FUTURE OF PHARMACEUTICALS

Experts in pharmacy automation

Omnicell®
Inspired by Care™

The publication of the Department of Health report earlier this year should be a wake-up call for us all - minimising medication errors is critical. That's why at Omnicell we are calling for a system wide approach to put automation in all pharmacies to significantly reduce the number of medication errors once and for all.

Safe dispensing of both medication adherence packs and original pill packs within pharmacy is critical. Stringent measures are in place to ensure medications being dispensed are checked by qualified staff as part of the dispensing process, however it's a sad and sobering reality that pharmacy dispensing errors still occur. Unfortunately, the risk of these errors can become more likely when there are increasing pressures on demand, time and resources.

It's no secret that community pharmacy funding is being cut – in fact by March this year, funding had fallen by a staggering £200m. Despite this, more prescriptions are being dispensed than ever before – more than one billion a year - and as the population gets older those prescriptions are becoming more complex.

However there is a solution that can not only help to dramatically reduce the risk of dispensing errors, but can also take the pressure off frontline staff so they can spend more time with patients. This means that community pharmacies can continue to evolve, grow and survive despite the climate of funding cuts.

The answer lies in embracing technology – that is available and ready to use right now - to provide an efficient and safer service for patients. Read how Pearl Chemist Group are using Omnicell automation to reduce errors and improve efficiencies at www.omnicell.co.uk/medication-adherence/technology/

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BANISH MEDICATION ERRORS IN COMMUNITY PHARMACY

FUTURE OF PHARMACEUTICALS

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Deadly diagnosis of Disease X

It is a matter of when, and not if, a pandemic will strike, so how prepared are we to combat a deadly virus infecting millions around the globe?

NICK EASEN

A few months ago, the death of 9,000 chickens on a single farm in northeast China didn't make global headlines; perhaps it should have. The poultry died from the lethal H7N9 virus. No humans suffered this time, yet this flu kills more than one in three people who catch it; 623 have already died in Asia. The next coughing bird could be incubating a lethal virus that humans could pass on too.

Like climate change, death and taxes, a global pandemic is a certainty, and with the 100-year anniversary of the Spanish flu making headlines, there's now a lot more interest in the next large-scale epidemic and what it could look like. In 1918, up to 100 million people died, this time the death toll could be three times as much, more than the population of America.

The new contagion might be a mutated form of the H7N9 virus evolving fast in the petri-dish-like pools of humanity who live cheek by jowl with their animals in China. It could come from other lethal candidates touted in a top-ten blueprint list released by the World Health Organization (WHO) earlier this year: Ebola, Zika, MERS, SARS, Lassa fever or Rift Valley fever. Then there's Disease X.

More elusive than the others, this is not a specific illness, but a hypothetical disease, like our potential new bug incubating in the poultry of Liaoning Province. "We just don't know where the next will strike. We cannot predict it. There is also the natural evolution of diseases already out there," explains Professor David Heymann of the London School of Hygiene and Tropical Medicine.

After all, new outbreaks appear surprisingly frequently. Aids in 1981, Nipah in 1998, SARS in 2003, H1N1 swine flu in 2009 and MERS in 2014, each were the Disease X of their time. "This sounds like a marketed brand, yet it isn't just an idle alarmist worry. It describes the regularly observed phenomena of previously unknown viruses suddenly appearing and spreading in human populations," says Dr Jonathan Quick, chair of the Global Health Council.

"Our greatest fear is being blindsided by a new virus, most likely due to animal-human spillover, which then readily spreads from human to human, has at least a 5 to 10 per cent fatality rate, does not respond to existing medicines, and for which an effective vaccine and accurate diagnostic test cannot rapidly be developed. Then there's the nightmare scenario of catastrophic mutations rendering existing viruses like flu, SARS or MERS highly contagious and deadly."


National Geographic Image Collection/Alamy

Gravediggers at the Freetown cemetery in Sierra Leone during the Ebola outbreak in 2014

The mega-trends don't bode well either. Mankind is a growing "food source" for our planet's hungry bugs. More than 50 billion chickens are reared each year, as well as 1.4 billion pigs. All hotbeds of disease. We're travelling more and urbanising rapidly, which puts us in closer contact with each other and animals. We're also projected to eat more meat, meaning more animals and potentially more antibiotics to keep them healthy, therefore more resistance to the antibiotics.

"A virulent respiratory virus spreading as fast as flu can reach all major global capitals within 60 days now. By June this year alone we saw concurrent outbreaks of six of the ten diseases in the WHO blueprint list of priority diseases," says Dr Richard Hatchett, chief executive of the Coalition for Epidemic Preparedness Innovations, which aims to derail epidemics by speeding up the development of vaccines.

"A highly virulent and transmissible virus like the Spanish flu could kill millions around the world within months. This may lead to widespread societal disruption, destabilisation of governments, and widescale shutdowns of international travel and trade."

$570bn

annual global cost of moderately severe to severe pandemics, equal to 0.7 per cent of worldwide GDP

World Bank

11k

people died in the West Africa Ebola outbreak between 2014 to 2016

Centers for Disease Control and Prevention

We're also talking huge costs. The World Bank estimates the price tag of a new pandemic could top $570 billion or 0.7 per cent of global income. This is enough to raise a few eyebrows in government, industry and civil society. But with pandemic preparedness, mankind needs to invest big now, not wait until people drop dead, otherwise we suffer from what World Bank president Jim Yong Kim calls the "cycle of panic and neglect".

"Experience and fear appear to be key motivators for change. We cannot expect that suddenly throwing large sums of money at an issue when it emerges will result in a positive outcome when the pre-existing capacity is simply not present," says Dr Arlene King, adjunct professor at the Dalla Lana School of Public Health, University of Toronto.

The Ebola outbreak in west Africa four years ago, which led to 11,000 deaths and cost at least $2.8 billion was a case in point, but it did result in one small slither of a silver lining; it was a turning point in how we tackle epidemics.

"We now have the framework for a true global response that has grown out of this; the authorities are getting better at communicating what they know and what they don't know," says Dr Irene Lai, medical director of medical information and analysis at International SOS.

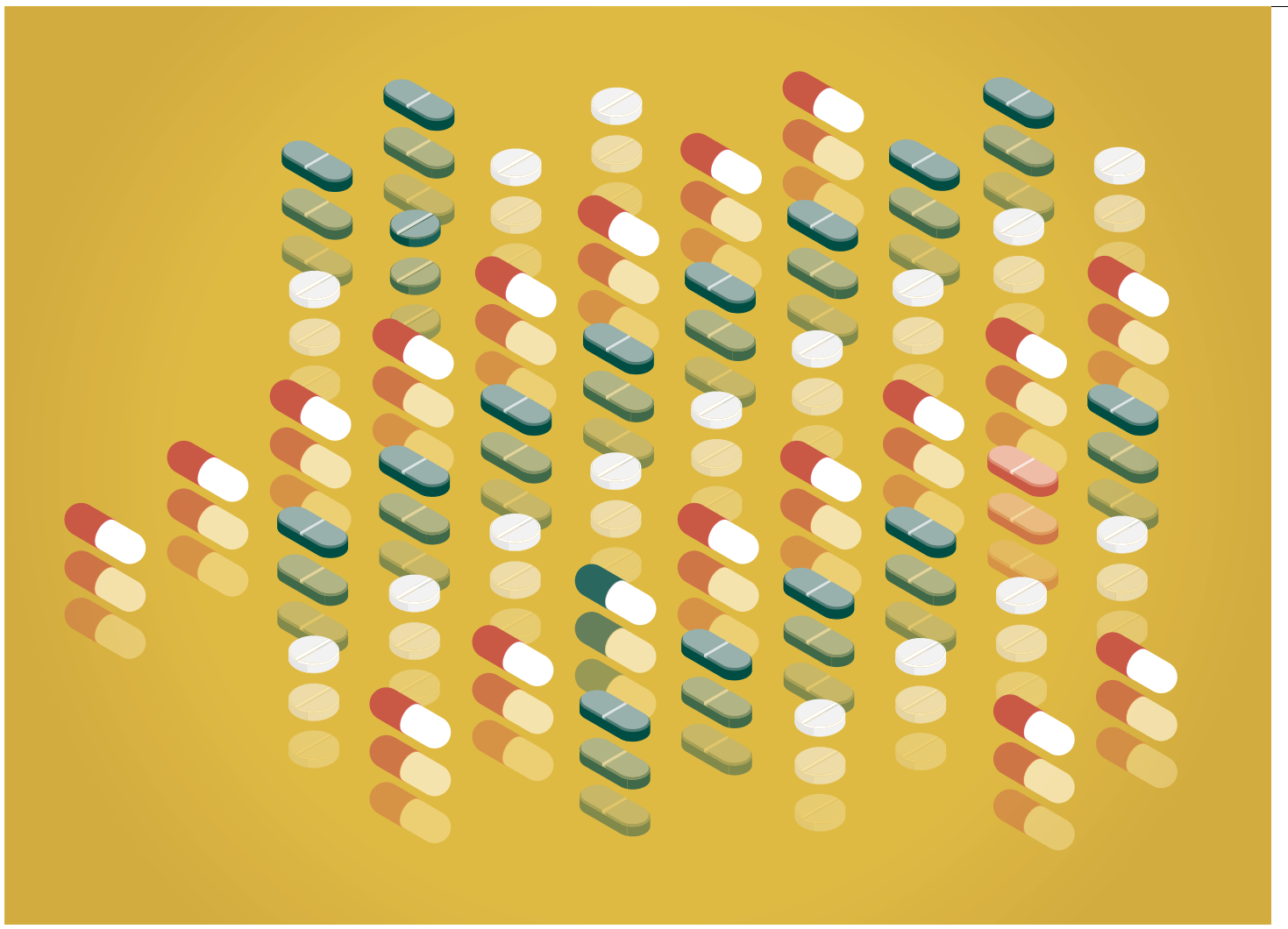
Those involved in the disease control community are slowly starting to break the cycle of complacency that has characterised past responses, realising collective action is now crucial.

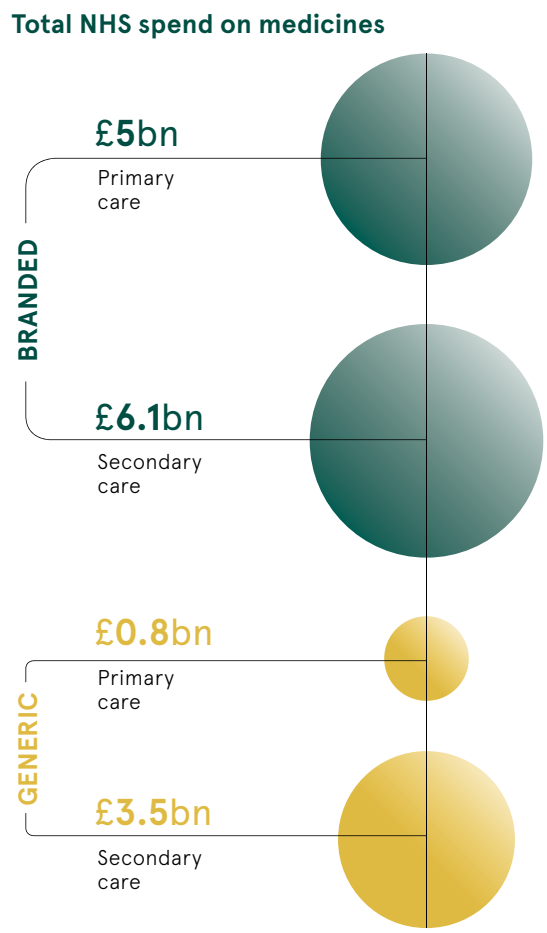
"These diseases do not respect borders, so as well as the medical challenge they pose, they also challenge our political and inter-governmental systems. No single measure alone is sufficient," explains Dr Hatchett.

Mankind is also getting better at real-time surveillance and employing early-warning systems. At least a half dozen universal flu vaccines are undergoing human clinical trials, although they may not combat Disease X. The next frontier will be dealing with antimicrobial resistance and fake news.

"The biggest gap in epidemic prevention is the lack of a collective strategy for combating junk science and junk news," cautions the Global Health Council's Dr Quick. The battle is on. ◆

GENERIC DRUGS





Department of Health & Social Care 2018

Are cheaper 'copycats' really good value?

Benefits of prescribing by brand, enabling the costly development of life-changing drugs, may be outweighed by higher costs, compared with cheaper generic bio-equivalents

JOHN ILLMAN

Imagine this: drug A is as effective as drug B, but costs ten times less and is actually the same drug masquerading under a different name. You are a doctor and must decide which one to prescribe. Well, of course, you choose drug A.

Such decisions may seem straightforward, but so-called generic and brand-name prescribing has provoked a long-running, multi-billion-dollar controversy.

Every medicine has both a brand or commercial name and a generic or chemical one. Take the world's best-known erectile dysfunction treatment. Viagra is its brand or commercial name and yes, it is no coincidence that it trips off the tongue very easily, unlike its generic name sildenafil, which sounds more like a villain from *Harry Potter* than a blue pill.

