FUTURE OF PHARMACEUTICALS

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FUTURE OF PHARMACEUTICALS

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WOMEN

Female pharma power

An increasing number of inspiring women hold senior roles in the pharmaceutical industry, but there is a long way to go until true gender parity is reached

Danny Buckland

The pivotal moment in the fight against coronavirus was delivered by husband-and-wife team Ugur Sahin and Oezlem Tuereci, who lead the development of the first effective vaccine that has sent waves of euphoria around the globe.

It was backed up by a second breakthrough and AstraZeneca heralding its vaccine with a high five between scientific researchers Federica Cappuccini and Sean Elias, while Oxford University's part in the joint discovery was characterised by senior team members Professor Katie Ewer and Professor Sarah Gilbert.

Their technical triumphs are obvious, but the vaccine vanguard may also prove instrumental in striking a secondary target of levelling up gender disparity in the pharmaceutical industry.

Becoming emblems of equal opportunity may be dwarfed by their scientific achievement, but images of the female high achievers, shoulder to shoulder in their laboratory coats, could become a beacon that draws more women into science and boosts gender parity.

The pharmaceutical industry is rated in the upper centile of sectors that provide space for talented women to achieve their dreams and progress to populate senior executive cadres and boardrooms.

Dame Emma Walmsley became the first women to lead a global pharma company when she became GSK's chief executive in April 2017 and the company's quota of women in senior management roles has risen annually to the present 36 per cent. It has a female chief digital and technology officer, Karenann Terrell, whose leadership team is a 50-50 male and female split.

Dr Deborah Dunsire leads Danish international company Lundbeck and US biotech firm Vertex has just appointed its first female chief executive, Reshma Kewalramani. Lundbeck grew its four strategic brands by 28 per cent across 2019 and Vertex revenue continues to prosper, with a forecast of $5 billion-plus in 2020.

But, behind the shimmering headline figures lurks cause for concern, with the WISE campaign, which advocates for greater opportunities for women in science, recording women account for only 24 per cent of the science, technology, engineering and mathematics (STEM) workforce. There is also concern that gender parity projects may be short lived and misfire through lack of focus and accountability.


MANDEL NGAN/AFP via Getty Images

Dame Emma Walmsley, chief executive of GlaxoSmithKline and the first woman ever to lead a global pharma company

"The glass ceiling has been cracked, but is it shattered all the way round? No. There's still more work to do," says Dr Kathy Gibson, former senior executive at Pfizer and now innovation and investment adviser at Pistoia Alliance, a global non-profit organisation dedicated to driving healthcare collaboration.

"Unconscious bias still exists and it is a blind spot for many companies. They want to bring more women in and promote them to senior roles but, because of the inherent bias, they are not necessarily focusing on the things that are going to drive the dial forward."

Dr Gibson says Pfizer improved its gender parity by a hard analysis of its own deficiencies and enshrining change that was measured, held to account and publicly backed by the chief executive.

"We found that women progressed until the mid-level of their careers and then they faced this cliff and didn't move up any more," she adds.

Less than **30%** of the world's researchers are women
UNESCO Institute of Statistics 2019

53% women in entry-level positions in the pharmaceutical talent pipeline

24% at the C-suite level

McKinsey & Company 2020

"One of the actions we took was that when a woman failed to get a promotion, we actively assessed why she didn't get the job and then provided opportunities to get any skills or experience that might have been lacking. To grow a crop of women leaders, who are able to become the CEO, you need to look deep inside and make it a data-driven exercise, even getting in an outside firm to go to the core of any issues.

"We also examined the kind of space women are given. Are they up there on the podium with the CEO at internal and external events? Are they representing the company at conferences? These things are measurable and help you construct and deliver change.

"The most compelling thing to do is to make it data driven. It takes effort and commitment, but it is worth it because we found our pipeline was more robust because of having women in senior roles, and there has been research demonstrating it can have a positive impact on a company's profitability."

Dr Samantha Barrell, chief operating officer at the Crick Institute, the biomedical discovery hub in London, believes science needs to be more inclusive in education to truly eradicate gender disparity. The Crick takes science to local schools to reach children from five years old and has a team working with teachers to bolster the delivery of the subject in the classroom.

"They need to feel excited by science and be given the school time to see what great opportunities and careers are open to them. The first step is to get all children more engaged with STEM subjects, regardless of gender," she says.

The Crick, which recently won an award for its approach to gender opportunities and diversity, boasts an even male-female split among its PhD students and post-doctoral scientists, while female representation in its senior group has risen from 17 to 30 per cent since its new building opened in 2016.

"The reason we have achieved that 50-50 gender balance across most roles, and women make up 53 per cent of the total workforce, is because we have really thought about it and really wanted it to happen. You need to have that senior-level commitment to make it happen," says Barrell.

The Crick is now advocating for university science departments and technical institutions to partner with local schools to improve access and ensure the gender gap is eradicated in the next generation.

REPUTATION

COVID is building trust in Big Pharma

Collaborating on a coronavirus vaccine has given Big Pharma a once-in-a-lifetime opportunity to redeem its reputation, but will the industry be able to sustain its improved image post-COVID?

MaryLou Costa

Big Pharma is having a moment. News of a coronavirus vaccine is casting the pharmaceutical industry in a new light, as collaborative and working in the public interest. It's a world away from previous perceptions of putting profits before people, keeping secrets and taking time to innovate.

Indeed, the 2019 *Edelman Trust Barometer* found only 57 per cent of the UK public had faith and trust in the sector. More recently, a survey of UK consumers by medication review site Drugs Disclosed revealed 93 per cent of patients are mistrustful of information about their medication, with 84 per cent believing the pharma industry influences prescription decisions.

What potential, then, does the vaccine have to redeem the pharmaceutical industry's reputation and how can this reinvigorated trust unleash its true potential? More importantly, how can Big Pharma maintain this trust post-COVID?

TOLGA AKMEN/AFP via Getty Images

The near-deserted streets of the City of London, as all hopes of economic recovery and a return to normal are pinned on a COVID vaccine

Consensus is that the collaboration, openness and public benefit demonstrated in creating a vaccine are what stands to rehabilitate the industry's reputation, with more of this needed beyond its rollout.

"The events of 2020 have given the public a window into the world of pharma research and development and, for many, have enhanced their view of the sector," says Dr Steve Arlington, president of pharmaceutical collaboration network the Pistoia Alliance.

"The importance of setting up collaborative programmes between companies that would normally compete was quickly recognised by the industry. The recent announcement by Pfizer is one of, we hope, many that will be made over the next few months and this success proves collaboration is hugely important in our quest to cure, treat and prevent disease."

The sector must carry this momentum and collaborative instinct forward to continue building trust, he adds.

This attitude needs to extend to the general public, notes Professor Sam Shah, chief medical strategy officer of men's health specialists Numan, with deeper transparency required on a range of levels.

"Advances in healthcare are likely to come from real-world evidence and citizen data. However, for citizens to share their data they need to know how it's going to be used, for what benefit and what outcome. Increased transparency within the sector would build this trust, but requires collaboration between regulators, industry and the public," says Shah.

> **A shift in the industry has to start with leadership at the top; they have to become more human**

"Mechanisms could include platforms where citizens control their own data, with visibility of who accesses it. These sorts of platforms don't yet exist in the UK or most parts of the world."

The incentive model for pharmaceutical companies must also move towards better patient outcomes and community investment, versus the current transactional model, allowing for better alignment with the public system, he adds.

"There needs to be a better way of matching needs to the pipeline. However, this requires a new relationship of co-production, one many public healthcare systems struggle with. They generally have a poor record of managing commercial relationships or working with industry," says Shah. It boils down to better engagement with citizens and the healthcare community overall.

Karina Malhotra, founder and managing director of patient experience consultancy Acumentice, believes this is easier said than done.

"Renewing an image that doesn't put profits against the greater good is key. It's the communication of that social-value piece, without coming across as opportunistic, that remains elusive," she warns.

A handful of pharmaceutical corporations are breaking the mould. Chiesi, for example, has become the largest pharma company to obtain B Corp accreditation. And, as Sana Alajmovic, founder and chief executive at preventative healthcare startup Sigrid Therapeutics, points out, they are already gaining ground in boosting the pharmaceutical industry's reputation.

"Merck's CEO [Ken Frazier] was part of a business advisory council in the Trump administration and when the President refused to crack down on white supremacist violence that was happening in 2017, he simply stepped away from that council," Alajmovic recalls.

"And Novartis' CEO [Vasant Narasimhan] is a great example of a modern leader. He has his own Instagram account, where he communicates with staff, shares books he has read; it's like he's talking to you.

"So a shift in the industry has to start with leadership at the top; they have to become more human. They have to take a stand because you don't operate in a vacuum. There are a lot of forces at play, like sustainability and leadership, through which pharma will have to change the way it works, to be better perceived."

