through an effective industrial strategy with the life sciences sector at the heart of it.

As we enter what is arguably the most challenging period for our sector and as we look to exit the European Union, the new government must secure a new relationship with the EU which retains co-operation, and secures an agreement that prioritises public health and ensures the swift availability of medicines for patients. Some 500 million people across the EU depend on this.

Science innovation has helped increase UK life expectancy by ten years since the 1960s. For every success, there have been thousands of failures. It is easy to forget what our industry has done to help people live longer, better lives.

The prime minister says: “It is hard to think of an industry of greater strategic importance to Britain than its pharmaceutical industry.” We should be proud. We must be ambitious for the future.

In my 20-plus years in this amazing industry, I’ve learnt one important lesson above all others. If you put the patient at the centre of any decision, you will not go wrong.

COMMERCIAL FEATURE

How to get life-saving new medicines within the NHS budget

We are living in an era of rapid scientific discovery. Significant advances in our understanding of human biology and genetics are creating the possibility of new treatments that can dramatically improve or cure some of the most common and debilitating diseases known to man

Since its creation in 1980, Amgen has been a pioneer in the science of using living cells to make biologic medicines. In less than 40 years, it has grown from a single building in California to a worldwide leader in biotechnology and the seventh largest pharmaceutical company in the world by market capitalisation. Today it has a valuable portfolio of therapies to treat cancer, cardiovascular, bone and kidney disease.

Key to Amgen’s success has been its approach to research and development. With a focus on treatments for patients with the most serious illnesses, it is using advanced human genetics to shed new light on the molecular roots of many diseases.

These medical advances are coming though at a time when healthcare budgets are increasingly strained, the result of ageing populations and a rise in the number of people living with chronic diseases including cancer and dementia. How healthcare systems reconcile these increasing demands for care and benefit from this new wave of medical innovation is a significant issue for us all.

According to John Kearney, managing director for Amgen UK and Ireland: “The challenge facing healthcare systems and companies like Amgen is how to work together so patients can have quick and consistent access to new medicines that help them live longer and healthier lives. This also includes finding more efficient and effective ways of delivering healthcare”.

Amgen has been at the forefront of companies that are working with local NHS organisations in England to enhance the delivery of patient care, with over 30 active projects that directly impact more than 15,000 NHS patients.

160
treatment opportunities freed up in a clinic each month by treating patients at home

100%
rating from patients for both satisfaction and meeting their needs

The multi-award winning project with the Clatterbridge Cancer Centre NHS Foundation has resulted in more patients being treated closer to home, reducing their travelling times and costs as well as improving patient satisfaction with their treatment. It also saved the NHS money and freed up important space on the cancer ward.

While local NHS organisations have been quick to work with companies like Amgen, Mr Kearney believes that “more needs to be done by NHS leaders to speed up and replicate these new and best practices across England”.

He also believes that the fragmented nature of decision-making in England works against the quick and consistent use of new medicines across the country. “We agree the price of new medicines with the Department of Health, NICE [National Institute for Health and Care Excellence] makes recommendations on the use of new medicines to the NHS, while the NHS manages the healthcare budget. The reality is that each of these organisations is working to a different agenda so we lack a coherent approach to the introduction to new medicines,” says Mr Kearney.

“I believe we need a new strategic partnership with government, NICE and the NHS to answer the conundrum on how we accelerate the use of innovative new medicines while balancing the need for the NHS to work within its budget. In England, this would create a singular agreement about the pricing, introduction and use of new medicines.”

Amgen are encouraged that last year prime minister Theresa May launched an industrial strategy and the life science sector remains one of its priorities.

As a company which has developed from a single building in California less than forty years ago, Mr Kearney’s message to government from Amgen is clear: “No matter how much you do to help a company discover, develop and make new medicines, this time and investment will be wasted if healthcare systems do not enable patients to have quick and consistent access to these new medicines.”

For more infomation please visit www.amgen.co.uk

GENE-EDITING TIMELINE

Timeline of scientific discovery is transforming people's lives

Gene editing has emerged from a long chain of discovery. These are just a few examples highlighting the international collaboration which shines through the CRISPR-Cas9 story

JOHN ILLMAN

1856–1863
FATHER OF GENETICS

Austrian monk Gregor Mendel revealed the probability of genes passing from generation to generation. In cross-pollinating pea plants that produce either yellow or green pea seeds exclusively, he found the first offspring generation always had yellow seeds, but that the next generation had a 3.1 ratio of yellow to green.