Pharmaceutical companies choose easy-to-remember brand names in the hope that doctors and patients will choose them in preference to cheaper generic ones. In contrast, the strapped-for-cash NHS actively promotes generic prescribing.

According to the British Generic Manufacturers Association (BGMA), generic prescribing saves the NHS around £13 billion a year, while the Organisation for Economic Co-operation and Development reported in 2016 that generics had accounted for 84 per cent of the volume of UK pharmaceuticals sales in 2014. The US figure is 90 per cent.

Given the spectacular savings, why are medicines ever prescribed by brand name? When a pharmaceutical company develops a new drug, it sells it exclusively under its brand name. The product is covered by patent protection, which means that only the manufacturer is allowed to make and sell it during the life of the patent. This enables pharma companies to recoup investment costs. Patents are estimated to account for 70 to 80 per cent of pharma income.

Developing a new drug can take up to 15 years or more and cost up to $5 billion. The Association for the British Pharmaceutical Industry claims for every marketed medicine that makes enough money to pay for its development, 25,000 compounds are tested. On average, about 25 of these are reported to go into clinical trials involving thousands of patients.

How long do patents last and what happens when they expire? Patent life varies from country to country, but can last up to 20 years. This may sound like ample time to turn a big profit, but medicine patents run from the date of invention. This is a bitter pill for big pharma because it can take ten years or more to generate enough data to bring a drug to market. But patents on medicines in the European Union can be extended for up to five years to offset development time and mandatory trials.

When drug patents expire, other companies can produce cheaper, non-branded generic versions, also known as me-too or copycat medicines, without making any contributions towards research and development.

Generic medicines have to meet the same standards as branded products. The US Food and Drug Administration explains: "A generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

"These similarities help to demonstrate bio-equivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as its brand-name version. In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."

However, bio-equivalence is a highly controversial issue. In 2015, for example, there were 267 so-called recalls of generic drugs in the US. These decisions to remove products from the market involved counterfeit medicines and quality issues such as contamination, says Erin Fox, adjunct associate professor in pharmacotherapy at the University of Utah. And the number of UK recalls is comparable to those in America, according to BGMA direction general Warwick Smith.

> **"There is an assumption that patent protection for a medicine involves just a single patent, but this is not so**

Professor Fox says: "A few high-profile recalls have shaken the belief that generic drugs are truly the same." But she claims: "The system intended to reward drug companies for their innovations, but eventually protect customers is systematically being broken. Drug companies are thwarting competition through a number of tactics and the result is high prices, little-to-no competition and drug quality problems."

For example, Professor Fox claims companies are stifling generic competition by "pay for delay" agreements in which branded drug companies simply pay generic companies not to launch me-too products. The US Federal Trade Commission estimates that such pacts cost US consumers and taxpayers $3.5 billion in higher drug costs each year.

Pharma companies are also said to extend exclusive rights to their medicines by filing additional patents to include treatment for conditions not covered by original patents. Mr Smith says: "There is an assumption that patent protection for a medicine involves just a single patent, but this is not so."

The BGMA website quotes examples in which single molecules have been the subject of more than 1,300 patent applications. This can deter generic manufacturers from investigating the potential of branded medicines nearing patent expiry. The BGMA says: "These practices limit competition and the prospect of lower medicine prices." Nonetheless, generic prescribing has resulted in significantly lower prices, making life-saving drugs more accessible to more people. ◆

Pharma commitment to the UK: is this certain with Brexit uncertainty?

Jess Smith and **Chris Rowland**, who lead on partnerships, policy and patient advocacy within the Ipsen UK organisation, discuss how a partnership mindset is of value at the core of their business

A deal or no-deal Brexit raises many questions for pharmaceutical companies in the UK, including stockpiling of medicines, as well as the approval of new medicines.

The Westminster government has called on pharmaceutical companies to stockpile a minimum of six weeks' supply in the UK, above their normal buffer supplies in case of disruption come Brexit day on March 29, 2019. The aim is to ensure minimal interruption whatever the outcome of a deal.

"There is no question that ensuring patient supply remains the priority for Ipsen," says Jess Smith from Ipsen UK, a leading global biopharmaceutical company with a focus on oncology, neuroscience and rare diseases, and with worldwide sales of more than €1.9 billion in 2017.

Planning is an issue as the industry's supply chains are complex and integrated across Europe. More than 2,900 medicinal products produced in the UK are supplied to European Union patients, with 3,200 individual drugs produced in the EU and supplied to UK patients. Every month, 45 million patient packs of medicine are supplied from the UK to other EU countries. Over the same timeframe, the UK receives 37 million packs from Europe. It's a complex arrangement.

"But this is more than just a question of medicine supply," Ms Smith adds. "The UK is one of the hubs for innovation across the life science and healthcare sectors worldwide, home to research institutions, clinical trial centres, licensing bodies and manufacturing, to name but a few.

"Brexit has been the spark to reignite Ipsen's discussions about partnerships, and how we must work together if we're to deliver optimal patient outcomes in the UK, Europe and beyond. So, when we talk about the future of pharma, it's simple, it must continue with the same ambition and commitment."

"For Ipsen, now is not the time to back away; we must stay true to our commitment here in Britain. We are all in this together. Yes, the dynamics are changing, but we have a responsibility to deliver the highest-quality medicines, meet stringent regulatory requirements and quality measures for patients, as well as continue to work with other groups and partners to advance research, and support the UK's position as a leading environment for health and life sciences."

Whatever type of Brexit occurs, the ecosystem of providers, including pharmaceutical companies, medical research institutions, industry bodies, public health organisations, the NHS and others across the UK and Europe, share enough common goals to find solutions so patients, wherever they reside, don't lose out come March 2019.

Ipsen, a company with headquarters in Paris, sells more than 20 drugs in over 115 countries worldwide and has had a presence in Britain since 1981. The UK is one of its three global hubs, employing more than 700 people across three sites with a focus on research, development, manufacturing and distribution. The company continues to invest heavily and expand here.

"We are optimistic about our presence in the UK and for future collaborations," says Ipsen UK's Chris Rowland. "Our partnership values must hold true over time, as we are committed to increasing the number of people and groups that we work with both within the UK and the EU. Our organisational priorities and commitment to patients remains the same: those who need treatment don't have time to wait."

Ipsen is proud to work in partnership with the NHS across a number of projects, including programmes that look at supporting the health service to ensure the processes and pathways are in place for clinicians to support patients. It is important that disease management and treatment suports the patient so they can enjoy their life while living, which is why we partner with multi-disciplinary teams and homecare service providers to empower the self-care of patients living with some forms of cancer, and their carers.

Jess Smith
Ipsen UK

Chris Rowland
Ipsen UK

In addition, Ipsen teams are collating real-world evidence on the use of their medicines. As clinical trials hold stringent inclusion/exclusion criteria to evaluate the efficacy and tolerability of a medicine, Ipsen is working with Trusts across the NHS to collate data on their medicines in particular within the area of neurosciences to evaluate their use in the real-world setting.

This is a critical step and part of our commitment as a partner to clinicians who care for patients. This data can be crucial to support clinicians to enable them to manage patients, using insights from those who may be living with other conditions alongside the one they are receiving treatment for.

"This is one example of partnerships we are proud of at Ipsen," says Ms Rowland. "We recognise that data, making use of data and digital tools to support research, which contribute to the improvement of patient care, is a priority within the life sciences industrial strategy, and we hope to be able to contribute to this and other priorities for the UK healthcare landscape.

"Ipsen continue to invest in a strong presence here, which is why we have research, development, commercial and corporate functions based in the country, not just supporting our UK operations, but our global businesses too. We have an ambition to bring one new medicine or indication to market every year. It is a partnership we want to continue for years to come."

There's no doubt that whatever happens with Brexit, partnerships are at the heart of the future of healthcare and the future of pharma in the UK, and a principle Ipsen is committed to.

> **"Brexit has been the spark to reignite Ipsen's discussions about partnerships, and how we must work together if we're to deliver optimal patient outcomes in the UK, Europe and beyond**

Across the pharmaceutical industry

2,900
medicinal products produced in the UK are supplied to European Union patients

3,200
individual drugs are produced in the EU and supplied to UK patients

45m
patient packs of medicine are supplied from the UK to other EU countries every month

37m
patient packs of medicine are supplied from Europe to the UK every month

IPSEN
Innovation for patient care

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Commercial feature

Prescription for change: transforming pharmacies with digital technology

Digital transformation comes to every sector sooner or later. Now the pharmacy industry, whose model has altered little in decades, faces its own version of the seismic changes that have swept through other consumer-facing businesses

Pharmacy today

1/3

of people have experienced stock issues when getting their medication

When no stock is available,

20%

of customers go to a different pharmacy

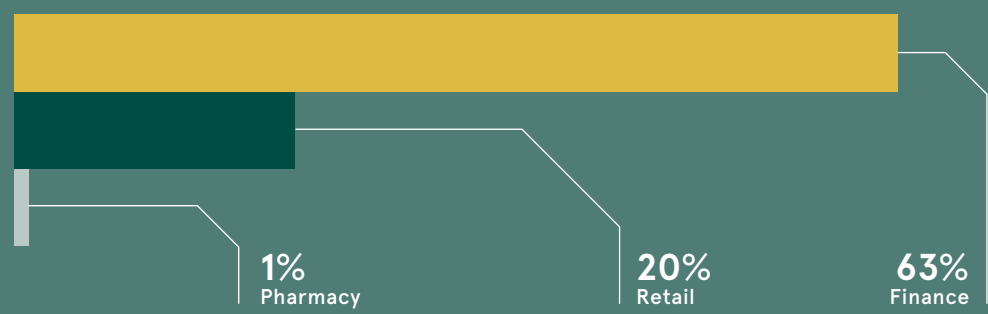
Customers expect delays in pharmacy, with

35%

agreeing that a ten-minute wait is acceptable

YouGov Omnibus survey, 2018

Online transactions by sector



December, 2017

Top 5 features of the ideal pharmacy

01 Fast track for repeat prescriptions

02 Text alerts when medicines are ready

03 An 'always in stock' guarantee

04 Reminders to reorder repeats

05 An app to help them manage their prescription ordering

YouGov Omnibus survey, 2018

Well Pharmacy is putting itself at the forefront of moves to catch up on the practices of retailers such as Amazon that have transformed customer expectations. At present only 1 per cent of pharmacy transactions are online, a situation that Well expects will change rapidly.

"We want to be pioneers in making the healthcare system better, showcasing the true value of community pharmacy," says Chris Ellett, director of transformation at Well, which has 780 pharmacies and 7,000 employees. It aims to be the market leader in online pharmacy.

He adds: "I don't think pharmacy has a choice. If we don't do it, somebody else will." There is speculation that Amazon, which bought online pharmacy startup PillPack in June, could enter the market directly, initially in the United States.

"The pharmacy experience from a customer perspective is pretty rubbish. It's really poor," Mr Ellett says, referring to the long-established model of getting a prescription from a GP, standing in a queue and waiting for it to be dispensed by a pharmacist.

At the heart of Well's strategy is its online pharmacy, which it launched as an iPhone app in July. This enables customers to order one-off and repeat prescriptions to be delivered to their door. Eventually Well plans to add other functions including ordering on behalf of family members such as children and elderly parents.

The digital strategy comes alongside other changes already under way, including creating a "hub-and-spoke" system in which prescriptions are fulfilled at a highly automated distribution centre in Stoke-on-Trent and despatched to pharmacies around the country.

Unlike some chains, Well has no plans to close stores. It has embarked on a revamp of its pharmacies and believes these will continue to fulfil an important role. It intends its changes to free up more time for highly trained pharmacists to advise customers on health needs and spend less time in the back room preparing medication.

That fits with the vision outlined by Matt Hancock, health secretary, to move towards a French model in which people often go initially to pharmacies rather than GPs. He wants to spend as much of the extra £20 billion allocated to the NHS as possible on preventing illnesses, with pharmacies playing an important role.

Well is the brand name given to the former Co-op pharmacy chain, bought in 2014 by Bestway, the wholesale, banking and cement group founded by its chairman Sir Anwar Pervez. It is the UK's third-largest pharmacy business after Boots and LloydsPharmacy, with a 6 per cent market share, which Mr Ellett believes could significantly increase.

Bestway's initial aim of expanding by acquiring stores was impacted by government cuts to funding of community pharmacies, which have led to some closures among England's 11,800 pharmacies. Its digital strategy is an alternative way to achieve growth.

Well went back to basics and asked customers what they wanted, via a survey of 4,171 people with a recent prescription, and by spending a day with customers to see how they use pharmacies. The lesson was to focus on transforming the prescription process, which accounts for more than 90 per cent of pharmacies' revenue.

> **"We want to give the best prescription experience in the UK**

The company translated that into five customer promises: medication must always be in stock; repeat prescriptions will be simple, right and on time, every time; staff will say hello the moment customers walk in; prescriptions will be fulfilled within five minutes; and customers will have choice over how they get their medication, whether online or in a store.

"We want to give the best prescription experience in the UK," Mr Ellett says. "If we understand what customers want and we can do that better than anybody else, then we believe customers will choose to come to us."