57%

per cent of the UK public have faith and trust in the pharmaceutical sector

Edelman 2019

80%

of pharma leaders say changes in consumer attitudes, behaviour and spending is the issue which will have the greatest impact on their company in the next year

Deloitte 2020

Chiesi

B Corps and Big Pharma

Becoming a B Corp is no easy feat, yet those who do can claim the highest standards of social and environmental performance, public transparency and legal accountability to balance profit and purpose.

With more than 3,500 companies worldwide now certified as B Corps, just 20 are in pharmaceuticals. The largest is Italian conglomerate Chiesi. Group president Alberto Chiesi believes coronavirus has accelerated a cultural shift from "shareholder capitalism" to "stakeholder capitalism", and Chiesi has a role to play to attract more companies to "embrace this way of doing and measuring business performance".

"The trigger point is when it will be clearly acknowledged that striving to generate shared value does not mean businesses should focus on positive impact at the expense of financial performance. Acting as a sustainable business is a key component of a long-term success strategy. That deserves also a concrete reflection on how forward-looking policies could support and reward sustainable business models," he says.

Yet Dr Steve Arlington, president of the Pistoia Alliance, caveats that becoming a B Corp is just one element of repairing the pharmaceutical industry's reputation. Co-ordinated efforts both across and outside the sector are crucial for lasting change.

"Companies need to be able to work closely and non-competitively with groups including other pharmas, regulators, patient advocacy groups, health payers and providers, and logistics and supply," he says.

"It's important to look outside of the sector, too. The crossover between technology and research and development, in areas like artificial intelligence and machine-learning, telemedicine and quantum computing, is growing all the time. We can only make sure everyone benefits from these innovations if we work together to put in place frameworks to guide adoption and pool resources."

Commercial feature

Seeing past the impossible

Biopharmaceutical company Vertex is used to challenges, so much so that its scientists see impossible as a good place to start

In an era when developing a medicine takes an average £1.2 billion over 12 years, taking on innovative projects could seem a risky strategy. But chief scientific officer **Dr David Altshuler** explains how the Vertex strategy has allowed the company to forge a string of innovative successes, including breakthrough treatments for cystic fibrosis (CF). The leading geneticist and pioneer of human genome projects tells how the company, which has a research laboratory in Oxford, is tackling serious diseases with unmet needs and seemingly intractable complexities.

Q What is Vertex's approach to developing therapies?

A We believe the greatest value to society, patients and other stakeholders is to discover and develop new medicines that transform the lives of people with serious diseases. That is our true north. We are not looking to make incremental advances or to treat downstream symptoms; we want to strike at the heart of disease.

Q How does Vertex decide which disease conditions to research?

A We start with a laser-like focus on serious diseases for which there is no transformative therapy. Next, we look for a deep insight into the human causal disease biology, compelling evidence about the root cause in people, not just in the laboratory or in a fruit fly. We look for breakthroughs in the science of therapeutics. In many of the diseases we're working in, there may not have been existing tools or approaches to treating the underlying cause of disease, and our scientists have had to invent or partner to bring new processes, techniques and therapeutic strategies.

Q Isn't that a risky starting point?

A Actually, we believe that a strategy focused on understanding the human causal biology is more likely to result in breakthroughs for patients. Take CF as an example. Thirty years ago, the cause of the disease was identified as a mutation in a gene that is responsible for transporting chloride, effectively salt, across cell membranes. The need was clear, but there was no existing technology to restore chloride transport. So others focused on treating infections downstream or to thin the mucus. These efforts helped patients and deserve praise but, crucially, did not address the underlying cause. Vertex scientists said 'well, we may be able to create a new type of medicine that can restore the function of the mutant protein'. And, amazingly, they were able to succeed in that goal.

Q How did that work in CF?

A As background, the majority of oral medicines act by blocking the activity of the target. But with CF our scientists had the unprecedented idea to create a medicine that acts on a mutant protein to coax it to work more normally. It was unclear how to do this, but over 20 years of work that is exactly what they achieved.

Q How does that differ from other approaches?

A Many companies use what's called a shots-on-goal approach. That is they try many different approaches based on laboratory models, hoping one of them will help patients. Our view is to focus our resources and innovation on those relatively few outstanding scientific opportunities where all the pieces line up: a serious disease with limited treatment options, a deep insight into human biology and the right biomarkers, and a new therapeutic approach. We believe these opportunities deserve more attention because that's where we can make the greatest impact for patients right now.

Q Can you give a concrete example?

A Because we select targets that are well validated, our clinical development strategy is to bring multiple therapeutic candidates into the clinic and investigate them in parallel. By studying multiple candidate medicines at the same time, we can mitigate risk of compound-specific failures and this enables us to select the best possible candidate based on patient data rather than laboratory data alone. In this way, the compound selected to advance into large, phase-III trials is intended to have the best profile we can achieve. This approach requires conviction on the target and greater upfront investment, but enables more rapid progress and lower risk of expensive late-stage failure, all with the goal of bringing the best medicines to patients as quickly and safely as possible.

Q What is in the Vertex pipeline?

A We are pursuing a number of exciting projects that fit our strategy, including research for patients with sickle cell disease, beta thalassemia, type-1 diabetes and alpha 1 antitrypsin deficiency disease. We've assembled a robust toolkit of technologies and capabilities, including cell and genetic therapy platforms that will allow us to directly address these diseases from multiple angles. We are confident our strategy has great promise for patients and, if we are able to help patients, everything else will follow.

Q What is the role of patient advocacy groups in your R&D strategy?

A Appropriate engagement with patient organisations is key to help us understand the lives and daily experiences of the people they represent. Patient communities have insights that are crucial to inform the development of a medicine, at all stages of the process. A good example of this is working with patient groups to continually improve the way we run clinical trials; patient-centric clinical trials will ultimately enhance the effectiveness and speed of drug discovery. In the case of CF, it has helped develop the first medicine to treat the underlying cause of CF and we aim to follow this approach in all the diseases whether it is sickle cell disease, beta thalassemia, alpha 1 antitrypsin deficiency disease or others.

Q How important is R&D to Vertex successes?

A Our strategy is to invest in scientific innovations that break open or create new possibilities to treat serious diseases. And we put our money where our mouth is: we spend more than 70 per cent of our operating expenses on research and development (R&D) and three out of five Vertex employees are dedicated to R&D.

Q What does the pursuit of COVID-19 vaccines say about the biopharmaceutical industry?

A The progress towards a vaccine has been astounding and makes you very proud of everyone involved: companies, academic scientists and doctors, the regulators and governments. Because of advances in genomics and therapeutics, the underlying cause of COVID was discovered in weeks instead of years, and multiple therapeutics and vaccines have been advanced all within 2020. This experience reminds us that when we tackle serious diseases with urgency, focus and collaboration, we can move forward in a manner that previously would have been seen as impossible.

$11bn

invested by Vertex into scientific innovation since 2000

Over 70%

of Vertex's operating expenses are reinvested into R&D, well above the average of the top pharmaceutical and biotechnology companies in the industry

500

employees based in the UK, with nearly 200 employees at our dedicated research facility in Oxford

For more information please visit vrtxpharma.co.uk

VERTEX

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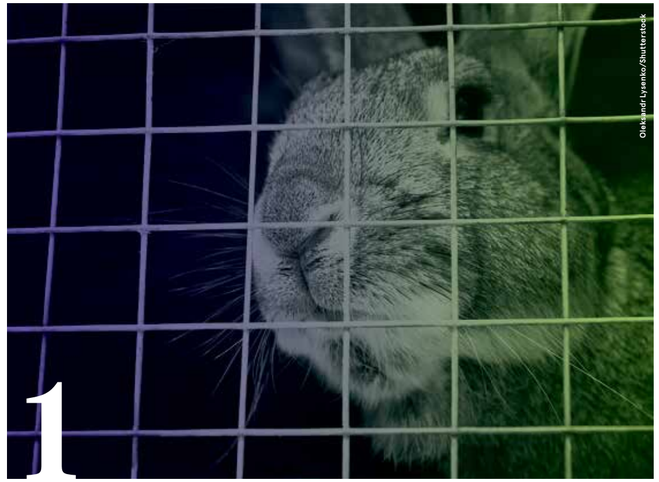
TECHNOLOGY

Five ways tech is changing pharma

Use of disruptive technology in the pharmaceutical industry can not only transform the sector, but also help to improve its image

Katrina Megget



Signalling the end of animal testing with 3D bioprinting

Estimates suggest approximately 90 per cent of all drug candidates that are tested in animal models fail when they move into human clinical trials because of species-specific differences. 3D bioprinting technology could change this.

By using a computer programme to direct the layer-by-layer printing of human cells, generating a model of a humanised organ, 3D bioprinting could replace animal testing and cut research costs by reducing the drug failure rate.

This is because bioprinted models reflect human pathology and physiology better than animal models, says Dr Jens Kurreck, professor of applied biochemistry at the Technische Universität Berlin. "Even if organ models cannot fully replace the reliance on animal testing, it may help to substantially reduce the number of animals needed by making a preselection of non-toxic and effective substances in a human setting."