1869
IDENTIFYING DNA

Swiss doctor Friedrich Miescher, who turned to research because of a hearing problem, became the first scientist to identify DNA as a distinct molecule, thanks to his study of blood cells from the pus of discarded bandages.

1953
DISCOVERY OF DNA STRUCTURE

Cambridge researchers Francis Crick and James Watson revealed that the human blueprint is wrapped in a double-helix structure, like a twisted rope ladder, with three billion rungs or letters. Knowing how DNA is put together helps today's scientists take it apart.

1961
CRACKING THE DNA CODE

RNA or ribonucleic acid transmits messages encoded in DNA. In discovering how RNA works, American biochemist Marshall Nirenberg revealed how DNA directs the building of proteins and thus of life itself.

1977
DNA SEQUENCING

British biochemist Frederick Sanger invented a method for "reading" the "letters" of the genetic code. He was the first scientist to decode the complete genome of any organism and his approach increased by a thousand times the rate at which scientists can sequence DNA.

2003
COMPLETION OF THE HUMAN GENOME PROJECT

The $3-billion, 13-year project enabled scientists to read nature's complete genetic blueprint for building a person. The number of single gene aberrations known to cause disease jumped from around 100 to nearly 3,000 and more than 200 genes were now linked to cancer, nearly three times the previous number.

2005
DISCOVERY OF CAS9 PROTEIN

Alexander Bolton, of the French National Institute for Agricultural Research, made the discovery while studying bacteria.

1983
COPYING DNA

US biochemist Kary Mullis developed a technique that can produce in a few hours 100 billion copies of DNA from, say, a single human hair, a drop of blood or a 40,000-year-old woolly mammoth frozen in a glacier. Polymerase chain reaction has many uses, from gene analysis to diagnosis of hereditary diseases.

2002
CRISPR

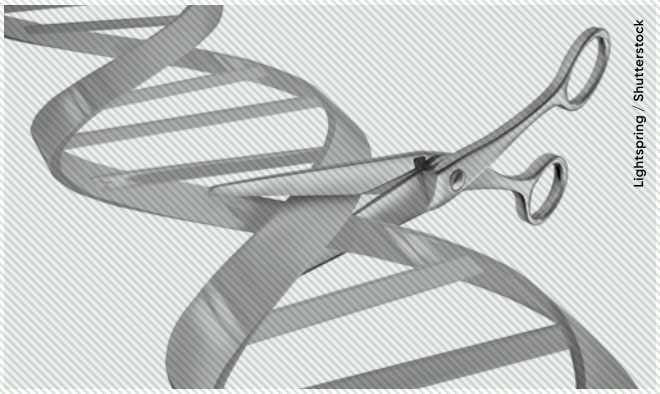
Dutch scientists first coined the term CRISPR.

2012
CRISPR-EDITING TOOL

Jennifer Doudna, of the University of California, Berkeley, and her collaborator Emmanuelle Charpentier were credited with co-inventing a tool for editing CRISPR. This becomes the subject of a bitter patent dispute, which is ongoing with US bioengineer Feng Zhang.

INSIGHT

GENE EDITING



Lightspring / Shutterstock

CRISPR-Cas9 has the potential, in theory, to change the lives of everyone and every living thing on the planet. Enabling scientists to edit our genes with unprecedented precision, ease and efficiency, it has been compared to cut-and-paste text editing. It comprises a chemical "sat nav" – an RNA or ribonucleic acid molecule – which is primed to guide "molecular scissors" – the Cas9 protein – to editing targets.

If it fulfils all its promise, CRISPR-Cas9 will eradicate family lines of hereditary, single gene disorders such as cystic fibrosis, sickle cell anaemia and Huntington's disease. It is already transforming research into gene therapies and helping to identify new drug targets.

Such is the excitement that one London researcher featured, along with Angela Merkel, Justin Trudeau and Pope Francis, in 2016's *Time 100*, which lists the world's most influential people. Dr Kathy Niakan's study of human embryos at London's Francis Crick Institute is taking her to where no scientist has been before.