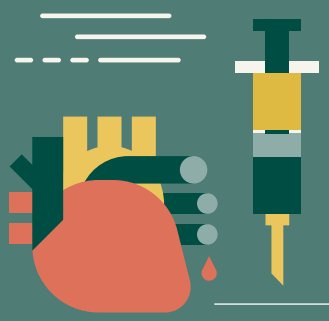
Bricks-and-mortar pharmacies will continue to play an important role because people value them and there are some things that cannot be done online or by phone, like the flu jab service.

Well believes the customer experience needs to be transformed, however, which it is doing by developing "essential pharmacy" concept stores. The first of these is in Northenden, Manchester, with ten to twelve more to follow over the coming year.

The flow of the new store is designed so it is easier for customers to see where to go for advice, to buy over-the-counter products or collect prescriptions. The dispensary is redesigned to enable pharmacists to work more efficiently. Most boldly of all, the dispensary is being opened up so customers

Ever-increasing pressure on the healthcare system

£7 in every **£10** spent by the NHS is linked to long-term conditions



15m

people in England have at least one long-term chronic condition, increasing to an estimated

18m

by 2025

The King's Fund

People with long-term conditions now account for approximately

50%

of all GP appointments, 13-day average wait time for a GP appointment as a result

64%

of all outpatient appointments

70%

of all inpatient bed days

71%

of all prescriptions are repeats and volumes are only going to increase

These are regular customers who need the same medication every month, so pharmacy is going to become even more transactional and commoditised

can see what happens inside, like the kitchen of a modern restaurant.

The new store will also have a type of vending machine that allows customers to collect their medicines, tracked by barcode, at any time of day or night.

Mr Ellett emphasises the importance of integrating online and offline to ensure a seamless experience, no matter what route the customer chooses. For example, a customer might order something in a store and have it delivered at home, or order something online and collect it at the store, or make a flu jab appointment online and have it done at the pharmacy.

Well has already invested £10 million in its transformation programme, which Mr Ellett thinks could double or triple over the next few years. He believes the online pharmacy market will grow rapidly. "We want a disproportionately large share of the online market; in fact, we want to lead that market," he says.

"Where will the market be in five years' time? Retail last Christmas was 20 per cent online and 63 per cent of banking transactions were online at the end of last year. I'm not saying it's going to be 63 per cent. I don't even know whether it's going to be 20 per cent. What's clear is the rate of growth and adoption of digital online pharmacy is going to be much quicker than it has been in retail and financial services because people are more familiar and used to using online services.

"Our owners and my executive colleagues are firmly focused on getting this right. We believe we have the right technology and the right capability in the team.

"The company's strategy is about growth. We believe we can grow revenue within that market and expect our overall market share to increase. We have big ambitions and over the next three years I think we will see massive growth. With the investment that our owners are making there is a very clear business case and set of assumptions, and we are confident that we will deliver that."

You can sign up to Well's online pharmacy at well.co.uk

+well

Q&A

A question of going online

Chris Ellett, director of transformation at Well Pharmacy, answers questions on establishing an online pharmacy

How does it work?
If you are using the app, you download it, register your details and put in your GP practice. All that is from databases, so it's easy to do. You put in a request for which medication you want. That request then gets sent to the GP. The GP decides whether they approve that or not. Sometimes people order too early or aren't on a repeat and sometimes that means we have to have a conversation with the GP and the patient. Then, assuming this all gets approved, you either pay or you are exempt, and then it gets despatched and posted through your letterbox via Royal Mail.

Why is an online pharmacy needed?
We are maybe 15 years behind other sectors in terms of the level of service that we are offering. As one customer put it: "GPs and pharmacies are two places where you know you just have to wait. It's not Amazon Prime, quick, quick, quick." Customers are having their expectations raised not by pharmacy, but by the Amazons and Airbnbs of this world. There has been a level of tolerance of a substandard service because people understand that the NHS is under pressure and they value what it has to offer, but if you look at the challenges the NHS is facing, and which the government is wanting to address, then something has got to change.

What is next?
Right now it's about acquiring customers, scaling the operation and delivering the best possible experience. We launched the app in July and since then over 10,000 customers have downloaded it and started to use it. We have had to build some back-end systems to do this. You might create a beautiful front-end experience for a user, but there is no point in doing that if you're going to fail in the experience with the back-end operations. We have to make the process efficient, so that you deliver when you say you are going to deliver and also make it easy for our colleagues at Well to operate.

How do you go about building a successful online pharmacy?
It isn't just about building an app and then getting customers; it's much more fundamental. People want a great user experience, simple and intuitive, such as they get with other online players. Efficiency and scale are an important part of it, and what is really important is trust. Buying a book online, for example, is quite different to getting your medicines online. The implications of getting medicines wrong can be quite catastrophic. So ensuring patient safety, building that level of trust with patients is paramount to everything we do in pharmacy, but even more so as you move into this world of online.

How will the service develop?
One of the next bits of functionality we want to add is ordering for your family, whether that is doing it on behalf of an elderly relative or particularly for small children. Then we have a roadmap for a whole bunch of other things. Over the longer term, we will start to look at things like click and collect, and the interaction of in-store and online services. As a pharmacy we offer other services commissioned by the government, such as reviewing a patient's current medication or helping them to understand a new medicine they have been prescribed. We're looking at how these important services can be supported digitally.

ONLINE DISPENSING

PillPack, acquired by Amazon in June, delivers personalised rolls of pre-sorted pills and a dispenser to make managing multiple medications easier

Will Amazon dispense pharmacies a bitter pill?

Online pharmacies, using pouch packaging technology, are disrupting the way medicines are dispensed

DANNY BUCKLAND

More than a billion prescriptions are dispensed by the NHS every year, and most are delivered with a reassuring reverence and over-the-counter simplicity by community pharmacies.

But the white paper bags, blister packs and the weekly pill boxes that are prime features of the medical landscape are being shaken by a disruptive earthquake from medication ordered online and delivered in pre-sorted pouches.

With a growing global population and predictions that the over-65 age group will rise from 22 to 28 per cent by 2030, the number of prescriptions will continue to rise and present opportunities for different delivery models.

Online pharmacies are not new, but when the retail giant Amazon enters a market, it is clear that rapid change will follow. The company has just signalled its burgeoning pharmaceutical ambitions by purchasing the company PillPack for around $1 billion.

PillPack's founders, from a pharmacy and technology engineering background, focused on the booming number of adults taking five or more prescription medicines. In the United States, this cohort has reached one in ten, or 30 million adults, while research by Omnicell reported that five million patients in the UK are taking four or more types of drugs.

Its approach, delivering pouched monthly supplies of medicines in a user-friendly dispenser along with labels that have pictures of each pill and notes on how to take them, has taken the market by storm and attracted the massive price tag Amazon was willing to play.

The sale indicates a wider shift in medication packaging with companies switching on to the power of design and delivery to both make it easier for patients to stick to their dosage and to increase significantly the number of people who comply with their prescriptions.

> **Whether the NHS will opt to partner with firms like Amazon is up for debate**

The UK already has its own version, PillTime, which is gathering momentum and helping to reduce the level of medication errors – 237 million in the UK annually with 66 million serious enough to cause patient harm, according to a 2018 study by the universities of York, Manchester and Sheffield – and the burden of patients failing to take their medicine, which costs the NHS £98.5 million a year.

Pill packaging has been a design backwater with little changes since the 1980s, but it is catching the eye of a number of innovative companies.

"Pharmaceutical products and many consumer health medicines provide below-par consumer experiences," says Chris Houghton of the Cambridge Design Partnership, which developed the innovative single-use BeeBetter pouch to deliver oral medication.

"Decades of standardisation and implementing cost-saving efficiencies have left the category bereft of any genuine consumer empathy or packaging design innovation," he says.

"With an ageing population, designs need to be inclusive and factor in difficulties people may have reading instructions or handling child-resistance closures. For other age groups there are issues such as convenience, money-saving, singled-handed use and sustainability.

"How blister packs are deemed 'fit for purpose' puzzles me because they have a mix of non-recyclable plastic and metal materials, and many children can open the so-called children resistance feature while the elderly, who need them most, often struggle."

The broadening of online pharmacy capabilities could have an impact on high street pharmacies, but they have responded by adapting and growing their clinical influence over the last decade, providing more face-to-face advice to the public, and becoming venues for screening and testing programmes as well as their dispensing duties.

"We don't see it as a threat. Any market is potential for disruptive entry, but there are already the beginnings of pharmacies looking at how they can play in this space," says Malcolm Harrison, chief executive of the Company Chemists' Association, which represents the major high street chains, with 6,000 outlets dispensing more than 500 million NHS prescription items every year.

"The way in which people want products and services is very different to the past. If you want a taxi, you go to Uber; if you want a takeaway, you go to Just Eat. People bank on their mobile phones and holidays are through Airbnb. Pharmacies need to be aware of this.

"We still need bricks-and-mortar pharmacies that provide face-to-face care. There are a growing number of people with long-term conditions, and we are getting older and living longer with ill health.

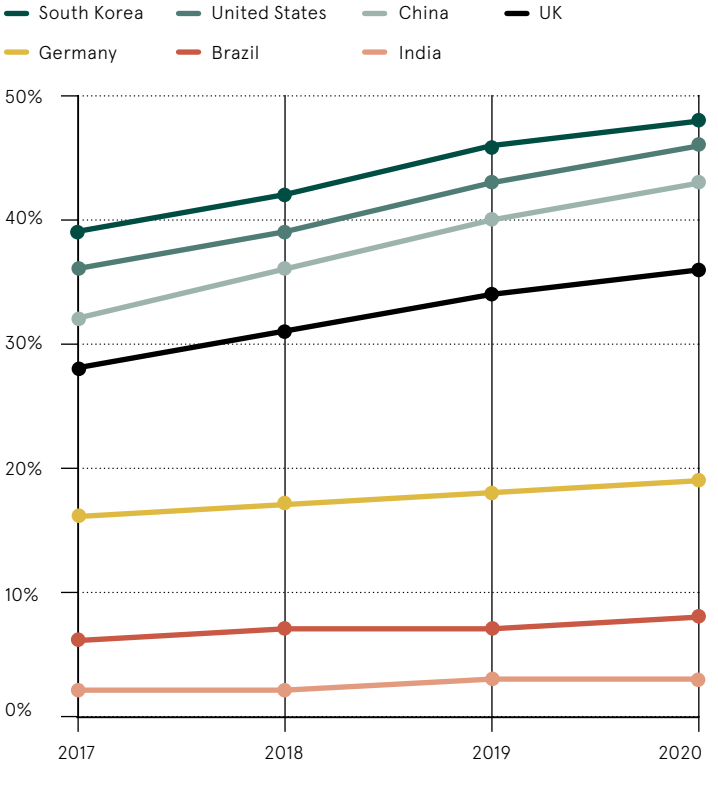
"Although some things can be delivered digitally, some can't, so how we can embrace the new to facilitate meeting new demands is important. Community pharmacies play a huge role in this, not only in long-term care, but also in helping deal with high-volume, low-acuity care that would normally take patients to the GP or the A&E unit."

Ruchin Kansal, healthcare leader of digital business strategy at IT services specialists Virtusa, believes Amazon's move is creating seismic change in pharmacy delivery. "Whether the NHS will opt to partner with firms like Amazon is up for debate," he says.

"But the reality is that, even if pouch packaging is strictly limited to online-use through non-NHS providers when it takes off in the UK, it represents Amazon's mission to make the life of their customers easier, from retail to medication consumption." ◆

Online pharmaceutical sales by country

Online share of total sales for over-the-counter pharmaceuticals only



Statista 2018

DRONES

Rising above delivery delays

Hospitals and clinics in congested urban areas and remote locations are trialling deliveries of urgent medical supplies by drones and mini-planes

DANNY BUCKLAND

The traffic-clogged highways of major cities and forbidding terrain of remote districts presents the ultimate challenge to urgent medicine, but the skies could soon be alive with salvation.

Drones and small fixed-wing mini-planes are proving they have the reliability to match technological promise in a series of trials ferrying medication, blood supplies and laboratory samples to isolated communities.

But pilotless flights also have the potential to impact urban areas and a recent feasibility study found that the rapid transport of medical supplies between hospitals, which need frequent and time-sensitive deliveries, is feasible.

It focused on the potential of connecting London's 34 hospitals and 28 accident and emergency departments with a drone flight grid to soar above the capital's congested roads where traffic speeds can be as slow as eight miles per hour.

The urban proof of concept has been established in the Swiss cities of Bern and Lugano, which have a prototype drone courier service between hospitals that is two-and-a-half times faster than bikes or vans.

The Flying High study, compiled by innovation charity Nesta, modelled the use of drones with a two-kilo payload making two to four-minute flights between neighbouring London hospitals Guy's and St Thomas' which, although less than two miles apart, are on hugely busy roads.

It highlighted the need to redraft legislation, work through logistical challenges and ensure safety, but concluded: "We find this use-case technically feasible; economic feasibility of a small-scale service would be challenging, but could be compelling at larger scale."