This technology is becoming more widespread, says Erik Gatenholm, co-founder and chief executive of bioprinting firm Cellink, with lung, liver and lymph-node tissues being developed. A shift to 3D bioprinting can improve the industry's reputation by reducing reliance on animal testing and result in better and faster drugs to market, he says.

Drug discovery with AI

Repurposing pre-existing drugs to treat other diseases isn't new, but it has gained traction since coronavirus with the pressure to find treatments. Artificial intelligence (AI) and machine-learning can speed up this drug discovery.

"Drugs that have already passed through clinical trials and have a proven safety profile can offer a quicker starting point [for new drug indications]," says Dr Nick Lynch, investment lead at the Pistoia Alliance, a not-for-profit organisation that promotes pre-competitive collaboration in the life sciences industry.

Add in an algorithm that examines the relationships between diseases and existing drugs, and development timelines and costs can be cut further. "AI can crunch data far faster than human researchers," he points out.

The technology is already being used to find drugs that can be repurposed as antibiotics and COVID-19 treatments. Last year, the Pistoia Alliance, in collaboration with information and analytics company Elsevier, used AI to identify five drug candidates that could be repurposed to treat chronic pancreatitis, which has no specific drug therapy.

Lynch says the potential for AI in drug repurposing is huge, but notes it will only be effective if projects are collaborative, where pharma works with other research stakeholders and findings are shared.

Blockchain safeguarding the supply chain

Blockchain is increasingly viewed as a way to deal with pharma's supply chain, which is becoming more complex with multiple stakeholders, where the risk of drug tampering, counterfeits and diversion is very real.

The digital ledger system is a way to log and record data as time-stamped blocks. These blocks are linked and secured in such a way that they cannot be altered. Using this technology can prove where medicines and their ingredients come from, providing authenticity, traceability and transparency. This is important when American and European Union regulators are now requiring pharma to include track-and-trace elements in their supply chains.

"Blockchain improves efficiency, reduces the likelihood of counterfeit drugs entering the market and prevents drug diversion," says Pistoia's Lynch, who believes blockchain could play a big role in the pharma and healthcare sectors in the future. Already a number of pharma supply chain pilots have been conducted, but blockchain could also be used to improve security and privacy of other data, such as patient details generated in clinical trials.

Improved patient engagement through AR

Engaging with patients has its challenges for a regulated industry like pharma, especially when medicines compliance remains stubbornly low. Augmented reality (AR) could provide a solution.

Such technology uses software on a phone or tablet's camera to attach a virtual image to a real-world object, says Luke Bracegirdle, director at Virtual Health SHED, which developed an AR app with the NHS to explain atrial fibrillation and is now applying this technology in the pharmaceutical industry.

"The person can use the camera in their smartphone or tablet to trigger information about a medicine, which can be presented in a visual way and can be 'attached' to a medicine's packet," he says.

For instance, an avatar can guide the patient through the risks and benefits of taking a medicine or explain a condition through augmented

visuals. AR can make health information more accessible, easier to understand and more engaging. Yan Fossat, vice president and principal investigator, labs, at Klick Applied Science, says by humanising medical information, AR makes it more impactful.

Professor Stephen Chapman, chief executive and director of Virtual Health SHED, adds: "By making information easier to understand, the pharmaceutical industry could increase confidence in their medicines and greater trust in the industry."

IoT and digital tech wrapped around a pill

There is increasing pressure for pharma to provide services beyond their drugs to improve health outcomes and become more patient centric. This can be achieved by digital technology, enabled by the internet of things (IoT), wrapped around a pill. Think wearable devices for data collection and disease monitoring, symptom-tracking apps that share information online with a GP, smart inhalers with a sensor linked to an app to track asthma symptoms and inhaler use, and devices continuously monitoring blood glucose levels to alert the patient if necessary. Even smart pills with an ingestible sensor that tracks medicine-taking are being developed.

Using this digital technology can provide remote patient-monitoring and data collection, improve medicine adherence and help patients self-manage their diseases better, particularly for chronic conditions such as diabetes or blood pressure. Ultimately, connected healthcare can give patients back their lives.

While most of the technology is being developed by tech companies, there is scope for pharma to collaborate, playing a broader role in improving the lives of patients. "The world of healthcare comes with endless challenges," says Cellink's Gatenholm. "Using new technology to explore possibilities outside what is currently available is crucial for success."

Commercial feature

Tapping into the '$100-billion digital opportunity' in pharma

Artificial intelligence in the pharmaceutical industry is regarded as the holy grail of digital transformation – a promise of clean, efficient and rapid processes for new data-driven business models – yet it is proving an elusive prize

A structured approach to deploy the driving force of data can help companies energise their business and create a landscape where innovations such as artificial intelligence (AI) and predictive analytics move closer.

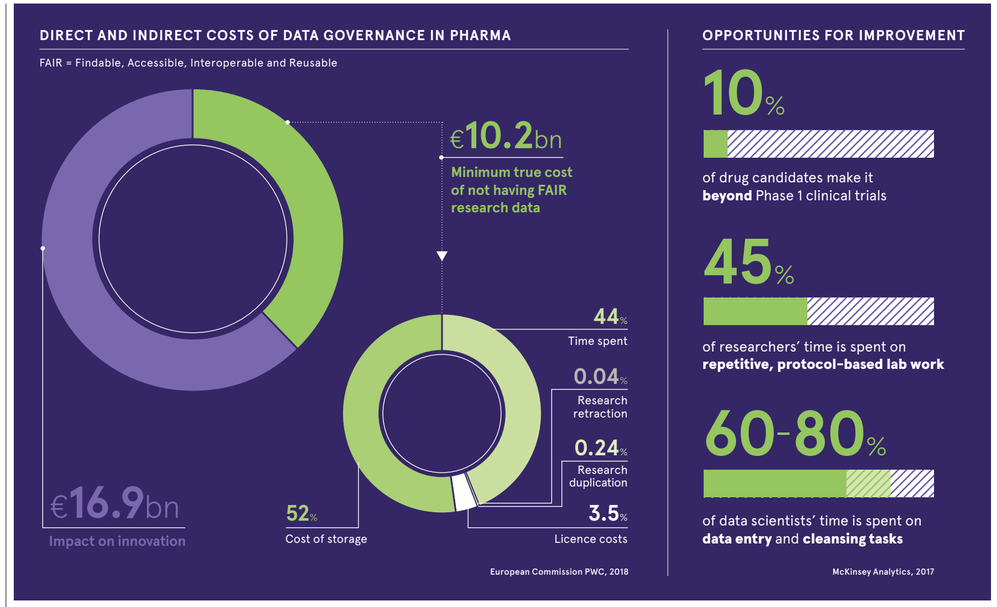
Research has shown that failures to realise digital innovation cost the industry €16.9 billion[1] a year, while labour-intensive procedures corrode the morale of scientists and compromise their ability to discover and develop new therapies.

"Getting your digital approach wrong has a massive impact on a company's bottom line," says Dr Haydn Boehm, head of commercial marketing at Connected Lab, a part of Merck, which is dedicated to unlocking the potential of data across the entire pharma industry value chain.

"Scientists are spending up to 60 per cent of their time on data entry and cleansing tasks when they should be concentrating on the science. But there are easy steps we can take to liberate their time and deliver value-based change, rather than viewing AI as something that will magically transform everything."

Analysts at McKinsey & Company have characterised digital in research and development as the "$100-billion opportunity"[2] with its potential to rewrite the current script of single drug development costing $2.6 billion[3], while return on investment continues to fall.

Boehm answers questions about the crucial steps needed to harness data to drive improvements across every aspect of pharma, from inventory to security and regulation to staff retention.



Q Why do pharma companies need to examine how they view and use digital?

A Everyone views AI as a panacea, but the real value is in drilling down into how your data can be used in your company. There could be many easy opportunities to leverage digital technologies and services to unlock the full potential of your business and increase process efficiencies. But if your data is not captured efficiently, or is not readily accessible to the people who need it, you are never going to be able to create data-driven business models.

Q What are the first steps to making data work for a company?

A It is important to recognise processes that involve a lot of human labour and motion waste, or unnecessary movements, which can be a significant element of how your data is captured, stored and used. Addressing this lays the foundation for utilising more AI and getting measurable benefits from it. Some companies are hiring scientists simply to cleanse data but, if you optimise data capture and input, you can employ those scientists to do what they are trained for and what they want to do.

Q What is the potential from enhanced digital practice?

A It can have a transformative influence where it matters, reducing costs, improving productivity, increasing capacity and speed of delivery, which has a huge impact on customer satisfaction. This enhances brand reputation and company equity. It also allows companies to optimise resources and the integrity of data, which is a fundamental springboard to greater use of AI across the organisation. The challenge is to analyse your approach to data and calculate where digital will be most effective.

Q Why is it important to have good data?