US biochemist Dr Jennifer Doudna, co-inventor of the CRISPR-Cas9 gene editing tool, says: "Niakan's work will answer previously unanswerable questions about what makes a healthy embryo, what factors contribute to infertility and what goes wrong when pregnancies don't progress as planned."

This could reduce, among other things, the huge tragedy of miscarriage. The Miscarriage Association estimates that more than one in five pregnancies end in miscarriage, probably more than a quarter of a million each year in the UK alone.

But there is concern as well as hope, especially over the possible emergence of eugenics and the prospect of designer babies produced to order with traits such as super strength or hyper-intelligence.

Ironically, CRISPR-Cas9's ease of use and cost is adding to ethical concern. On line DIY kits cost as little as $120, up to 200 times less than a leading earlier system. stem. But the benefits are stacking up.

Although it was only discovered in 2012, CRISPR-Cas9 has already helped to correct the genetic defect in Duchenne muscular dystrophy in mice, deactivate 62 genes in pigs so organs of animals grown for human transplants won't be rejected, excise HIV from human cells in a laboratory and from living animals, create therapies that turn off cancer genes, force a gene that kills malaria parasites to spread through a whole population of parasite-bearing mosquitos, and create genetically modified animal models of human disease to study genetic changes that trigger illness or confer protection.

The world's first human CRISPR-Cas9 trial is underway at Sichuan University in China on ten patients with lung cancer.

CRISPR-Cas9 is not, of course, foolproof. For example, gene edits can occur at the wrong place, which could result in the disabling of a tumour suppressor gene or the activation of a cancer-causing one.

Translocation, the cause of chronic myeloid leukaemia, when pieces from two different chromosomes converge, is another potential problem. So there is currently research by many investigators to establish which regions of the genome could be accidentally "CRISPR'd". And there could also be unforeseen downstream consequences of unleashing altered organisms into the human gene pool, hence the caution around moving from laboratory to clinical trials.

COMMERCIAL FEATURE

Treating eating disorders

Ellern Mede, the specialist centre for eating disorders, is pioneering evidence-based ways to improve outcomes. Will short-term intensive inpatient stays be the future for this devastating mental illness?

"When evidence clearly shows that early intervention in eating disorders is crucial to reversing what can rapidly become an enduring and debilitating condition, waiting for more than 100 days for treatment is very worrying," warns Peter Curtis, managing director of Ellern Mede, a London centre which has one of very few eating disorder specialist high-dependency units in the world.

If eating disorders are addressed in time, treatment outcomes improve and potentially life-threatening complications affecting both physical and mental health can be prevented.

Incidence is highest among teenagers, with many patients eligible for NHS Child and Adolescent Mental Health Services. The Department of Health has set a target to reduce waiting times for treatment for eating disorders to four weeks by 2020. Health policy is steering providers to outpatient and shorter-term services for eating disorders, and provision of care from the independent sector will play an important role in helping to beat this devastating illness.

The focus of health policy is to make treatment more accessible and affordable through short-term inpatient stays, supplemented by linked outpatient care. By intervening earlier in the eating disorder, Ellern Mede's team of experts believe many more families and their loved ones can be spared a lifetime of suffering.

> There is a real possibility that by offering short-term accessible, affordable eating disorder treatment as soon as it is diagnosed, we may see a tangible improvement in recovery rates

Recent international research suggests that access to specialist eating disorder treatment within the early months of its onset is likely to result in 60 to 80 per cent recovery rates.

Ellern Mede is a specialist hospital that focuses on providing care for eating disorders and commonly related conditions. The hospital currently cares for young people from anywhere in the UK and globally.

This May sees the opening of Ellern Mede's new purpose-designed hospital, Ellern Mede Barnet. This complements its current provision at Ellern Mede Ridgeway inpatient hospital and outpatient clinics in Harley Street and Wimpole Street, London. It also sees the introduction of an evidence-based family therapy-centred treatment model adapted by Ellern Mede for UK private clients, as well as the launch of a short-term "symptom interruption" adult bulimia inpatient programme.