Taking to the skies to transform public health is already well advanced in Africa with DHL's Parcelcopter, which can carry loads of up to four kilos, completing 180 take-offs and landings, and logging 2,000 flying minutes in the Deliver Future project.

It has been able to reach a remote island district of Lake Victoria, in Tanzania, in less than an hour compared to the six-hour journey time via road.

Zipline, a small GPS-guided fixed-wing-style airplane capable of cruising at 80 miles per hour, has also proved its worth in Rwanda, central Africa.

The service takes text or WhatsApp orders from doctors in remote areas and loads up its craft, which is catapulted into flight from a metal rail at its central base. It flies at an altitude of 500 feet before descending to around 20 feet to release its package attached to a parachute that floats to pinpoint delivery sites.

The 15 Zips in Rwanda have flown more than 200,000 miles, delivering 7,000 units of blood in 7,500 on-demand flights. Its future cargos will include HIV medicine, snake anti-venom and drugs for rabies, which kills around 2,000 people, mainly children, a year in Tanzania.◆

A Swiss Post-Matternet drone transporting laboratory samples between hospitals in Lugano, Switzerland

Swiss Post

Commercial feature

Pharmaceutical protection is primed for take-off

Advances in packaging technology are helping to preserve the integrity of pharmaceuticals in transit, saving lives

A raft of recent technological developments in pharmaceutical logistics has enabled global drug manufacturers to move temperature-sensitive consignments around the planet with new confidence. The necessity has arisen from an industry that increasingly turns to biological products to replace blockbuster drugs.

"With next-generation biopharmaceutical products, which are derived from living cells and acutely temperature sensitive, it is more important than ever to ensure the control and visibility of the cold chain during distribution. We must remember that these safeguards are there to benefit us all; it could be our family, friends or co-workers who are receiving these life-saving medications," says Richard Wood, technical director at Softbox Systems.

With the cold chain biopharmaceutical logistics market expected to rise from $13.4 billion this year to $16.6 billion by 2021, according to Pharmaceutical Commerce, the advances in temperature control packaging (TCP) are a welcome fillip.

The material revolution is already in full swing. New TCP systems combine vacuum insulation panels and phase change materials to protect the integrity of biopharmaceuticals. They freeze and thaw in transit to regulate product environments at strictly +2C to +8C or +15C to +25C. Being recyclable and offering high performance, they also satisfy the desideratum of the industry's sustainability initiatives.

Market leader Softbox Systems has leveraged some of these material advances in the production of their new Skypod, a thermally-insulated packaging system designed to be carried by LTE/UAV-connected drones. After successful trials, it launches early next year. A global pharmaceutical giant originally identified the need for a solution in the wake of devastating damage and loss of life from Hurricane Maria in Puerto Rico in 2017.

> With Skypod, pharmaceutical companies will be able to deliver medicines quickly to remote locations and in their correct state for people to use

"The big pharma company we have been working with wanted to find ways of getting medication to desperate people in disaster areas and we developed the Skypod packaging system to carry in medicines that struggled to get through in the aftermath of the hurricane," says Mr Wood. "With Skypod, pharmaceutical companies will be able to deliver medicines quickly to remote locations and in their correct state for people to use."

The package has been designed to house a smartbox powered by internet of things (IoT) technology. It's geared to track the Skypod so data can be transmitted then viewed on a web and mobile app dashboard. This includes its location, near-real time external and internal box temperatures, as well as light exposure data that signals any tampering during daylight. The dashboard app will flash different alerts to prompt appropriate action.

This brainchild is a nod to the future. The combination of new materials and IoT can help form a new frontier for packaging manufacturers. In fact, Statista expects the IoT market, in healthcare and life sciences, to increase from $520 billion in 2014 to $1.335 trillion by 2020.

But it's not just the drones that are taking off; innovation is flying, right across the board. The patient has been the trigger, digitisation the enabler. It is us who will be sitting at the centre of proceedings rather than the pharmacy or hospital, receiving diagnoses and treatments at home. Smart technologies and linked healthcare systems are paving the way for this interaction.

New levels of connectivity, however, need to be accompanied by new levels of security. Serialisation – the practice of assigning unique, traceable numbers to individual units – is already leading the charge against counterfeit and falsified drugs, as well as diversion and theft. Advances in cryptography, where combinations of private and public keys protect data, are also building a robust security layer; similarly, with the rise of blockchain technology, where the entire decentralised user network forms a shield against amendment or tampering.

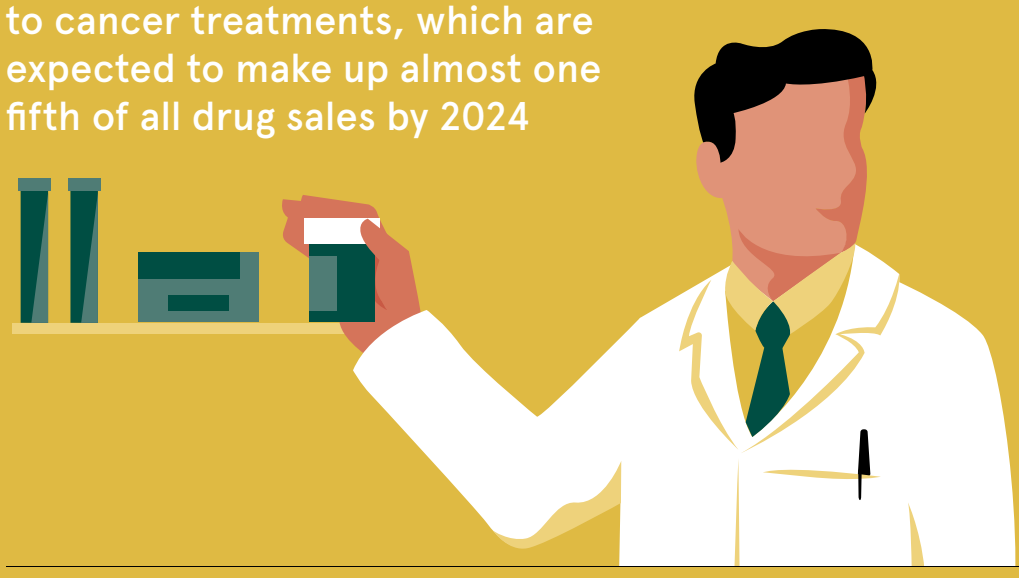
Pioneering cold chain solution providers are prepped for this new, transparent, super-connected era. They have to be. With the stakes so high, safeguarding medication logistics has become as important as any part of the drug development process itself.

For more information please visit softboxsystems.com

Softbox
TEMPERATURE CONTROL PACKAGING SYSTEMS

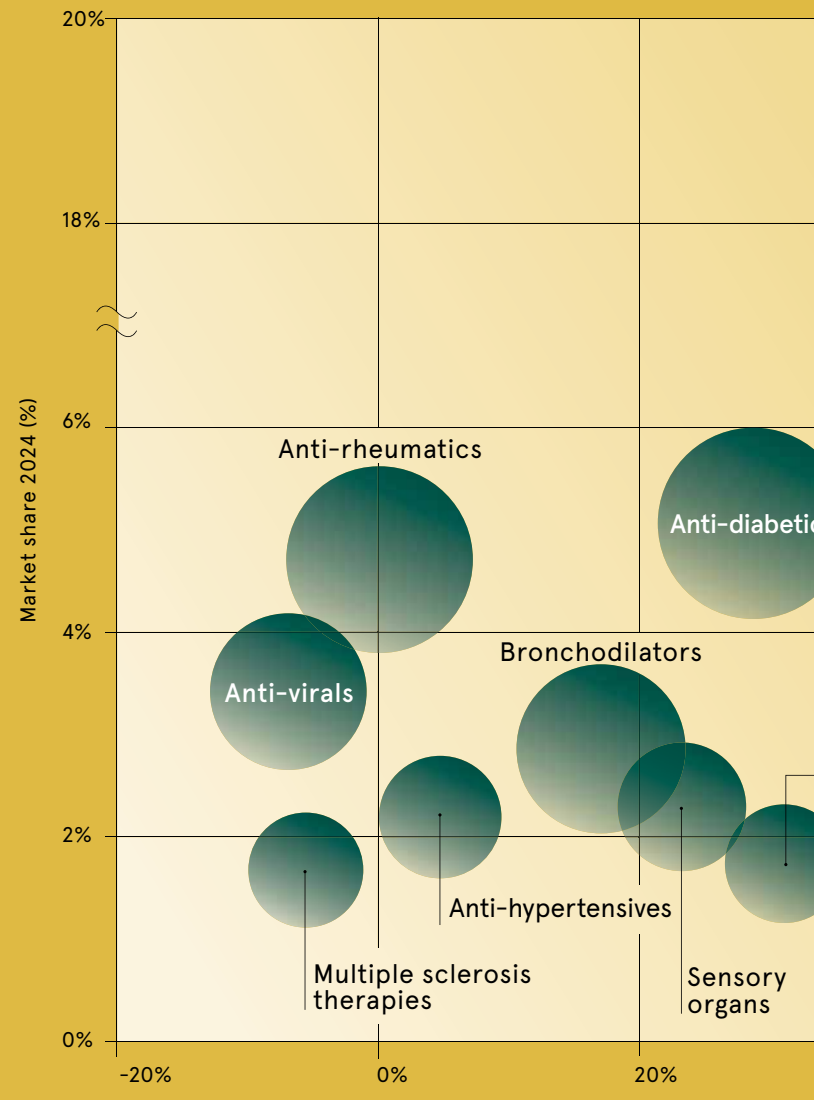
DRUGS MARKET OUTLOOK

Anticipating the most needed drug in the future is a key role of pharmaceutical companies and recent years have seen a big shift in focus to cancer treatments, which are expected to make up almost one fifth of all drug sales by 2024



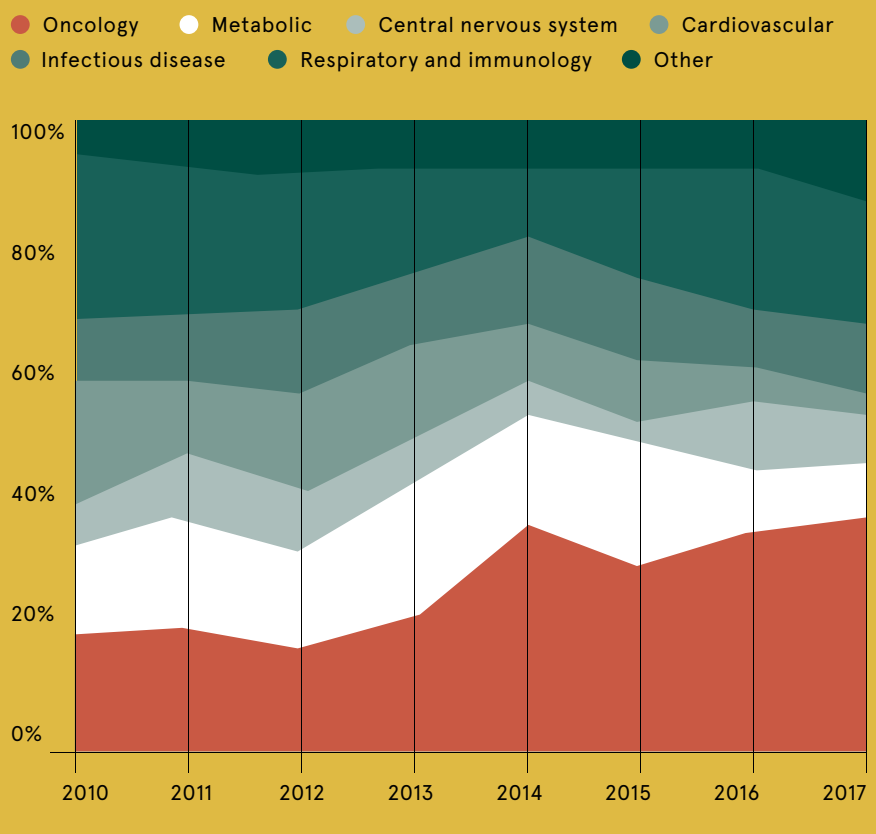
Top ten therapy areas in 2024

2017 figures sourced from company results; 2024 forecasts are b



Changing compositions of pharmaceutical majors

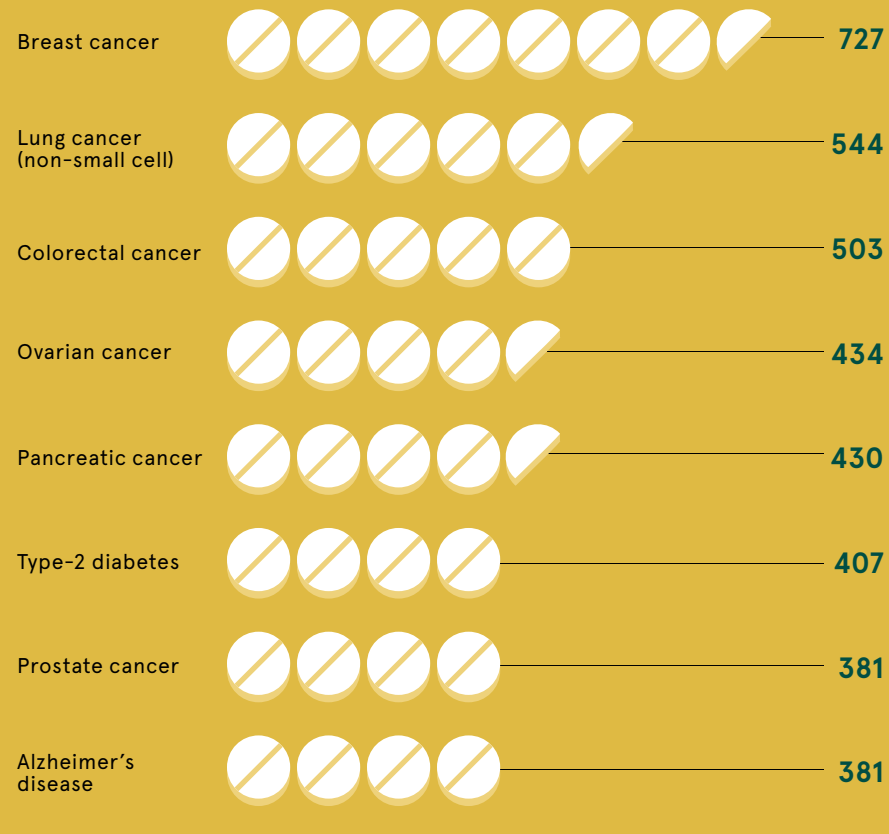
Breakdown by therapy area of 12 large-cap biopharmaceutical companies' late-stage drug pipelines