A If your data is clean and trustworthy, you can achieve so much more scientifically and structurally across the company. It is also vital for security and compliance, which are very important factors. Having data that cannot be shared with external partners, or even internally, hampers development, and pursuing the industry-standard practice of producing trial and safety data on PDFs can cause issues with regulatory authorities. The US Food and Drug Administration and European Medicines Agency are moving away from paper reports and into digital, so companies need to synchronise with their requirements or run the risk of censure. Having data that is not compliant with FAIR (findability, accessibility, interoperability and reusability) principles is another issue that hits the bottom line and a PwC report estimated it costs the European economy €10.2 billion a year in delays and lost opportunities.

Q Can it improve drug development?

A This is exactly what it does. Enhancing and harmonising processes and reducing motion waste creates more time and space to innovate and pursue discovery. The targeted use of digital technology can help deliver better predictors of what would be a successful molecule. Better data governance means you can collaborate on more productive terms and also interrogate historical data to generate new leads and speed up discovery processes. There are so many opportunities going to waste because the data is not clean or reusable, or it is difficult to locate and share. At the core of this is the scientist and anchoring them down with data-cleansing tasks and multiple transcriptions of reports is counter-productive. They need to be spending 100 per cent of their time problem-solving and driving scientific programmes forward. They should not be shackled when digital resource management can free them to do their job.

Q What are the downsides of not addressing data?

A The impact of lost opportunities is immense and it means companies lose out to competitors on many fronts. Contracts are lost, confidence is affected, staff retention becomes an issue and, ultimately, brand reputation suffers. All these negatively impact the balance sheet. It is key to look at areas where utilising digital technology can make a difference, such as producing reports or responding to regulatory affairs, which can be a massive human burden, or having scientists spending 45-60 per cent of their time cleansing data.

[1] Cost of not having FAIR research data, PwC EU Services March – 2018

[2] *Digital in R&D: The $100 billion opportunity*, McKinsey Analytics 2017

[3] Tufts Center for the Study of Drug Development, *Briefing: Cost of Developing a New Drug*, November 18, 2014

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MENTAL HEALTH

Is it time to rehabilitate psychedelics?

With mental health disorders on the rise, promising research suggests psychedelic drugs may offer revolutionary treatment options. But first, we have to stop the 1960s flashbacks

Sam Haddad

In 2009, Professor David Nutt, then the government's chief drug adviser, claimed that certain illegal drugs, including LSD, were less harmful than alcohol and tobacco. An expert in neuropsychopharmacology, he was citing scientific evidence, but the stigma that had shrouded psychedelic drugs since the 1960s cast a long shadow. Nutt's stance caused political and public uproar; he was promptly sacked.

Fast forward to today and Imperial College London has its own Centre of Psychedelic Research, where Nutt is Deputy Head. It has a prolific research output and enviable global reputation when it comes to studying psychedelic experiences. Research many believe will offer revolutionary treatment avenues for a range of mental health disorders.

LSD was first synthesised in a laboratory in 1938, but its popularity as a recreational drug invoked a moral panic that led both UK and US governments to make it illegal, stymying scientific research on psychedelics for the rest of the century.

The hiatus ended in the early 2000s when Roland Griffiths, a Professor in Psychiatry and Neurosciences at Johns Hopkins School of Medicine in the USA, who had become interested in "altered states of consciousness" managed to convince the US government and university to let him use healthy volunteers to study psilocybin, the psychedelic compound found in magic mushrooms.

The results were fascinating, with 70 per cent of volunteers saying they'd had one of the five most meaningful experiences of their lives while on the drug, comparable to the birth of a child or death of a parent. His findings were published in 2006 in the journal Psychopharmacology, and kickstarted a new dawn in psychedelic drug research.

"Understanding consciousness is the major frontier of our age," says Dr Robin Carhart-Harris, head of the Centre of Psychedelic Research at Imperial College London, and a protégé of Professor Nutt. "[The 2006 Griffiths study] helped to contextualise why psychedelics were interesting. They induce these big experiences that can change your life."

The potential benefits to people with mental health disorders are especially significant. Johns Hopkins has demonstrated the therapeutic effects of psychedelic drugs in people suffering from addiction, existential distress caused by life-threatening disease, and treatment-resistant depression.

At Imperial, Carhart-Harris has made similarly striking discoveries including studies which have shown psilocybin to be an effective treatment for eating disorders, suicide ideation and severe depression. In one, published next year, psilocybin performs far better than a conventional antidepressant drug.

Normally, pharmaceutical drugs target a particular disease state or symptoms, so why are these single interventions potentially effective for so many different disorders? "Psilocybin increases plasticity in the brain, its ability to change," says Carhart-Harris. The drug provides a pivotal mental state he describes as "a fork in the road".

"With depression and anxiety, people have developed these maladaptive ways of thinking and behaving, or in addiction, behaviour is channelled towards whatever the object of addiction is. What psychedelics do is they go in and target that core, the fact you've fallen into a certain way of being, and they increase your ability to change it."

> **Psychedelics target the fact you've fallen into a certain way of being, and they increase your ability to change it**

And these changes stick long after treatment. "Patients rewrite their own life narrative; they change the course of their lives going forwards," says Griffiths.

"Psychedelics are very disruptive scientifically to our assumptions about paradigms in mental health," says Carhart-Harris. Though he also cautions: "They're not party drugs, they're incredibly powerful and should be treated with respect." Research treatments are always done in the presence of trained therapists and volunteers are well screened in advance.

Almost all of the pioneering research into psychedelic experiences over the last 20 years has been funded by private foundations or individuals. As Griffiths says: "Without philanthropic support, the re-emergence of psychedelic research and treatment would not have occurred."

JR Rahn is the founder of MindMed, a New York-based startup developing psychedelic drugs to treat mental illness and addiction.

MindMed are already listed on Canada's NEO exchange with a market cap of 463.15M and aim to be the second psychedelic company to be listed on Nasdaq. Rahn believes people want to invest in a company like MindMed to enact a positive change in society.

"Every family in America has a story to tell," he says. "40% of US citizens had some form of mental health incident or substance abuse disorder in the midst of Covid-19; 40 per cent of investors might have the same variation."

On November 3rd 2020, along with voting Trump out of office, citizens in the state of Oregon voted to decriminalise psychedelic drugs for therapeutic use. Rahn thinks this is a step in the right direction, and evidence of how many people are looking for help with mental health disorders and addiction right now. But he believes the more sensible path to getting medicines approved is through the FDA at a national level.

"We want to pursue everything in a federally compliant manner," he says. "The cannabis industry didn't provide the data or do the research [to ensure their products were] federally compliant substances and I don't want to make the same mistakes."

Rahn feels getting the drugs approved would help reassure those with a more conservative mindset when it comes to psychedelics. "You show them the drug approvals...that vote of confidence as an industry."

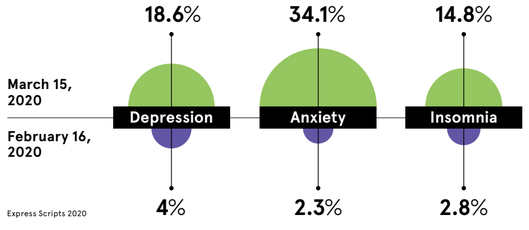
What would Carhart-Harris say to the UK government about the potential upside of licensing psychedelic drugs for therapeutic use? "I'd say they don't want to fall too far behind in this legitimate and exciting domain of mental healthcare. I do believe fortune will favour the brave here, in a way that medicinal cannabis has benefited the Canadian economy."

It would be a big boost to the psychotherapy industry, and to pharmaceutical manufacturing businesses in the UK, as a lot of psychedelics, including psilocybin, are synthesised here.

"Economically there are good reasons for the government to be thinking about psychedelics," he says, alongside the humane incentives, which would bring huge cost savings to overstretched mental health services in the NHS. Politicians just need to stop having 1960s flashbacks.

ARE CURRENT MENTAL HEALTH STRATEGIES WORKING?

Lockdown saw a fierce spike in prescriptions for mental health conditions in the US (percentage change of prescriptions filled per week, between Feb and March 2020)



Express Scripts 2020

Commercial feature

Q&A

Getting value for money in health care

Value-based contracting is the talk of the health care sector. But is it a game-changer or a passing fad? As publicly funded health care systems around the world look for innovative ways to improve access to new treatments, **Daniel Mathews**, EY's Europe, Middle East, India and Africa health sciences and wellness lead, discusses an emerging payment model

Q What is value-based contracting?

A Value-based contracting is a type of payment model that ties the price of a drug and supporting patient services to specific health, economic or experience outcomes. What we're trying to move towards is a model that better aligns all stakeholders' objectives for the long term. With value-based contracting, there should be a "triple win" so patients, health care payers and life science companies benefit. At its simplest, if a drug and associated services deliver a pre-agreed outcome, an agreed price is paid; if the drug and service fails to deliver then health care payers do not reimburse the cost.

Q Why is this a hot topic now?