Affordability for people who seek to fund their own treatment lies in the time-limited nature of Ellern Mede's treatment programme. Similar programmes have been proven to improve significantly eating disorders among patients in the United States over the past ten years.

"There is a real possibility that by offering short-term accessible, affordable eating disorder treatment as soon as it is diagnosed, we may see a tangible improvement in recovery rates," says Dr Hind Al Khairulla, clinical director of Ellern Mede.

"We could see a consequent reduction in both numbers of patients requiring longer-term inpatient care and also a reduction in the average length of stay at inpatient units. At Ellern Mede, our positive experience with recovery through intensive interventions, even for the most seriously ill patients, indicates that our new outpatient and inpatient programmes can make a real difference to recovery rates."

At least **725,000** people in the UK are affected by an eating disorder

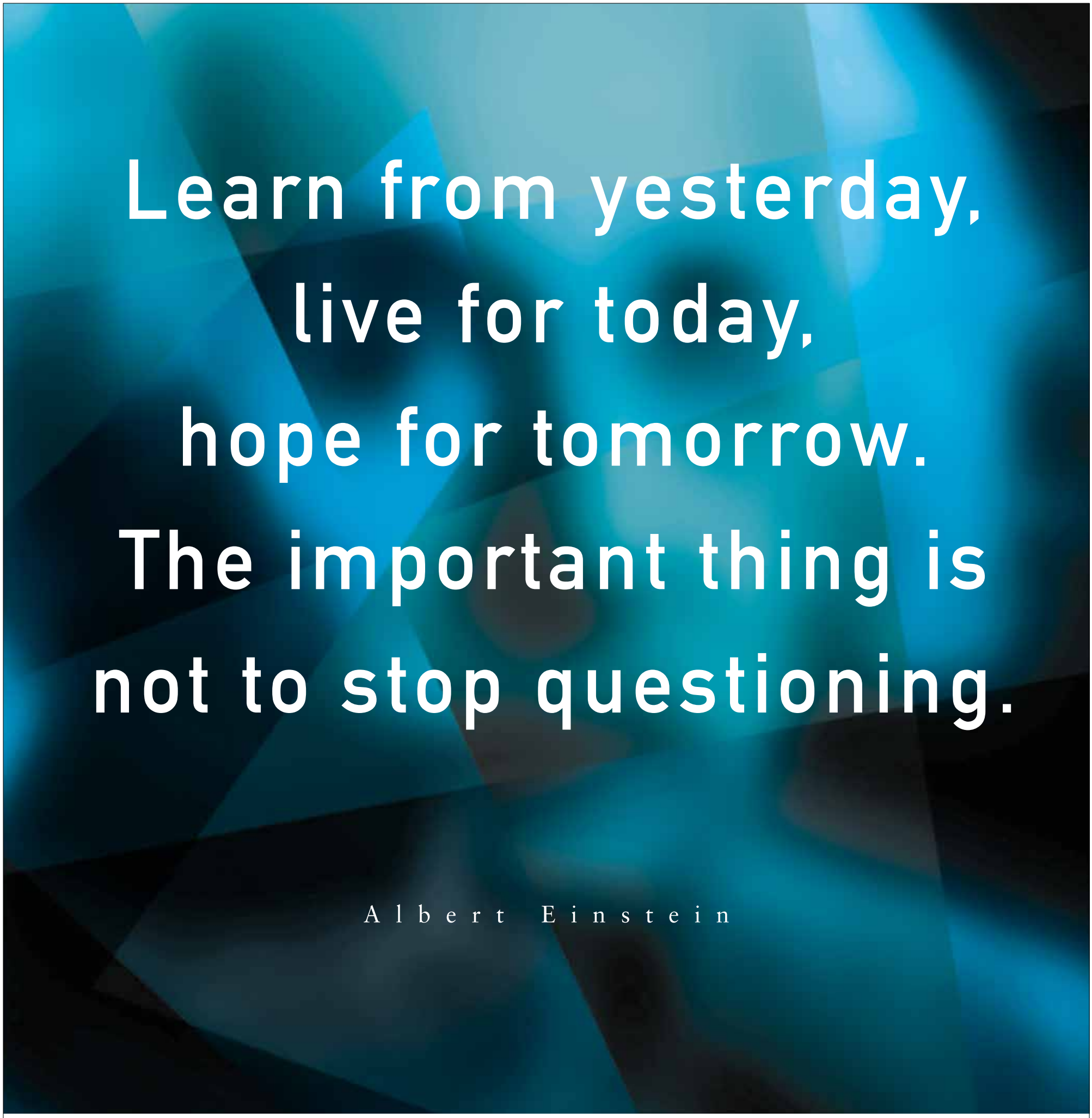
The sooner someone gets the treatment they need, the more likely they are to make a meaningful recovery