Deloitte 2017

Top drugs by disease or condition

Number of active drugs in 2018

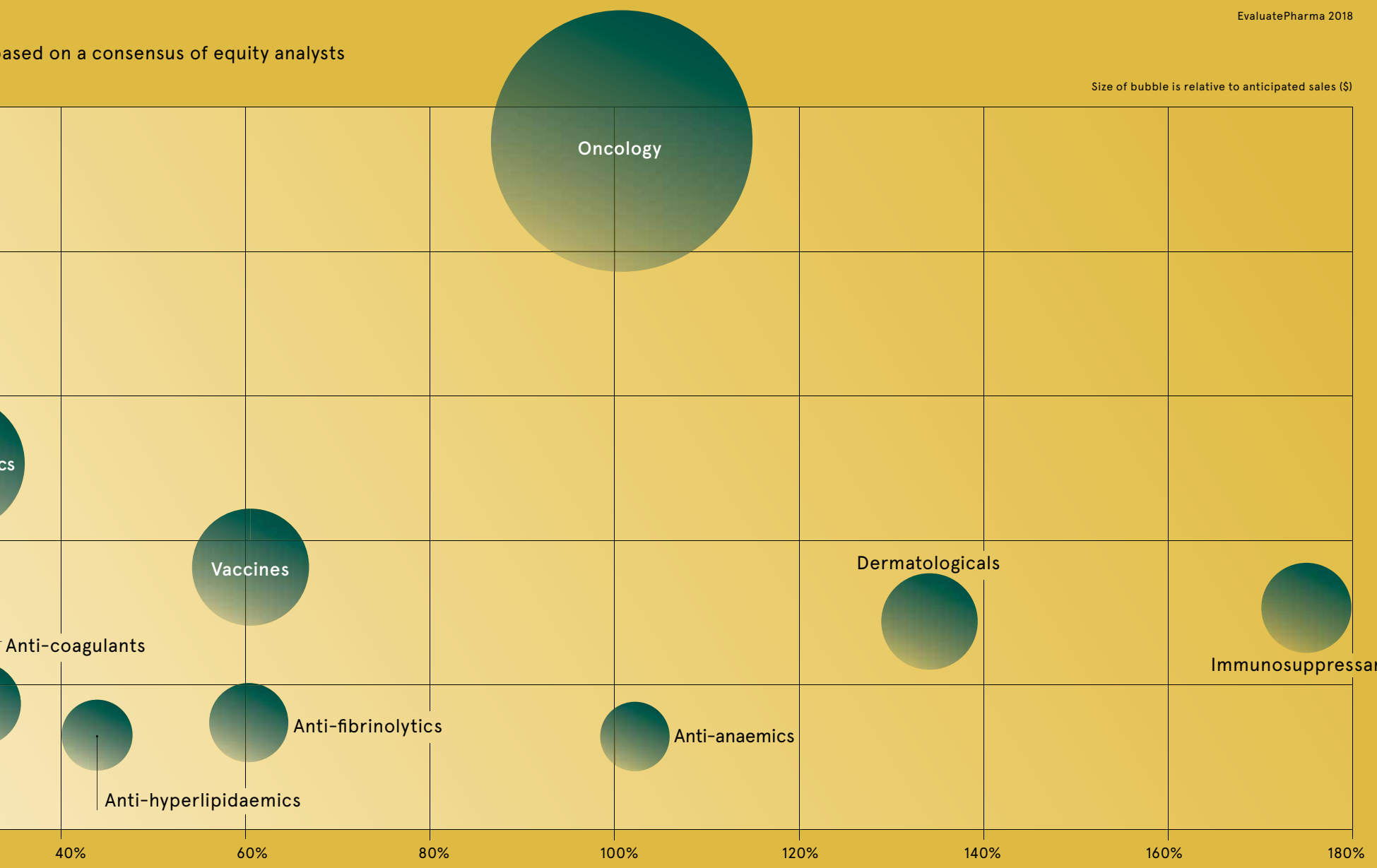


Pharmaprojects 2018

EvaluatePharma 2018

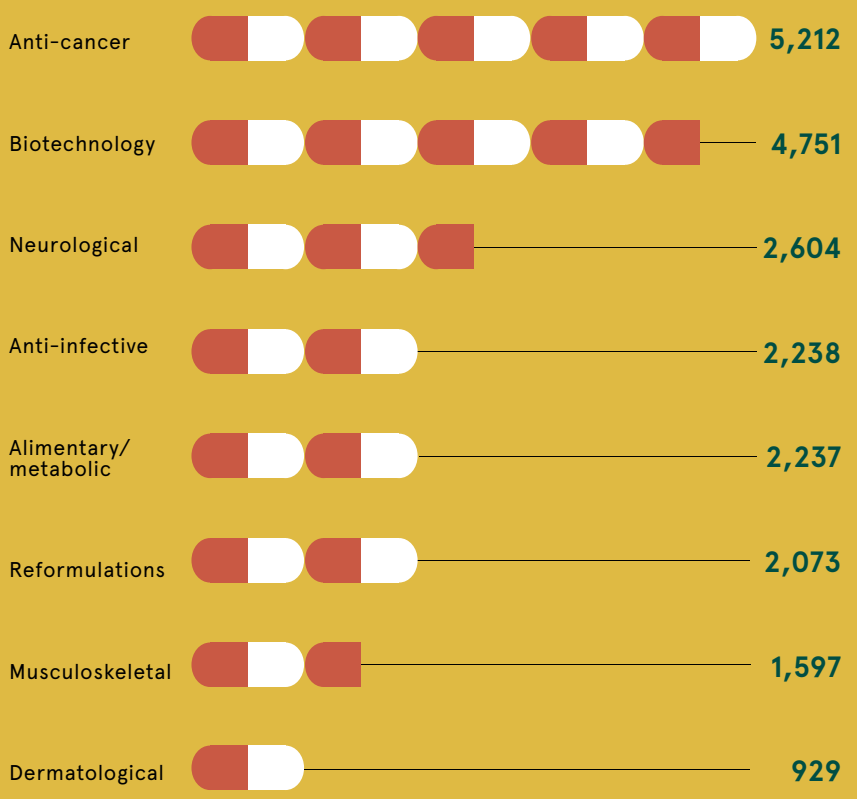
based on a consensus of equity analysts

Size of bubble is relative to anticipated sales ($)



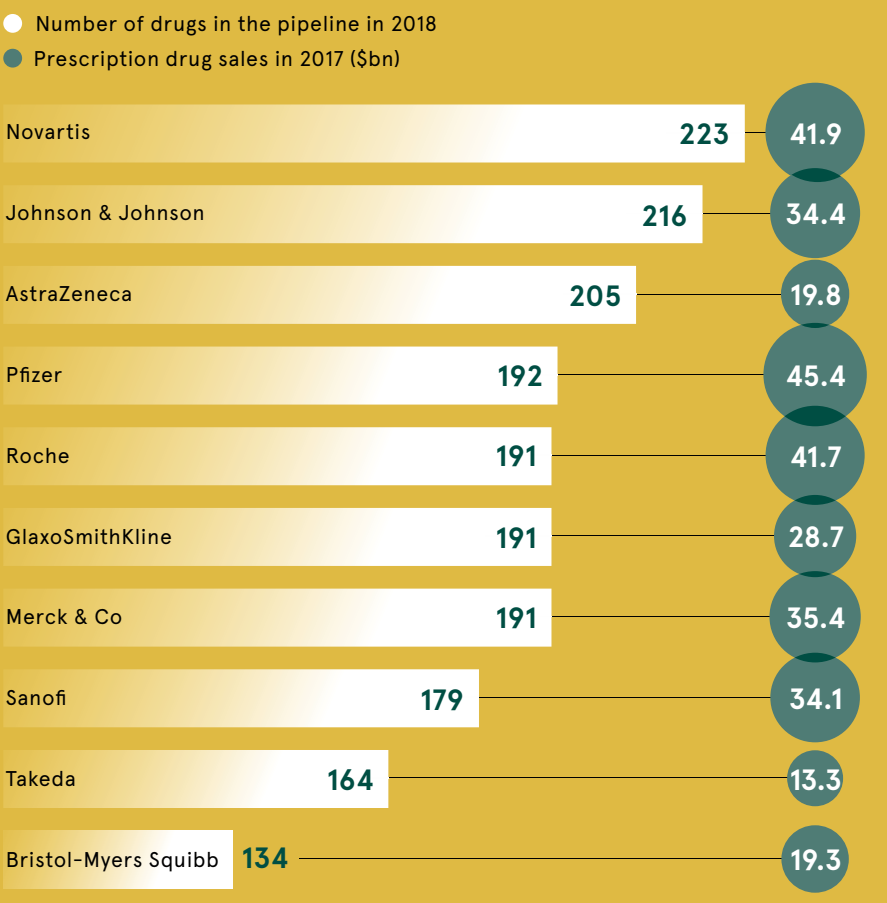
Percentage growth 2017 to 2024

Drug pipeline by therapy area



Pharmaprojects 2018

Biggest pharma companies by pipeline



Pharmaprojects 2018

TECHNOLOGY

Tech benefit from combating fake drugs

Regulation targeting fake medicines could speed up the adoption of technology in pharmacies

MARTIN BARROW

Community pharmacies are critical to the delivery of healthcare. More than 1.6 million people visit a pharmacy every day and the NHS spends £17.4 billion a year on medicines, more than half of which is in primary care.

Given this important role, you might expect pharmacies to be highly connected to the rest of the health service, sharing patient information and data with GPs, doctors and nurses.

The reality is very different. Pharmacy is fragmented, made up of thousands of owner-managed businesses and operating independently of health centres and hospitals. Community pharmacies were early adopters of new technology in the 1980s, but little has changed since. Pharmacists spend much of their time performing tasks that could easily be automated.

Reliance on paper-based processes gets in the way of connectivity with other parts of the NHS, which causes a huge administrative burden. It not only costs money, but it also increases the risk of errors. Up to half of patients don't take their medicine as intended and one of the reasons is that pharmacists don't have the time or resources to support patients as they would like.

> **Digitising the prescribing and distribution of medicines has an enormous potential to improve patient care, increase safety and make our system in the NHS more efficient**

Digitising the prescribing and distribution of medicines has an enormous potential to improve patient care, increase safety and make the NHS more efficient. There are hopes that a catalyst for change could be the implementation of a scheme introduced across the European Union aimed at eradicating fake medicines.

The scheme, known as the Falsified Medicines Directive (FMD), comes into effect on February 9, 2019. From this date, UK pharmacies will be expected to scan medicines before they are dispensed, using a unique identifier in the form of a barcode. This will be registered on a database called the European Medicines Verification System.

Compliance with FMD requires community pharmacies to adopt new software and cloud-based repositories of data. This could be the ideal moment to consider further opportunities afforded by new technology. NHS England, through its Digital Medicines programme, is encouraging pharmacies to harness the power of technology, so there is significant support across the health service.

However, progress has been held up by uncertainties over the future of FMD, which cast a shadow over plans for broader technological innovation in pharmacies. Brexit is a significant issue, which makes it unclear whether UK pharmacies must comply with the EU directive that drives FMD.

Many other questions remain, including which scanners can be used and who will bear the cost. This is a particularly pertinent issue at a time of tough financial settlements with the Department of Health and Social Care. And many pharmacists question whether the problem of fake medicine is actually big enough to justify this major investment programme.

With the clock ticking down, many of the systems and pieces of equipment required to implement the policy are still being designed. This makes it difficult to assess how much FMD will cost pharmacists. Estimates vary between £522 million and £813 million, which includes training.