A Public health systems all over the world are under great pressure to deliver value for money at a time when demand for care is growing. The big question is how do we fund health care over the next five to ten years? At the same time, the life sciences sector is producing some amazing science and coming forward with an extraordinary number of new medicines. The top ten life science companies will deliver somewhere between 350 to 400 new medicines between now and 2026. These new drugs are likely to be more focused and more effective. But they are also likely to require additional funds. Value-based contracting could be an attractive option to assure appropriate outcomes are achieved.

Q What are the advantages of value-based contracting?

A The triple win of value-based contracting means everyone benefits. Patients get access to the best new drugs, health care payers get better value for money and life sciences companies are reimbursed a fair price for the medicines, which enables research and development to produce the next generation of drugs. Value-based contracting also creates greater transparency using readily available, but fragmented, data to help us understand what works best in terms of outcomes, as well as best value for money. Ultimately, value-based contracting enables better collaboration between the stakeholders for the long-term benefit of patients.

Q What are the barriers to value-based contracting?

A Value-based contracting represents a big change over the way we have worked for so long and it takes time for the many stakeholders involved to understand the impact and make the necessary adjustment. Most people in health care agree value-based contracting is the right step in principle. But they are looking for the evidence that it is practical. The life sciences industry wants to be sure they are still going to get a fair price for their medicines. Payers want to be sure it will lead to better value for money. Patients need to be reassured it will improve access to drugs, particularly those currently considered too expensive. So these stakeholders are looking for proof points. Inevitably, processes, mindsets and relationships need to change. One of the interesting practical challenges is agreeing what specific outcomes we are going to measure to determine whether "value" has been achieved and how we are going to measure it. We have clinical outcomes from trials, but other measures are less well understood, such as the economic impact of, say, enabling someone to return to work or to remain in their own home for longer. Then there is quality of life: how do you measure the value to someone of living with less pain or of a good night's sleep? It is pretty complex.

Q Does the NHS have systems in place for the adoption of value-based contracting?

A Generally, public health systems such as the NHS do have good quality data. The issue is that it is fragmented and in many different formats. In the UK, we have clinical data from the NHS and also some data from NHS administrators on economic cost and patient throughput. But value-based contracting also needs to harness data from many other sources, including social care and local authorities. Employers will have information about patients returning to work. Other data will come from wearable devices or patient apps. Data is there and we can always create data if there are gaps. But there needs to be the confidence and trust to share data appropriately, especially in health care.

> **With value-based contracting, there should be a "triple win" so patients, health care payers and life science companies benefit**

Q What is the role of the patient in data collection?

A It is important to address any concerns patients have around the confidentiality of their medical records. The data that underpins value-based contracting can always be anonymised. Personalised, targeted medicine and treatment needs will require patient data to succeed; the more data we have, the better the understanding of outcomes. One of the reasons why coronavirus is being resolved relatively quickly is because so much data has been shared, not just in the UK, but across the world. This has led to the development of vaccines, but also to improvements in the way we care for COVID-19 patients in hospital. I'm excited EY has managed to create the Health Outcomes Platform, a novel secure digital solution that brings health care stakeholders together seamlessly and encourages collaboration.

Q Will value-based contracting transform care?

A I am very excited about the potential for value-based contracting to help deliver significant improvements in outcomes for patients, while achieving better value for money for publicly funded health systems such as the NHS. There is much work to be done, to build trust among all stakeholders and to put in place agile systems that respond to changing information and requirements. But we are moving in the right direction.

The EY solution: Health Outcomes Platform

The EY Health Outcomes Platform is an industry-leading digital solution designed to help reduce the complexity, cost and risk of value-based contracting for all players in the industry. It has been designed from the start with the principle of providing the "triple win" for patients, health care payers and life science companies, and has been developed and tested in collaboration with leading health care stakeholders. In fact, the first proof of concept was in the UK. The platform works for any value-based contracting scheme and meets all the health data-sharing standards. Within six weeks, it could be possible to start managing contracts in a new way which we think is essential for the creation of an industry platform. Our Health Outcomes Platform can help unlock value-based contracting at scale for the benefit of all. It takes something complex and uncertain, for example agreeing the health outcomes measures and the sharing of data securely, and simplifies the process, providing the essential ingredients to manage and reduce the risk. By arming each party with the information required for success, we not only provide real-time transparency, but foster an environment of trust that is essential for long-term shared value creation.

For more information please visit ey.com/lifesciences

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Building a better working world

THE ANTI-VAXXERS

For as long as there's been talk of a COVID-19 vaccine, there have been people against it. But as optimism starts to spread, and many start to look ahead to a possible return to normality, the increasing backlash against the vaccine could threaten the effectiveness of its roll-out. From conspiracy theories to safety concerns, this infographic explores the reasons behind the growing and concerning 'anti-vax' movement

ANTI-VAXXERS ONLINE

An analysis of 409 English language anti-vax social media accounts in October 2020

58m people follow anti-vax accounts on social media

31m of the 58 million total followers follow anti-vax accounts on Facebook

17m follow anti-vax accounts on YouTube

7m follow anti-vax accounts on Instagram

2m follow anti-vax accounts on Twitter

19% increase in followers since 2019 for 147 of the largest accounts*

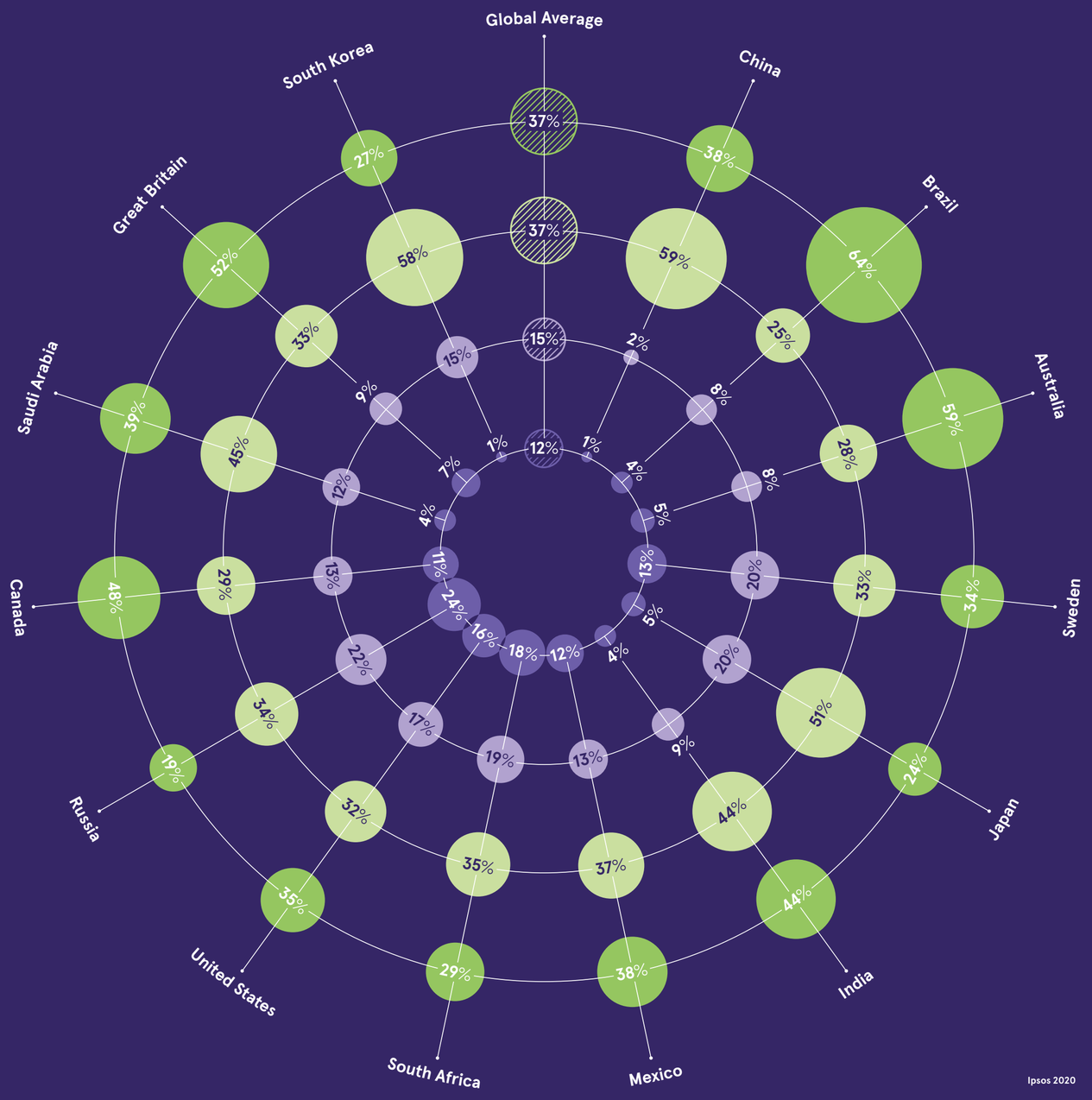
*Figure reflects only the 147 accounts where it was possible to establish the number of followers at the end of 2019