Eating disorders are serious mental health conditions and anorexia nervosa has the highest mortality rate of any psychiatric disorder

Ellern Mede currently treats more than 100 patients a year in its 26-bed unit at Mill Hill, many of those funded by the NHS. Its expansion to outpatient services and the model of short-term inpatient stays at its new unit nearby in Barnet is expected to increase significantly the number of patients it treats.

So, will this private sector-led model prove to be the beginning of a solution that the health sector will embrace for the future of eating disorder treatment? With as many as 725,000 people in the UK alone thought to have eating disorders, which have a higher mortality rate than any other mental illness, this is something health professionals will be watching with interest.

For more information on eating disorders or Ellern Mede please visit www.ellernmede.org or call 0203 210 2030



True breakthroughs in science cannot be achieved without pushing boundaries and taking risks. Unmet needs require new solutions to old problems, which is why we push ourselves to see challenges from different perspectives, constantly questioning and forging new paths toward solutions, both in the lab and in our communities. We have a responsibility to ensure that patients have access to the most appropriate medicines, and our pioneering ethos drives our commitment to making this happen.

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RARE DISEASES

New drugs for not-so-rare diseases

Just how rare are rare diseases in the UK? Not as rare as you might think

MARTIN BARROW

Although each patient group is small, about 6 per cent of the population will be affected by a rare disease at some point in their life, which in the UK equates to about four million people. To put that into context, there are 1.5 million people with a learning disability. What's more, rare diseases are becoming less rare as around five new types are described in medical literature each week.

The prevalence of rare diseases is an important principle to establish. For years, policy around the allocation of resources for the treatment of rare diseases has been influenced by the perception that few people are affected and there are more urgent priorities.

As a consequence, access to treatment for a patient with a rare disease historically has been poor. Pharmaceutical companies have focused on blockbuster drugs aimed at treating millions of people and public health systems have been designed to support large population groups. Despite advances in drug development, many rare diseases lack any treatment options.