01

01 Reliance of inefficient, paper-based processes is holding back the potential for digital transformation

02 Under new regulation, pharmacy staff will have to check anti-tampering devices, scan and verify all medicines before supplying to patients

Aileen Bryson, practice and policy lead for the Royal Pharmaceutical Society, says: "The FMD is a way of working between countries. It is intended to improve the patency of the supply chain from manufacturing right through to patients." If the UK did not adopt this way of working and counterfeiting was to increase in future, "the UK would be the weak link in the chain", she says.

There are concerns around how the outcome of the Brexit negotiations will affect the UK system linking with Europe. Despite this, pharmacies recognise the system is required for patient safety and are working to meet the deadline for FMD.

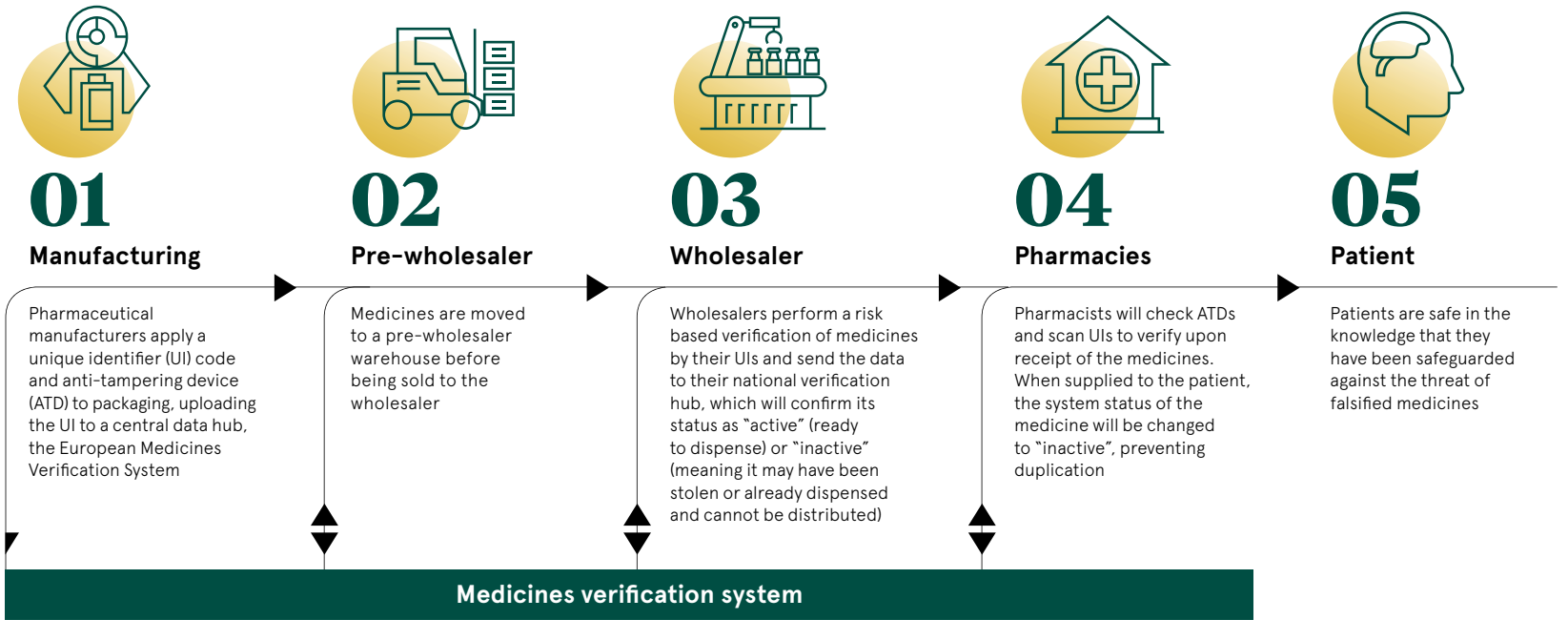
But Ms Bryson hopes the Medicines and Healthcare products Regulatory Agency, or MHRA, would take a proportionate approach to penalties as indicated in recent consultation, reserving criminal sanctions for wilful disregard for the new legislation.

Given all this uncertainty, FMD is becoming something of a drag on investment by community pharmacists, rather than a catalyst for change. This is a concern for NHS Digital, the NHS body responsible for information and technology across health and social care.

Vishen Ramkisson, senior clinical lead at NHS Digital, says: "Digitising the prescribing and distribution of medicines has an enormous potential to improve patient care, increase safety and make our system in the NHS more efficient. We have made great progress, but there remains a reliance on inefficient, paper-based processes, which slow us down, increase the potential for errors and cost money."

How the Falsified Medicines Directive will work

Europewide regulation will take effect from February 2019 and affect the entire pharmaceutical supply chain




Simon Dawson/Bloomberg via Getty Images


I viewfinder/Shutterstock

02

Integrating community pharmacy into the wider health service is a priority for NHS Digital. The ambition is to give pharmacists and their teams access to relevant clinical information, enabling them to communicate more easily with patients and other health professionals.

NHS Digital also wants community pharmacists to be able to contribute to patient records, so pharmacists, doctors, nurses and other health professionals will have more up-to-date information about their patients.

At the same time, it should be possible for NHS 111, GPs and hospitals to refer patients directly to community pharmacies, which will relieve the pressures on GPs, speed up hospital discharge and ensure patients have the support they need at home.

A critical element is the extension of electronic prescribing, or EPS. Instead of a paper prescription, patients have a token with a unique barcode which can be scanned at any pharmacy to retrieve the medication details.

At the moment, electronic prescriptions account for around 40 per cent of all prescriptions issued in England. Steps are being taken towards making electronic prescribing the default option for prescribing, dispensing and reimbursement of prescriptions in primary care. The latest phase of EPS will increase the proportion of prescriptions sent electronically to around 90 per cent.

Technology also offers possibilities to reduce labour-intensive work, freeing up more time for pharmacists to spend with patients. In Scotland, pharmacies have been able to invest in dispensing robots with the help of the Scottish government. Financial grants were offered to support investment in robotics and scanners as part of its Prescription for Excellence strategy for the sector. Scotland also has its first 24-hour automated prescription collection point. ◆

OPTEL offers immediate solution for EU FMD compliance and beyond

World's leading traceability provider is equipping one of the UK's largest pharmacy chains

With the EU's Falsified Medicines Directive (FMD) coming into force in February 2019, pharmacies are gearing up to comply with the new regulations requiring that all prescription medicines be authenticated before patients receive them.

The FMD aims to safeguard public health by stemming the growing tide of counterfeit medication in the supply chain, no easy task without a significant investment in scanning technology to ensure each medication is authentic and safe for human consumption.

Leveraging nearly three decades in the pharmaceutical industry and proven expertise in the integration of supply-chain traceability solutions, OPTEL has developed an effective and user-friendly solution to ensure pharmacies meet the compliance deadline. This technology is currently being implemented across all branches of one of the UK's largest retail pharmacy groups.

OPTEL's end-to-end traceability ecosystem at a glance

300k
producers

6bn
products tracked per year

15k
consumers engaged

700k
deaths caused every year by counterfeit medication

10%
of medications in the global marketplace are counterfeit, according to the World Health Organization

OPTEL Certa™ Software performs barcode verification as well as "decommissioning" of prescription medications, so when a medication has been dispensed to the patient, its barcode and related data are officially deactivated in the National Medicines Verification System (NMVS) database. By providing fast, safe and secure communication with the NMVS in countries across the EU, this unique, web-based tool provides healthcare professionals with an immediate solution for FMD compliance.

OPTEL Certa Software has been tested and proven in several pilot projects in community pharmacies as well as public and university hospitals across Europe, in conjunction with OPTEL's scanning hardware. Certa also has the flexibility to integrate into existing pharmacy systems.

In addition to verifying the authenticity of prescription medications, OPTEL Certa Software tracks data, such as expiry dates and recall status, going beyond compliance to optimise time and resources. As a result, pharmacy staff can focus efforts on what matters most: delivering the highest quality of patient care.

Features include a proven solution for immediate FMD compliance, either standalone or integrated into existing pharmacy equipment; efficient customer support and online training; a simple, user-friendly interface; flexibility to integrate into existing systems; and a complete line of compatible, ergonomic devices designed to adapt to all work environments.

Founded in 1989, OPTEL is the leading global provider of traceability systems. The company's mission is to use its innovative technologies to create a better world through its Intelligent Supply Chain™.

The only company with the ability to offer true end-to-end traceability, providing visibility across the entire supply chain, OPTEL enables the Intelligent Supply Chain by leveraging technologies such as cloud computing, artificial intelligence (AI) and the internet of things (IoT), to connect all the dots along the product life cycle, from raw materials to the patient.

"With the intensification of traceability and transformative innovations enabled by technological advances such as AI, blockchain and IoT devices, we can now increase the efficiency of supply chains and secure them completely," says Louis Roy, founder and president of OPTEL GROUP.

OPTEL's solutions enable diverse industries to benefit from actionable, real-time data to ensure the quality, integrity and authenticity of consumer products, help stop counterfeiting and reduce waste.

Headquartered in Québec City, Canada, with additional facilities in the United States, Ireland, India and Brazil, OPTEL, a Certified B Corporation, has expanded significantly to meet growing industry needs and support its humanitarian values.

For more information, please visit www.optelgroup.com/healthcare

OPTEL™
Traceability technologies for a better world

Eight ways to revitalise

A potential resource to ease pressure on GPs and hospitals, community pharmacies are seeking greater government funding

NICK EASEN

Community pharmacies are facing tough times; around 165 have shut up shop since October 2016 with a steep increase in closures recently, according to the Pharmaceutical Services Negotiating Committee (PSNC). Slashed government funding hasn't helped or the NHS crackdown on prescriptions for cheap over-the-counter medicines.

Like many high street traders, pharmacies face a barrage of competition from supermarkets and online providers. Their economic viability is in question at a time when health secretary Matt Hancock wants pharmacists to help ease the pressure on the NHS.

"It's vital that we maintain a network of fully funded community pharmacies, but it needs a new business model with sustainable funding," says Simon Dukes, chief executive of the PSNC. "We want an extension of existing services so community pharmacies can offer more support for patients and local communities."

There's no magic wand, yet pockets of excellence and best practice exist. Some pharmacists are being more creative with innovative services. The idea is to meet the growing demands of patients, while at the same time supplement income lost due to cuts.

"The future is about delivering services that patients really want. We have highly trained health professionals in the community. Let's use them in the best way possible," says Paul Mayberry, who owns a small chain of pharmacies in South Wales.

01 Adding value

It's time that pharmacists were more visible. "A lot of opportunities for guidance, prevention advice and patient care are lost when pharmacists are tied to the dispensing bench and rely on counter staff to perform this role," says Claire Anderson, professor of social pharmacy at the University of Nottingham. Reconfiguring the work of the business so the highly skilled pharmacist is not doing the boring or mundane tasks, but more of the value-added services with patients front of house, makes sense. "We don't want them to just be dispensing medicines, but offering an invaluable service to people who come in," says Mr Mayberry.

02 New services

From travel health to flu vaccines, advice on a sore throat to reviews of medication, or healthy living pharmacies (HLPs), there is a lot more to community pharmacies than dispensing. There are now 9,400 accredited HLPs in England. "These offer public health advice, self-care support and clinical services. Evaluations show they help avoid GP visits and are valued by patients," says Mr Dukes. The good thing with new services is they support community pharmacies in boosting income, diversify their revenue streams, therefore make them more resilient and in the long term ensure they're more valuable to the communities they serve.