Center for Countering Digital Hate 2020

VACCINE ENTHUSIASM BY COUNTRY

Consumers were asked in July and August whether they would get a COVID-19 vaccine if one was to become available; selected countries

Strongly agree · Somewhat agree · Somewhat disagree · Strongly disagree

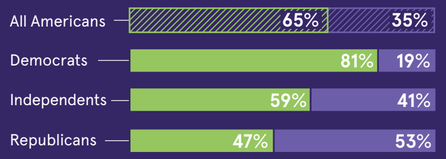


Ipsos 2020

POLITICS HAS A PART TO PLAY

US citizens were surveyed in August to find out if they would get a Covid-19 vaccine if it became available

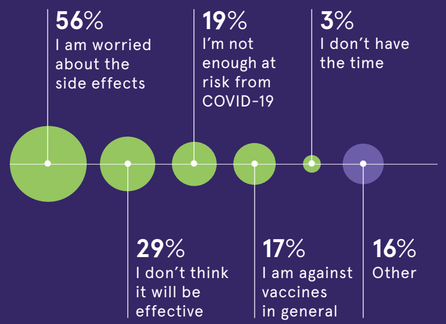
Yes · No



Gallup 2020

REASONS TO ABSTAIN

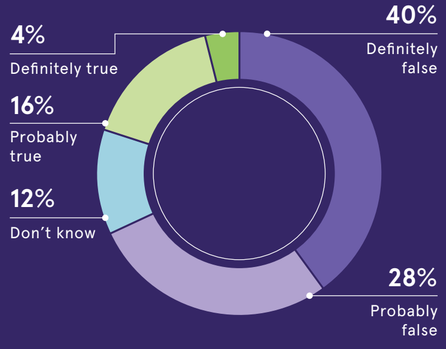
Global consumers, who said they would not get a vaccine if it became available, gave the following reasons



Ipsos 2020

VACCINE SIDE-EFFECTS?

UK consumers were asked in August if they think vaccines have harmful effects which are not being disclosed; survey was about vaccines in general (not just the COVID-19 vaccine)



YouGov 2020

Ray Tang/Anadolu Agency via Getty Images

A protester with a model COVID-19 vaccine syringe is detained by police at a demonstration against a vaccine education event with the Bill and Melinda Gates Foundation in London this year.

VACCINES

Vaccine hesitancy undermining the fight against coronavirus

A coronavirus vaccine is on the way, but a big challenge will be convincing vaccine-hesitant people to have it and combating misinformation about the jab

Natalie Healey

In 1796, Edward Jenner administered the world's first successful vaccine. It is considered one of the most important medical breakthroughs in history, but not everyone was happy about the smallpox jab at the time. Jenner was widely ridiculed and tens of thousands of people later took to the streets to protest against compulsory immunisations for the "speckled monster" disease.

Since the English doctor's discovery, vaccines have cut rates of infectious diseases all over the world. But for all their success, many still don't trust them. The World Health Organization (WHO) lists "vaccine hesitancy" as one of the top ten threats to global health. It says 1.5 million deaths could be avoided if more people had access to vaccinations.

In the UK, there's been a worrying resurgence of measles in the last few years as some parents refuse the MMR vaccination for their children. Vaccine hesitancy could also be a dangerous hurdle in the pandemic. On Dec 2, the UK became the first country in the world to approve the Pfizer/BioNTech Covid-19 vaccine. But alongside sorting the logistics of manufacturing and distributing a jab for millions, experts will have to convince ordinary members of the public that the discovery the world has been waiting for is safe.

Public health experts estimate that up to 80 per cent of people will need to be vaccinated to reach population immunity. This will be hard to achieve if too many are unwilling. A British Academy and Royal Society report found around 36 per cent of people in the UK and more than half of those in the United States are either "uncertain" or "unlikely" to be vaccinated against COVID-19.

Within hours of Pfizer and BioNTech announcing early results showing their coronavirus vaccine had 90 per cent effectiveness, "Bill Gates" began trending on Twitter. Some conspiracy theorists claim the Microsoft founder is using the pandemic as cover to implant humans with trackable microchips.

But Dr Heidi Larson, professor of anthropology at the London School of Hygiene & Tropical Medicine, believes vaccine hesitancy is a more nuanced problem than this fringe, and completely false, view. More insidious claims about immunisations are those that sound credible, but come to the wrong conclusions and create a narrative of doubt. "I think the problem is harmful misinformation and the fact we have a very distrusting and anxious public," she says.

Larson and colleagues surveyed 4,000 people in the UK about their attitudes towards a COVID-19 vaccine. Some 54 per cent said they would take it. But when the participants were exposed to some of the most frequently circulating vaccine rumours on social media, this dropped by 6.4 percentage points. The research, which has not yet been peer reviewed, suggests the impact of misinformation should not be underestimated. "At 54 per cent, we're already wobbling on or below herd immunity," says Larson. "So all it takes is a few percentage points to knock it down. And that's why we're so vulnerable."

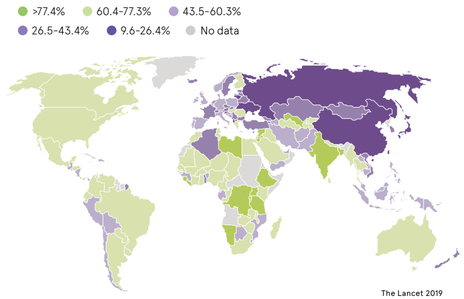
Kolina Koltai, a researcher from the Center for an Informed Public at the University of Washington, says vaccine hesitancy could be more prevalent than we realise because research on this subject has tended to focus on parents with young children. For a successful COVID vaccine rollout, more people will have to be on board.

"I think there are a lot more people who haven't necessarily thought about vaccines, who will be hesitant to take this vaccine," she says. Speed of development and uncertainty around side-effects are two quite reasonable worries people might have. Although the scientists leading the trials haven't taken short cuts on safety, never before has a vaccine been developed so quickly. "You might see people say, 'I'm pro-vaccine, but I'm not sure about the COVID one'," says Koltai.

Like Larson, Koltai believes misinformation circulating on social media could exacerbate the problem. "There's been backlash ever since there have been vaccines. But social media makes it easier to connect with people who hold these sorts of views and there hasn't been much moderation on these platforms in terms of combating vaccine misinformation," she says.

VACCINE HESITANCY AROUND THE WORLD

Respondents who think vaccination is safe



The Lancet 2019

Anyone could be anxious about immunisations, but there's some evidence that anti-vaccination groups are likely to target marginalised communities. For instance, a 2017 outbreak of measles in Minnesota was found to be fuelled by extremists influencing a Somali community, using a widely debunked claim from the 1990s that the MMR vaccine causes autism.

Context is key though. People are not "empty vessels" absorbing information put out by campaigners or public health authorities, says Melissa Leach, director of the Institute of Development Studies. "They will always interpret this in the light of their own experiences, community relationships and their broader trust in state and global agencies and authorities," she says.

Gender, ethnicity, class and many other factors shape who hesitates. In some US polls, black Americans have been particularly sceptical about a COVID-19 jab. Longstanding racial biases in medicine could explain why. Many African-American men died of syphilis in the infamous Tuskegee Study which ended in 1972. For 40 years doctors had willingly monitored men they knew wouldn't survive without treatment in a US government trial. The participants had been told they were getting free medical care and were never informed they had the sexually transmitted disease.

Ethnic minorities are under-represented in clinical trials to this day and many people cite the Tuskegee experiment for their reluctance to participate in medical research. Trust in a COVID-19 vaccine is important for everyone, but especially those at greater risk of experiencing severe illness with the virus. Official figures have confirmed black people are more than four times as likely to die of COVID than white people.

Access is another concern, says behavioural scientist Dr Alice Forster from University College London. Practical issues disproportionately affect people on lower incomes, she says. Studies on childhood immunisation have found travel to a clinic and problems getting time off work can prevent a parent vaccinating their child. Language barriers are another stumbling block. "Making sure the whole population is getting equitable access needs to be a focus," says Forster.

Efforts to tackle vaccine hesitancy and ease anxieties are critical if we are to snuff out the pandemic. The Labour Party is calling for financial penalties for social media companies that don't remove false scare stories about vaccines. But Forster believes leaders need to not only address circulating misinformation, but generate an open dialogue that does not dismiss people's very real concerns.

Health workers are likely to play a key role in encouraging and reassuring the public. "We know the general public really trusts health professionals and being able to sit down and have these detailed discussions would be a real benefit," says Forster. That the UK's deputy chief medical officer Professor Jonathan Van-Tam said he'd be "at the front of the queue" for the COVID-19 vaccine if he could might be a good starting point.

Getting the vaccine should be made as convenient as possible and messaging must be available in multiple languages. But Larson's big worry is what happens when someone who has had the vaccine experiences complications. Mishandling the communication around an adverse event, even one later found to be unrelated to the coronavirus jab, could be a disaster for public trust. The government will need to address any potential side-effects transparently with the public.