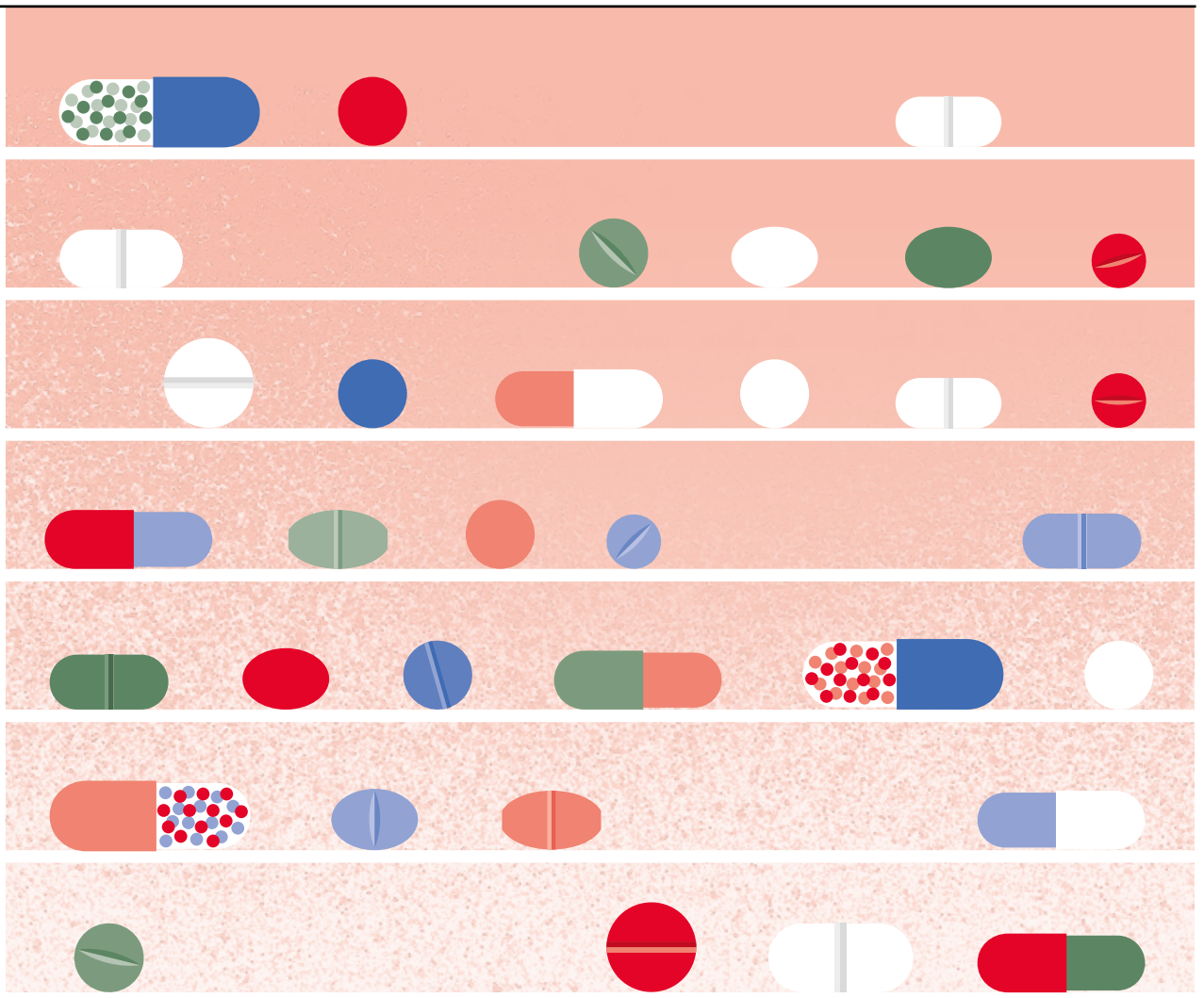
> Breakthroughs are being made at a time when blockbuster drugs are coming off patent, forcing pharmaceutical companies to explore new revenue streams

The stage is set for this to change. There has been a surge in investment in so-called orphan drugs, which are targeted at rare diseases, bringing hope to millions of patients and their families. Last year the US Food and Drug Administration (FDA) received a record 582 requests for orphan drug designation from biopharma companies, 110 more than 2015 which was itself a record year. Emerging science is giving drugmakers the tools they need to develop new drugs for conditions that were previously too complex to treat.

Breakthroughs are being made at a time when blockbuster drugs are coming off patent, forcing pharmaceutical companies to explore new revenue streams. Evaluate Pharma, the life sciences intelligence firm, estimates that orphan sales hit $114 billion in 2016, a 12 per cent increase over 2015. The market is set to double over the next six years, accounting for one fifth of the total prescription drug market by 2022, according to some forecasts.