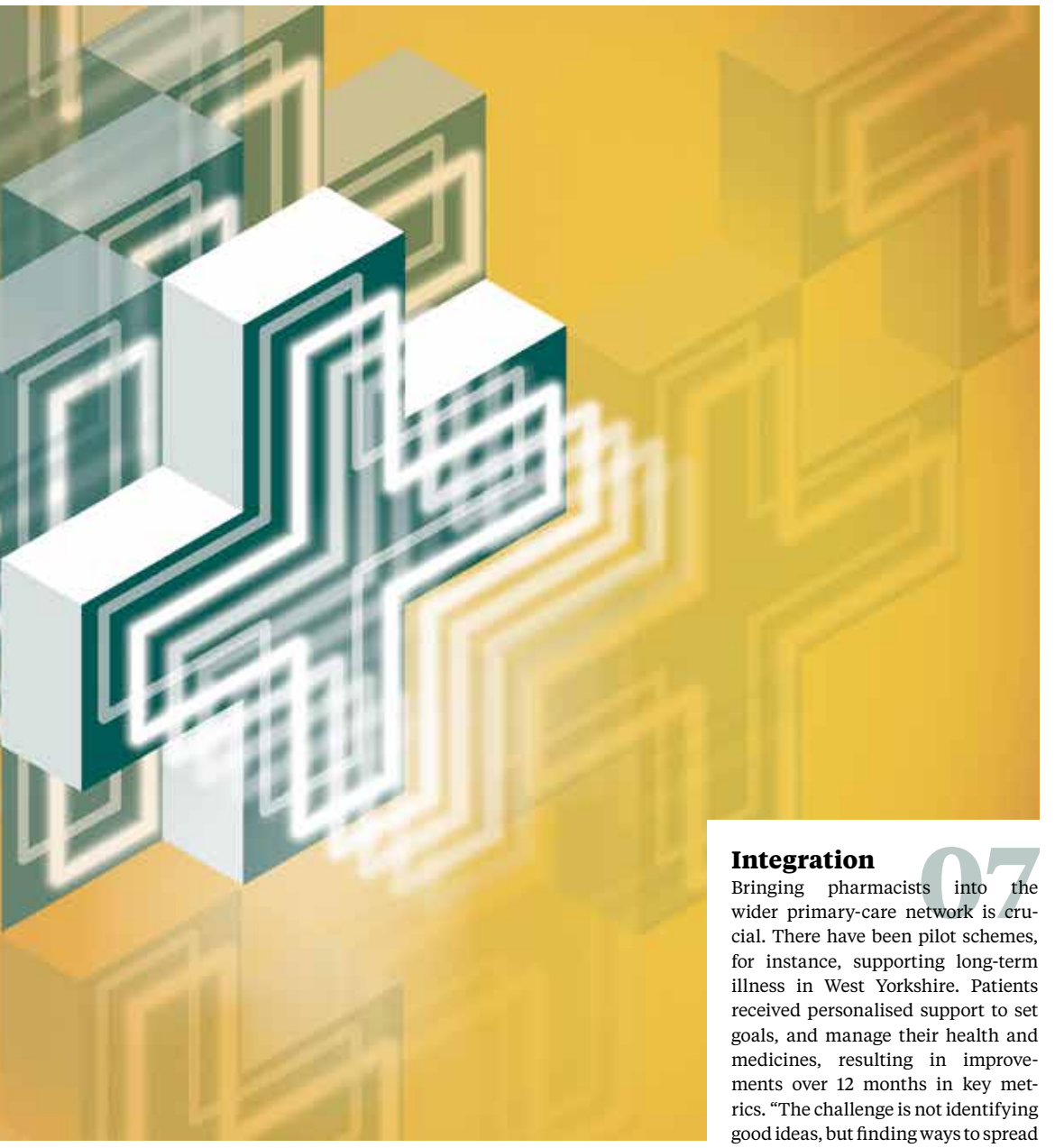
03 Pharmacies first

Let's face it, doctors are overworked. The first thing that Mr Hancock did when he became health secretary in July was pledge investment in community pharmacies in a bid to relieve pressure on hospitals. Pharmacies are in a good position to be a first port of call for patients. However, the operating model needs to evolve. "Community pharmacies cannot really progress unless they change from a fee per item dispensed, or medicines use review completed, to a more patient-centred approach where they're paid to provide care to the community. Contracts should be more aligned to those of GPs," says Professor Anderson. Pharmacies First, rolled out in Devon, has saved thousands of GP appointments and hundreds of A&E visits. The campaign, funded by the NHS, allows patients to receive care for minor ailments direct from pharmacies.

04 Automation and tech

Automating the laborious tasks, such as dispensing and labelling medicines, with robots, even offering some forms of advice via screens, can help free up pharmacists' time so it can be used for high-value tasks, especially in dealing with complex patient issues. There's also space for web-based pharmacies and virtual

community pharmacies



consultations. There are now apps that help patients comply with taking medicines. If patients offer to share their adherence data, pharmacists can then monitor and track what medicines people take. Wasted medicine is a growing problem in the NHS. It is estimated that as much as £300 million is wasted every year in this way as 50 per cent of people regularly miss doses. "This is just the tip of the iceberg. I believe billions of pounds is lost in this way. There are many indirect costs as well, not to mention the long-term effects of say diabetes patients and others with long-term illnesses not taking their medication. Pharmacists can help with this," says Mr Mayberry.

05 Realising social capital

Pharmacists, unlike GPs, have more time to talk. They provide a lot of unrealised social capital in local communities. Not only are they a good centre for health promotion, they are supportive when it comes to disease prevention and promoting self-care. They can also refer people to social support. "Healthy people and patients visit the pharmacist more than any other health professional. There is strong evidence that pharmacists can help to reduce risk of cardiovascular diseases, support smoking cessation, screen for diabetes and provide sexual health services, including emergency contraception," says Professor Anderson.

06 Government support

The NHS is under pressure, even though chancellor Philip Hammond gave a £20.5-billion, five-year boost for NHS England in this year's Budget. However, community pharmacies are still awaiting publication of the NHS Ten-Year Plan. With better funding, they could become well-being hubs on the local high street. "Achieving that requires a bold future vision from the UK government and the provision of a multi-year funding settlement which will enable community pharmacies to transition towards providing services that do more to relieve pressure on the NHS," says Mr Dukes. In Wales, money has been ringfenced by the Welsh Assembly for pharmacies to offer new services. These funds make good use of pharmacists' skills, relieve doctors' surgeries and improve access to smoking cessation and other services.

07 Integration

Bringing pharmacists into the wider primary-care network is crucial. There have been pilot schemes, for instance, supporting long-term illness in West Yorkshire. Patients received personalised support to set goals, and manage their health and medicines, resulting in improvements over 12 months in key metrics. "The challenge is not identifying good ideas, but finding ways to spread them at scale and pace. Ideally, national commissioning would give all patients access to the best services and ensure full integration of services regardless of their location. However, the government's drive is for local commissioning," says Mr Dukes.

08 Customer experience

"People are so used to pharmacies being there that they do not appreciate them as a social-infrastructure commodity. Like parks, train tracks and youth centres, they're only truly missed when they're gone," says Mike Bereza, managing director of Voyager Medical. The fact is pharmacies need to do more in terms of promoting themselves. Customer expectations are at an all-time high in an Amazon-driven era of instant gratification. The good thing is that community pharmacists are in a great position to bolster patient experience. "Much of healthcare is actually surrounded by compassion, human contact and care. When I, as a pharmacist, serve your grandmother's stroke medicine, I am not just giving her an object and sending her off. I am talking to her, asking her about how she is and what she is up to," says Mr Bereza. ◆

Commercial feature

Q&A Meeting the challenges of biosimilars

Napp Pharmaceuticals is a Cambridge-based company that provides prescription medicines to treat a wide range of diseases. Managing director **Hywel Day** discusses how his organisation has risen to meet some of the challenges of the biosimilars landscape and the wider industry

What has Napp's role been in the uptake of biosimilars?
It is remarkable how far the NHS has come with biosimilars, when you think that the first monoclonal antibody biosimilar was launched in the UK in 2015 and a further four since then. In the space of a few short years, NHS policymakers and commissioners have helped to change attitudes throughout much of the service towards this new area of medicine, and ensured their rate of uptake has increased significantly. Prior to 2015, Napp had no experience of biosimilars and now, nearly four years on, our medical and scientific teams are at the forefront of biosimilar education, working alongside the British Biosimilars Association, healthcare professionals, the National Institute for Health and Care Excellence, and NHS England. Biosimilars is a classic example of how we work quickly, efficiently, but with precision and expertise. We're a lean and agile business that can adapt to change and move quickly, that serves us, the NHS and ultimately the patients who use our medicines, well.

What does the future hold for biosimilars?
Delivering cost-effective medicines is the obvious, mutually beneficial goal for industry and the NHS. Our hope is that our efforts can build confidence in prescribing and help the NHS achieve the cost-saving potential of these important medicines – an estimated £300 million annually – which could be reinvested in staff and facilities to improve services for patients. It is also important that patients and the broader public understand that biosimilars are not just a cost-cutting exercise, but a way of delivering equally effective outcomes at sustainable costs.

The biosimilars landscape has shifted dramatically in a short period. How does Napp keep up with the constant evolution of the NHS?
We've been working side by side with the NHS since its inception. We recognise the increasing financial pressure on our health service. As the NHS environment has evolved, so has Napp, ensuring we have the right expertise to mirror what the NHS needs from us. We understand NHS priorities, what influences and drives their decision-making. Unlike many other pharmaceutical companies, we are part of a global network of independent companies, which gives us the freedom to make locally driven decisions quickly. When I joined the business, I was determined to shape us into a genuine, partnership-based organisation. Placing partnership at the heart of everything we do and every relationship, from our wholesale distributors to NHS decision-makers. I see it happening daily in the organisation and I believe it's innate at Napp to work in that way.

3
monoclonal antibody biosimilars launched by Napp in the UK since 2015

£300m
could be saved annually from biosimilar prescribing

What is Napp doing for UK healthcare today and for the future?
We recognise that adding value comes in different shapes; it's not always about price. Napp looks at the whole picture and just one of the many ways we deliver for our NHS partners is by providing educational programmes to meet their needs. The Napp Academy is one way we provide high-quality training and educational resources to healthcare professionals, supporting them in delivering the best possible care for their patients. Our education activities don't stop with healthcare professionals. We believe in a collective responsibility to contribute to the education of the next generation and, with that in mind, we set up the Science Ambassadors scheme. The scheme, which runs across our wider network of independent associated companies in the UK, provides free, exciting, hands-on science activities for local primary schools, and careers support to secondary schools and colleges within a 20-mile radius of our Cambridge head office. Formed in 2005, the scheme reaches more than 10,000 young people each year.

And what are Napp's plans for the challenges facing the UK health environment?
We've developed our working practices to ensure we can act quickly and efficiently, and are able to help our partners address challenges head on. I believe this expertise will be increasingly important as we confront one of the most complex and challenging futures the industry has ever faced. With so much uncertainty around Brexit and increasing concerns from scientists on the impact on life sciences, strong partnerships are more important now than ever to help find smart solutions.

For further information please visit napp.co.uk

NAPP The way to market.

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BIOSIMILARS

Andrew Brookes/Getty Images

Biosimilars boost gathers momentum

Manufactured when an original biologic drug's patent expires, biosimilars can increase access to treatment options and improve patient outcomes

JOHN ILLMAN

Four so-called biosimilar drugs were launched in the UK last month as part of a programme set to save the health service up to £300 million by 2021, according to NHS England.

They are clinically equivalent to biologic drugs, which are derived from living cells or organisms. Biologics have provided revolutionary treatments for inflammatory and autoimmune diseases and enzyme and hormone deficiences.

Biosimilars have been used for many years, so why are they generating so much interest now? It is because of the increasing range of biosimilar medicines emerging as biologic originator medicines come off patent.

What makes the recent launches critical is that all four medicines are biosmilars of the blockbuster Humira or adalimumab, to give its chemical or generic name. Between 2017 and 2018, the NHS is reported to have spent some £400 million on Humira, the world's best-selling pharmaceutical product between 2012 and 2016, with global sales of $16 billion in 2016.

Made from a synthetic antibody, adalimumab belongs to a family of medicines called anti-TNF therapies. It targets the protein TNF-alpha (tumour necrosis factor-alpha). Your body produces TNF-alpha as part of its immune response to infections.

TNF-alpha overproduction is thought to be partly to blame for the type of chronic inflammation associated with inflammatory bowel disease. Adalimumab binds to TNF-alpha, reducing inflammation and relieving symptoms.

The adalimumab story is just one of many in the exciting new biosimilar era. In 2017 alone, the European Medicines Agency approved sixteen biosimilars for seven different originator products. Potential savings from biosimilars are also expected to drive down the costs of biologic treatments.

The NHS drug bill highlights the need for saving. Estimated spending on medicines in England grew from £13 billion in 2010-11 to £174 billion in 2016-17, an average rise of 5 per cent a year.

This is not just because the NHS is prescribing more costly drugs. The NHS is a victim of its own success. The better healthcare is, the longer people live and the more expensive they are to look after, so every saving helps.

Norway is held up as a spectacular example of biosimilar success. Use of the infiximab biosimilar instead of the originator Remicade has resulted in a 66 per cent cost-reduction. Used to treat rheumatoid arthritis and inflammatory bowel disease, this biosimilar has won an 80 per cent market share. ◆


Cultura RM Exclusive/Matt Lincoln/Getty Images

Fresh thinking needed to finance treatments

Devising funding strategies to develop drugs for the treatment of rare diseases remains a challenge as patient groups are often too small

HEIDI VELLA

It is estimated there are more than 7,000 identified rare diseases, yet only around 400 have licensed treatments.

A rare disease is defined as affecting less than 200,000 people, but in some cases it could be as few as one or two families. Therefore, due to the smaller end-market, traditional drug-discovery financing models are often inadequate.

While legislation in both the United States and European Union, known as orphan drug designation, incentivises development for rare "orphan diseases" by providing a guaranteed market, it is far from a panacea.

To accelerate the discovery of affordable new therapies for those living with such diseases – around 30 million people in the EU alone, according to the European Medicines Agency – new, innovative thinking and funding models are required.

One burgeoning area of activity is repurposing of existing or in-development drugs. This means running trials and testing drugs already available on the market or taking therapies that proved ineffective in their original trials, but whose toxicity and safety record are known, and retrialling them to test their effectiveness in specific rare diseases.

Tim Hoctor, vice president of professional services at Elsevier, a global information analytics firm, says the business model to repurpose drugs is strong and compelling, particularly as ongoing research through genomics and other studies have made it easier to test for and understand the molecular detail of rare conditions.