"Lack of empathy is part of what's alienating people around vaccines; we need to be extra sensitive in the context of COVID," Larson concludes.

> **Lack of empathy is part of what's alienating people around vaccines; we need to be extra sensitive in the context of COVID**

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GEOPOLITICS

Fight for pharmaceutical supremacy

India's position as a pharma powerhouse is well established, but a galvanised China has set its sights on overtaking rivals

Meera Navlakha

As the world races to develop and distribute a vaccine to combat coronavirus, there is a parallel contest gathering momentum between India and China's pharmaceutical markets. The pharma industries in both countries are perceived to be competing for a position at the head of the global market. While India retains its position as a world leader in generic medicine production, China has increased its investment in research and development, signalling an interest in overtaking competitors.

India, recognised as a pharmaceutical powerhouse, is facing a threat. In *Made in China 2025*, China's industrial policy aiming to make the country dominant in global high-tech manufacturing, biomedicine is a key strategic goal. A laser-sharp focus on expanding their burgeoning pharma market is providing China with a distinct edge in drug development compared with India.

In 2016, China's pharmaceutical market was worth $123 billion, but this figure is projected to surge to $573 billion by 2022. McKinsey & Company hails China's biopharma industry as only second behind the United States in global numbers. Its imminent transformation will arise from the investment and support being put into innovation.

"China is investing heavily in R&D and they know this is the first step to achievement in this industry," says Dr Kamal Rashid, founding director of the US Center for Biopharmaceutical Education and Training. "Investment in the workforce is also essential. To produce a good product that will receive approval, you need both manpower and facilities. There is a need for a good workforce to make innovation a reality. This is something China is getting into more aggressively."

The Chinese government has created a support system to incubate new firms, allowing them to leap from old technologies into creating biologics. Key players in their domestic market include Sinopharm Group and Shanghai Pharmaceuticals, but multinationals such as AstraZeneca, Pfizer, and Novartis make up a substantial component of the ecosystem. In China, the latter contribute to global pharma revenues at an average of 8 per cent.

A dearth in the creation of biologics sets India a few steps behind China's vision for their pharma market. Yet India continues to be hailed as the largest provider of generics globally. "India is referred to as the pharmacy of the world and with good reason," says Nithya Balasubramanian, director at investment management firm Bernstein.

> **India is referred to as the pharmacy of the world and with good reason**

At present, generic drugs manufactured in India account for 20 per cent of the global consumption of generics, in addition to 40 per cent of prescriptions dispensed in the United States, which is safely positioned as the largest pharma market. In 2019, Indian pharma was worth $38.8 billion, contributing significantly to the country's economic growth.

"While the US market has been in the driver's seat dictating valuations, the Indian domestic market remains the ever-reliable vertical for most Indian generics and is slowly gaining prominence," says Balasubramanian,

While their growth will continue in the supply of generics, innovation has been given far less attention in India compared to China. Balasubramanian notes that most recent product launches in India have been "incrementally innovative". India's market growth will stem, instead, from the "commercial muscle of Indian generics", she says.

According to the Indian Pharmaceutical Alliance (IPA), there are several challenges to the exponential growth Indian pharma could achieve. For one, an environment conducive to long-term investment decisions in the pharmaceutical industry has yet to be established. Other key challenges include lack of innovation, less access to skilled workers and stricter guidelines in quality compliance in international markets. The IPA reports there are about 29 skilled workers available for every 10,000 people in India, in comparison to China, where there would be about 41.

A noticeable dependence in India on external markets, including China, for intermediates and active pharmaceutical ingredients is an additional factor. However, analysts believe India will persevere and show growth in this sector.

"We remain optimistic about the growth prospects for the industry in the next four to five years and believe they will continue to be the largest contributor to profitability for Indian generic manufacturers," says Balasubramanian.

All eyes remain on the Chinese as they climb the global market rankings, foreshadowing a possible change of leadership in new technology and life science.

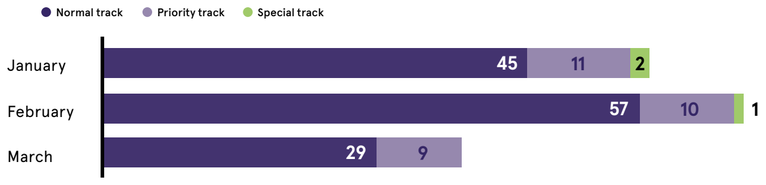
This clash of global pharmaceutical titans is ongoing. However, it begs the question of whether this race will result in the potential cutting of corners in manufacturing and approval processes, ultimately lowering standards?

"We can't play with human health, so cutting corners would be the last thing to do," says Rashid. "In the United States, the federal government heavily regulates innovative drugs. In other countries, regulation may not be as stringent and this will need to be discussed."

The impact of the next pharmaceutical powerhouse may extend far beyond healthcare markets, spilling over into global influence and soft political power. China's pharmaceutical companies appear to be playing a very different game to India's and this strategy is likely to clinch the position of pharmaceutical supremacy.

HOW COVID HAS IMPACTED CHINA'S PHARMA PATHWAY

The number of approved drug applications in China in 2020, along regulation pathways



McKinsey 2019

OPINION

'Partnerships will help us beat COVID-19 and the lessons we have learnt can be used in other areas of healthcare'

As the world waits for a pandemic exit strategy, we know that the organisations researching and developing medicines and vaccines are our best hope for beating coronavirus.

As new vaccines become a reality, we are seeing scientific partnerships that were forged in the spring leading us out of the pandemic. And among them is a home-grown UK vaccine from AstraZeneca and Oxford University.

More than 200 global research teams are working on vaccines. Our industry is involved in over two thirds of these projects. Eleven are in phase-3 clinical trials, where the vaccine is tested on thousands of volunteers. One, Pfizer-BioNTech, has already been approved for use by the UK regulator.

The development is happening in under 12 months, maintaining the same safety and efficacy standards. A combination of intense global focus and expertise, with phases of development and regulation carried out simultaneously, is making this a reality.

People talk about unprecedented times. Over the past ten months, we've seen unprecedented ways of working. Companies are collaborating with each other, with academia and global health systems, and sharing data.

Fifteen global companies are central to the Gates Foundation's COVID-19 Therapeutics Accelerator, a public-private initiative looking for treatments. To accelerate development, the companies involved agreed to share data of molecular compounds from proprietary libraries.

As Julie Kim, president of Plasma-Derived Therapies at Takeda said, "unprecedented times call for bold moves."

Takeda is one of the founding companies of the CoVIg-19 Plasma Alliance, working together on an investigational product made from convalescent plasma, unbranded by any of the participating companies, and now being evaluated as part of a global phase-3 clinical trial.

Seventeen pharmaceutical companies are involved in successful proposals funded by the EU's COVID-19 Innovative Medicines Initiative, another public-private consortium demonstrating commitment to open data-sharing for COVID treatments and diagnostics.

Companies have pledged to bring vaccines to people wherever they are in the world. Johnson & Johnson is studying a lead vaccine candidate with plans to bring an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.

Pfizer and BioNTech have worked at unprecedented speed to develop, test and manufacture a potential first-in-class mRNA-based vaccine.

The UK's GSK and France's Sanofi combined their technological and manufacturing capability to develop a vaccine. The two companies have pledged to work with health authorities and governments around the world to ensure timely and affordable access.

GSK is making its adjuvant tech available to scientists working on candidate vaccines. Adjuvants are of particular importance in a pandemic since they may reduce the amount of vaccine protein required per dose, allowing more doses to be produced, protecting more people.

The swift government prioritisation and approval for Urgent Public Health Research studies is important.

It is these partnerships that will help us beat COVID-19 and the lessons we learn can be used in other areas of healthcare.

Despite the World Health Organization declaring that only clean water beats vaccines in reducing the burden of infectious diseases, research indicates vaccine hesitancy remains an issue worldwide.

As vaccines are given to millions, they must meet the highest safety standards or companies won't progress them and regulators won't approve them.

Amid the misinformation about COVID-19 vaccines, we need a collective effort to make sure the public continue to have confidence in them.

Pharmaceutical companies have a role to tell their story. If we can help people understand the value of vaccines, we stand a much better chance of beating the virus should a vaccine be approved.

Richard Torbett
Chief executive
Association of the British Pharmaceutical Industry

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Commercial feature

Taking a 'trip' to improve mental health

A clinical trial involving a psychedelic drug and psychotherapy aims to help patients with hard-to-treat depression and other mental health disorders

A UK neuropharmaceutical company is planning the world's first clinical trial to treat depression by combining psychotherapy and the mind-expanding psychedelic medicine dimethyltryptamine (DMT).

DMT is a naturally occurring chemical found in tiny amounts in the human brain and in larger amounts in plants. Chemically similar to the neurotransmitter serotonin (5-HT), it is involved in a variety of physiological functions, including eating, sleep and mood regulation.