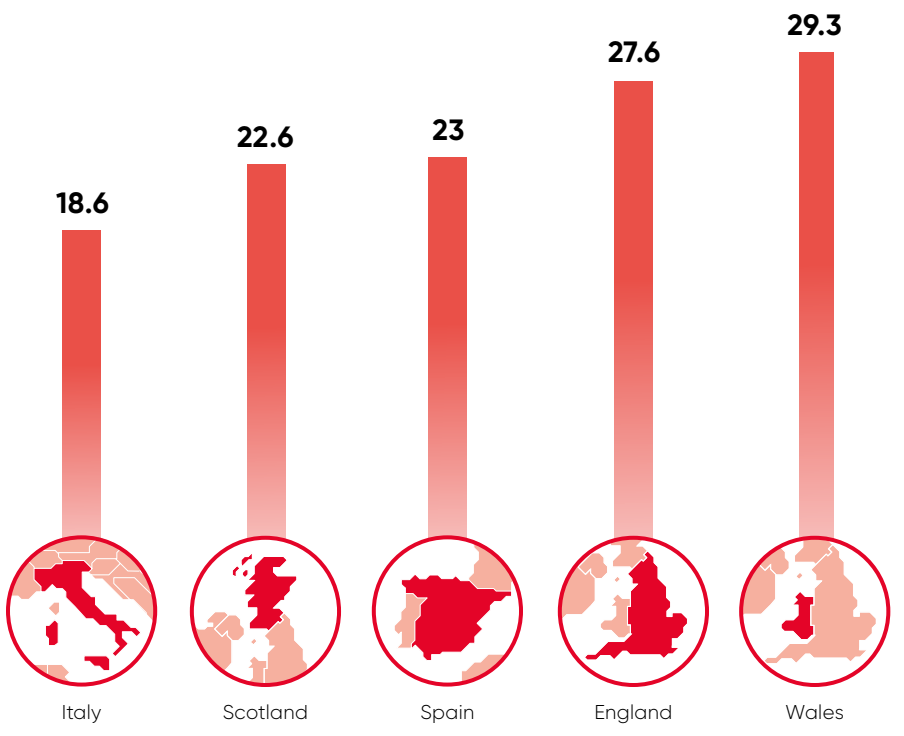
Historically, orphan drug development was mostly performed by small biotechs, but more than half are now created by mid to large pharmaceutical firms. In 2016, the ten best-selling drugs for rare diseases were made by companies including Celgene, Roche, Teva, Bristol-Myers Squibb, Biogen, AbbVie, Amgen and Novartis.

However, the advent of a new generation of drugs and treatments for patients who previously had no hope creates new challenges for healthcare providers. While systems are being repurposed to speed up access to innovative drugs, the high cost of new medicines remains a formidable barrier.



FUNDING WAITING TIME FOR ORPHAN MEDICINAL PRODUCTS

AVERAGE TIME IN MONTHS



Shire 2017

In England the National Institute for Health and Care Excellence (NICE) takes decisions based on cost effectiveness, including the impact on quality-adjusted life years. This approach has resulted in a number of promising drugs being rejected, despite their proven effectiveness.

A case is point is Alexion's Kanuma to treat the rare inherited genetic disorder lysosomal acid lipase deficiency (LAL-D). Infants with LAL-D normally do not live to see their first birthday without treatment. In clinical trials with Kanuma, five out of nine infants survived beyond three years of age, achieving normal developmental milestones. Yet earlier this year, NICE decided the high cost of the drug, at around £500,000 a patient, could not be justified by its long-term treatment benefits.

A recent report by Shire Pharmaceuticals, the biotechnology company, revealed that patients with rare diseases in England must wait an average of 28 months for their treatments to be funded by the NHS, longer than in Germany, Italy, France, Spain and Scotland. The report also found that 52 per cent of medicines for rare diseases approved in the last 15 years in England are not funded for routine use. By comparison, Germany funds all orphan medicinal products as soon as they are approved by the European Medicines Agency.

Sebastian Stachowiak, general manager of Shire UK, says: "Patients living with a rare disease in the UK face significant barriers to access life-saving medicines. The UK lags behind European counterparts in speed and access to rare-disease medicines with an assessment process that is not fit for purpose.

"With a general election, the new government has an opportunity to take a bold step to make sure that no patient living with a rare disease is left behind. Industry, government, patient groups and wider stakeholders need to come together to build a bespoke, fit-for-purpose process for evaluating medicines for rare diseases that enables access to treatments for patients living with a life-threatening condition."

The pharma sector says development costs are the same for orphan medicines as they are for blockbuster drugs, but the cost per patient is exponentially higher. Health providers say developers are abusing the system and must be more open about the true cost of innovation.

This tension has encouraged new research into approved drugs, which may be used to treat another illness and carries less risk than starting from scratch, since the drug has already met regulatory requirements and undergone post-market monitoring.

Elsevier's R&D Solutions is working with the charity Findacure to tackle rare diseases such as congenital hyperinsulinism and Friedrich's Ataxia. Tim Hoctor, vice-president of professional services at R&D Solutions, says: "With these kinds of collaborations, the healthcare system saves money, and patients get access to effective and affordable drugs sooner."

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