"The more we know about rare diseases in the general population, the more we can potentially target a therapy that has already been developed, and is known to be safe, and bring it to market relatively quickly and cheaply for another disease," he explains.

According to Global Data, drug repurposing can reduce the development cost of therapies from more than $1 billion for new chemical entities to under $50 million. It can reduce the time to market by half – five years compared to fourteen – as well as limit failure risk.

Cydan, a US-based drug discovery accelerator for rare diseases, through its spin-off company Imara, is testing a drug candidate for sickle cell, a rare, genetic blood disease. The candidate had previously been shelved by a pharmaceutical company.

"We look at firms that have molecules sitting on the shelf and spend time working out how to identify a mechanism that can work for that molecule, which has been tried for one thing, but didn't succeed," explains founder and chief executive Chris Adams.

Cydan, he says, have developed a unique way to secure investment for potential rare disease drug candidates by de-risking them upfront.

"Our team acts like a diligent venture capital fund, but also de-risks by defining what the 'killer' experiment is that could lead to an investment decision to invest," he says. "Financiers can then, for $1 million to $2 million, get to an asset that is de-risked before they put in the further $30 million to $40 million needed."

For example, for its sickle cell candidate, the company licensed the relevant molecule from Lundbeck at the preclinical stage and de-risked it in animal and cellular models of sickle cell. Then in 2016, the company raised $31 million to begin phase-II testing that should be completed by 2019. Cydan has spun off three companies so far, two that are still active, and is preparing for its fourth.

Drugs that are already licensed are an even cheaper source of potential therapies for rare diseases. Yet, because many of these drugs are already, or will be imminently, off patent, there is little financial incentive to retrial them for other disorders.

Fran Platt, professor of biochemistry and pharmacology at the University of Oxford, explains: "A repurposed drug could be given orphan designation, but if it is freely available, it would be difficult to enforce pricing, meaning there is a risk drug companies won't recoup their costs."

Findacure, a UK-based charity founded to drive research and development for rare disease treatment, wants to bypass pharma altogether.

Chief executive Dr Rick Thompson says orphan designation incentive, though good, often leads to highly priced drugs. "There is a worry we get to a stage where there are drugs developed, but no one can afford to access them," he says.

Therefore, Findacure is proposing a radical new funding strategy: a social impact bond. The charity wants to issue a bond funded by private investors to pay for ten clinical trials for repurposed drugs, specifically targeting diseases that have a high management cost for the NHS.

In theory, successful trials would lead to off-label prescription of drugs for rare diseases within the NHS, which would then, from the saving it makes via reduced demand for surgery, care, appointments and so on, pay a proportion of money back into the bond to reimburse investors and fund new trials. The NHS has yet to agree to trial the model, however.

"I think it is a really unique and disruptive idea that proposes a different way to tackle a difficult problem," says Dr Thompson. "It just needs more time to soak into the consciousness to the NHS."

Findacure is currently working with US charity Cures Within Reach to help develop the idea further.

Unfortunately, Mr Adams believes that of the estimated 7,000 rare diseases, the addressable number is probably only 500 to 600, with the others not warranting investment, due to the size of patient groups.

However, for these smaller populations, Dr Thompson says, early-discovery work is being catalysed by patient groups themselves, even very small ones.

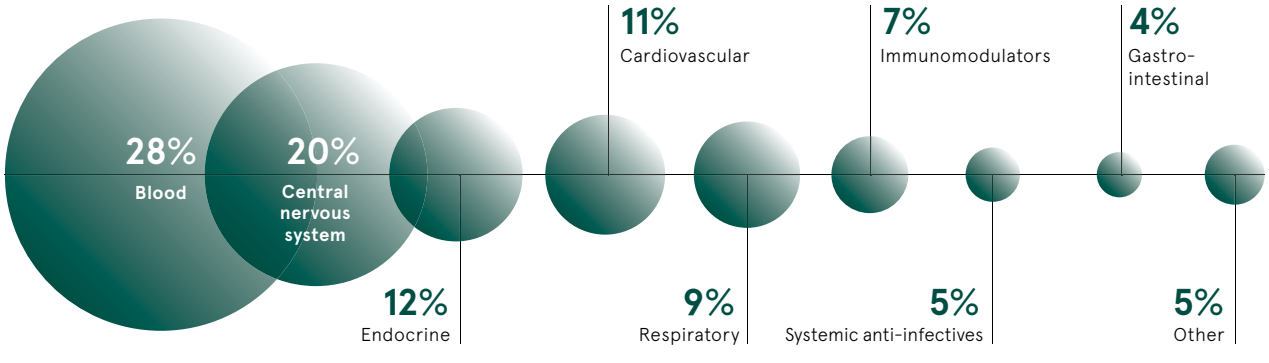
For example, the AKU Society, which represents the extremely rare genetic disease alkaptonuria, also known as Black Bone Disease, has been repurposing an existing drug called nitisinone, currently licensed for tyrosinaemia type 1, for treatment of the disease after animal experiments and research studies showed it could be effective.

Drug discovery for rare diseases remains problematic; orphan designation encourages investment, but results in high-priced drugs, while thousands of diseases, even with incentives, will never be commercially viable to treat.

However, experts agree that better data-sharing across all stakeholders in the sector will be pivotal in accelerating and de-risking drug discovery faster for pharma companies, charities and small patient groups by helping them find new therapy candidates from existing research and studies. ◆

Market share of global orphan drug sales by therapy category

All therapies excluding oncology



Percentages do not equal 100 due to rounding

Evaluate Pharma 2018

PERSONAL CONTACT

Combining tech with the human touch

With online consultations on the increase, many patients are opting for the human touch to complement technology

JACQUI THORNTON

As demand for health services continues to rise and time-pressured doctors attempt to treat their patients as efficiently as possible, it's not surprising that digital technology has come to the fore to solve many of the problems.

However, studies indicate that patients still value the human touch. A Populous survey of more than 2,000 people in the UK for Doctaly, a face-to-face private doctor service, showed that ideally 79 per cent want to see their GP in person rather than virtually or online.

But a growing number of digital healthcare providers are integrating the human element into their offerings to provide the best of both worlds.

MedicSpot offers private online video consultations with GPs, but crucially these are carried out in pharmacies.

As a result, the patient has the ability to conduct self-examinations using equipment such as a stethoscope, blood pressure machine, thermometer and pulse oximeter under the instruction of the doctor, with a pharmacist always on hand if they require assistance.

Chief executive Dr Zubair Ahmed, who is a GP, says this remote examination capability improves the safety and accuracy of digital healthcare while providing patients with convenience and accessibility.

"We know how important retaining a human element in delivering primary care is and recognise that no amount of technology can or should replace an in-person consultation with your own GP," he says. "With our hybrid model, we hope to give patients the benefits of digital healthcare while also ensuring patients can have human interaction with a healthcare professional."

The same technology could soon be used by paramedics and nurses on home visits, beaming in a doctor or even a specialist when needed. A pilot study is beginning in six months.

"Doctors waste a lot of time travelling while on home visits and many paramedics take patients into hospital when they might not have needed to go," says Dr Ahmed. "This will greatly improve the care unwell patients can receive while at home."


Westend61/Getty Images

Other providers say it's not the case that the human element has been removed by the digital revolution. But, more importantly, high-tech algorithms can direct patients for face-to-face care with the right healthcare professional, which is not always the GP.

For example, DoctorLink works like a virtual health assistant that can be accessed through a smartphone. A digital triage tool enables patients to access the help they need, whether that is referral to a nurse or specialist, advice from a pharmacist or GP appointment.

Andrew Gardner, chief executive of DoctorLink, says: "What we're doing doesn't dehumanise healthcare at all. We help patients get to see the right people. The focus of our technology is reducing stress and pressure on the people that work in the NHS so they can work more effectively, rather than trying to replace them."

One area of healthcare that has mushroomed online is prescription services and these too are having to incorporate the human element. While some, like Chemist Click, have a chatbot that is manned by pharmacists so patients can address any concerns, others have gone further after realising human engagement is the vital issue when it comes to client satisfaction.

Healthera has developed a pharmacy app that enables patients to order prescriptions and get reminders for medication as well as to message their local pharmacist directly with queries.

Launched in 2017, initial evaluations show patients are more satisfied with the service and it saves the pharmacist time; on average, ten minutes are saved per prescription compared with manual management.

It has also reduced phone calls from patients to the pharmacists about minor matters. Instead when they do call or visit the pharmacist, they have deeper, more engaged interactions, according to chief executive Quintus Liu, which can further reduce pressure on GPs.

Digital health company Now Healthcare also supplies repeat prescriptions, via an app and delivered free to patients' homes, but offers video consultations with their own GP as well as the opportunity to talk to a pharmacist.

Sandra Gidley, chair of the Royal Pharmaceutical Society's English Pharmacy Board, says: "This model is an encouraging combination of the use of technology, while maintaining the interpersonal link between patient and pharmacist."

In the area of prevention, a mixture of technology and the human element is also proving successful. In the United States, a number of hospitals are using a technology called EmmiPrevent to telephone patients with an "Alexa of healthcare". The solution, by Wolters Kluwer, makes it possible to reach many more patients than would be possible if nurses or hospital staff were diverted from other duties to make calls for hours.

In one example, interactive voice calls asked 4,774 women in Greater Greensboro, North Carolina whether they had been given a mammogram recently, offering them the opportunity to book one though a "real" person at the doctor's office. Some 120 days after the call, 32 per cent of women, who interacted with the Emmi automated call, had a documented mammogram.

It is this consistent engagement and the combination of automated systems working with healthcare professionals that makes the difference and improves health outcomes, according to Dr Denise Basow, chief executive of Wolters Kluwer's Clinical Effectiveness Business Unit.

"It gives patients the confidence and ability to successfully manage their health at home," she says. "Emmi provides the technology to deliver this level of engagement at a scale which hospital staff simply can't match." ◆

70%

of people in the UK regard face-to-face advice from a pharmacist or other pharmacy professional as very important to them

93%

of older people are against a shift away from local pharmacies supplying NHS medicines towards online retailers

Philips 2017

OPINION COLUMN

‘Our challenge is to use technology to achieve efficiencies and integrated care, without losing the human touch’

The NHS has a chronic access problem, and too often there are long waits for advice and treatment. Quite apart from the inconvenience for patients, this creates knock-on inefficiencies throughout the health and social care system.

Community pharmacy, a walk-in service near where people live, work and shop, is surely part of the solution.

Pharmacies already offer support that encompasses prevention, treatment for common ailments, health surveillance and the routine medicines management of long-term conditions.

Patients generally have access to the pharmacist within minutes of entering the pharmacy, usually without an appointment. Some 89 per cent of the population are within a 20-minute walk of a community pharmacy and opening hours are generally longer than many other settings. There are 1.6 million visits to a community pharmacy every day; that adds up to 14 visits per person a year.

By developing local pharmacies as neighbourhood health and wellbeing centres, and allowing pharmacists to put their clinical skills to full use, more capacity can be released into an NHS system under very severe strain.

For example, pharmacies in the north-east of England have been brought into the urgent care pathway, bringing into play an extensive network for the assessment, advice and treatment of patients for a range of low-acuity conditions, such as coughs and colds. On referral from NHS 111, patients are clinically assessed in pharmacy consultation rooms rather than urgent care centres.

Meanwhile, a recently evaluated scheme in Sheffield showed how pharmacies could release 18 million GP appointments nationwide by conducting medication reviews in the pharmacy and providing other dedicated support to practices.

Next month, NHS England is expected to unveil its ten-year plan for the health service, unlocking an additional £20 billion in government funding and determining the trajectory of the health service for years to come.

Health secretary Matt Hancock has confirmed that a large proportion of the investment will be focused on prevention through primary and community care services.

National Pharmacy Association and other pharmacy leaders have briefed officials developing the plan about the potential of community pharmacies to prevent disease and maintain good health. We believe that more screening, diagnostic capacity and ongoing monitoring services in pharmacies would help improve outcomes in relation to cardiovascular disease, respiratory conditions and cancer, three of the clinical priorities identified by NHS England. Such developments would achieve great population health results in the long term and achieve system-wide efficiencies by preventative care closer to home.

Seven in ten people regard face-to-face advice from a pharmacist or other member of the pharmacy team as very important to them, a proportion which increases among key groups of pharmacy users, including carers, older people and parents of young children.

But the high levels of satisfaction people express about their local pharmacies is no reason for complacency. As far as the future of community pharmacy is concerned, we need to go forwards or we will go backwards. There can be no standing still, given the constant evolution of consumer behaviours, as well as developments in digital technology, which will undoubtedly be an increasing feature of healthcare.

Our challenge is to use technology to achieve efficiencies and integrated care, without losing the human touch in healthcare. It’s important that pharmacies are progressive and modern, while at the same time being true to the historic values of pharmacy as a personal, caring profession. Tech should be deployed to enhance, rather than undermine, pharmacies’ locally based service proposition to be responsive, accessible, caring and community focused.

Nitin Sodha
Chair
National Pharmacy Association

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