The Small Pharma trial follows on from the drive, led by the world-renowned Imperial College London, to bring psychedelic-assisted therapy out of the fringe into the scientific mainstream. Small Pharma is focused on identifying rapid-acting treatments for depression and other mental health disorders, and is collaborating with Imperial's Centre for Psychedelic Research.

Dr Robin Carhart-Harris, the centre's head, says: "Psychedelic therapy holds a great deal of promise for treating some very serious mental health conditions and may offer new hope to vulnerable people with limited treatment options."

Potential patients include many people with depression, who cannot find an antidepressant that works for them or cannot tolerate the associated side-effects.

Coronavirus has exacerbated a critical situation, causing disturbing increases in suicidal thoughts, especially among young adults, according to a study published in October in The British Journal of Psychiatry.

Psychedelics have been shown to have therapeutic benefits in disorders such as depression, substance abuse and post-traumatic stress disorder. These so-called internalising disorders are characterised by debilitating flows of recurring negative thoughts.

DMT was selected for Small Pharma's trial following preclinical and clinical research suggesting it may have benefit in treating depressive disorders.

Small Pharma has produced its own DMT-based product in line with good manufacturing practice guidelines laid down by agencies controlling authorisation and licensing of pharmaceutical products.

Psychotherapists will support the 36 trial patients before, during and after the intravenous administration of DMT, which is designed to produce a short psychedelic experience or "trip" lasting about 20 to 30 minutes.

The psychedelic experience has been proven in other studies to be critical for the therapeutic process of treating the mental health condition. The experience can induce visual imagery or hallucinations, such as seeing colourful patterns, seeing or hearing things that are not real, and a sense of detachment from thoughts and feelings, changes in sense of time and space, and intense emotions, including happiness and grief.

Dr Carol Routledge, chief medical and scientific officer at Small Pharma, explains: "Published research into psychedelic treatment for depression has concluded that difficult emotions and upsetting content during a trip can be therapeutically beneficial as they can lead to important insights, which can be discussed with the therapist. They will help patients to interpret and deal with the experiences they have on their trips."

How does psychedelic-assisted therapy work? Routledge explains: "Think of a Christmas 'snow globe': you shake up the snowflakes and then allow them to resettle. DMT is equivalent to the shaking up, and the resettling process to the psychotherapy.

"The shaking up disrupts unhealthy, ingrained thought patterns, allowing the brain to reset itself by creating new neural pathways. This helps the patient to receive and benefit much more from the psychotherapy that wraps around the administration of DMT."

Clinical research has shown DMT increases connectivity between different brain networks. In turn, this increases synaptic plasticity – the biological process of brain cells changing their connections – enabling learning and memory.

The Small Pharma trial will compare the effect of giving either one or two doses of DMT. Patients will be assessed at intervals of up to three months and given additional psychotherapy if necessary. The benefits of treatment are expected to last six months, but could be significantly longer.

> Think of a Christmas 'snow globe': you shake up the snowflakes and then allow them to resettle

For more information please visit smallpharma.co.uk

References
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Small Pharma

OBESITY

Exploring the "holy grail" of weight loss

As coronavirus pushes obesity back onto the front pages, a range of new pharmaceutical treatments is being explored

John Illman

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Sir Simon Stevens, NHS England chief executive, described obesity as "the new smoking" when calculations forecast 360,000 people will have weight-related cancers by 2030, a rise of 62 per cent.

Diet and exercise alone will not resolve the multi-billion-pound obesity epidemic. Bariatric surgery, which reduces stomach size, is the most effective treatment. It has even been acclaimed as the most effective intervention in healthcare, but only 0.1 per cent of eligible UK patients opt for it, according to the National Institute for Health and Care Excellence (NICE). This has created a huge, unmet need for weight-loss drugs.

An effective, safe, cheap, anti-obesity pill could become one of the biggest-ever pharma blockbusters. In 2014-15 obesity cost the NHS £6.1 billion. The bill is projected to reach £9.7 billion a year by 2050, with overall costs to society of nearly £50 billion annually.

But the multi-billion-dollar game of pharmaceutical roulette generates many more losers than winners. The history of weight-loss drugs is littered by disaster and drugs taken off the market amid safety concerns, from heart attacks to depression and suicide.

> **We cannot treat a quarter of the population with liraglutide**

Only two years after being acclaimed the holy grail of obesity drugs, lorcaserin was withdrawn this year. Other weight-loss drugs had been found to increase the risk of heart attack, which is a threat to obese patients even before they take any drugs. A US trial of 12,000 patients concluded lorcaserin patients were not similarly at risk, but they were judged to be at increased risk from cancer.

Irrespective of cancer fears, the chances of lorcaserin being licensed for the NHS were limited by costs ranging from £1,860 to £2,700 per patient a year. Other notable drugs taken off the market included rimonabant in 2008 and sibutramine two years later.

Sibutramine worked by boosting levels of norepinepherine and serotonin, two chemical messengers in the brain, and inducing feelings of fullness after eating. But the European Medicines Agency suspended all its European licenses, ruling that potential side-effects, including stroke and heart attack, outstripped any benefits.

This left the NHS with only one officially approved weight-loss drug. Sold under the band name Xenical, orlistat helps to avoid weight gain and produces weight loss, but it is only about a quarter as effective as bariatric surgery. It prevents absorption of a third of fat in food. Undigested fat is excreted. Many patients struggle to tolerate orlistat's unpleasant side-effects which include diarrhoea.

A major plus of orlistat is cost at about £18 a month. In contrast, the so called list price of the gentler liraglutide is £196.20 a month or more than £2,350 a year. Liraglutide mimics a natural hormone, glucagon-like peptide (GLP-1), that helps to regulate hunger.

Last week, NICE recommended making liraglutide available on the NHS after a confidential discount had been agreed with manufacturers Novo Nordisk.

But the new licence is restricted to only about 3,000 patients who are at high risk of cardiovascular disease, have pre-diabetes and a body mass index (BMI) of at least 35kg. A person's BMI is their weight in kilograms divided by the square of their height in metres. Normal BMI ranges from 18.5 to 24.9kg.

Another form of liraglutide, with the brand name Victoza, has a lower dose and is approved to treat diabetes, but not obesity alone.

Why has NICE limited liraglutide prescribing? Its unenviable job is to balance infinite demand with finite, scarce resources. In 2018 the Nuffield Trust reported that 28 per cent of the UK population was obese. As Professor John Wilding, of the University of Liverpool and president of the World Obesity Federation, says: "We cannot treat a quarter of the population with liraglutide."

The picture might sound gloomy, but bariatric surgery is playing an unforeseen role in filling the therapeutic vacuum.

Wilding explains: "Bariatric surgery has given us new insights into the physiology of the gut. We now know that by altering the anatomy of the gut and altering the way gut hormones work, we can overcome the problems people have when they diet.

"The big problem with a diet is that however hard you try, your body is going to fight you, by making you feel hungrier and slowing your metabolic rate. This is why it is so hard to lose weight and why people inevitably lose the battle."

It is also why Wilding insists obesity should be treated as a disease. He challenges the popular idea that obesity reflects personal irresponsibility rather than policies pursued by the food industry to promote cheap, high-fat, high-sugar food with super-sizing, meal deals and buy-one, get-one-free offers. Last month more than 800 food and drink manufacturers signed a letter attacking government proposals to ban online advertising for products high in salt, sugar and fat.

"The 'personal responsibility' argument is incorrect as it fails to recognise the powerful genetic and environmental pressures that cause obesity in the first place," says Wilding.

"If you told people with asthma they needed to work harder at breathing, or those with depression to pull themselves together, it would be considered inappropriate. This is what those advocating that obese people should eat less and move more are doing. It's far more complicated than that."

Research arising from bariatric surgery is highlighting this complexity. Much of it is focused on so-called incretin hormones, including GLP-1, the hormone liraglutin so effectively mimics. Stimulating a decrease in blood glucose levels, incretins are released after eating and enhance secretion of insulin, helping glucose enter the body's cells.

Even though liraglutide has just been licensed by NICE as an obesity treatment, its days may be numbered. It has been surpassed by semaglutide, a once-weekly injection used to treat type-2 diabetes.

Wilding says: "Semaglutide is cheaper than liraglutide even though it is made by the same company. It is not approved for treating obesity, but it has been tested as an obesity treatment. The average weight loss in the one year trial was 16.9kg, which is more than double what we've seen with liraglutide. It may become available to treat obesity in the next 18 months."

In future, powerful combination therapies could match bariatric surgery. These include tirzepatide which targets GLP-1 and another hormone, glucose-dependent insulinotropic polypeptide (GIP), released by the small intestine to control digestion.

> **The 'personal responsibility' argument is incorrect as it fails to recognise the powerful genetic and environmental pressures that cause obesity in the first place**

11,117

hospital admissions in 2019 were directly attributable to obesity

4%

increase on 2018, when there were 10,660 admissions

NHS Digital 2020

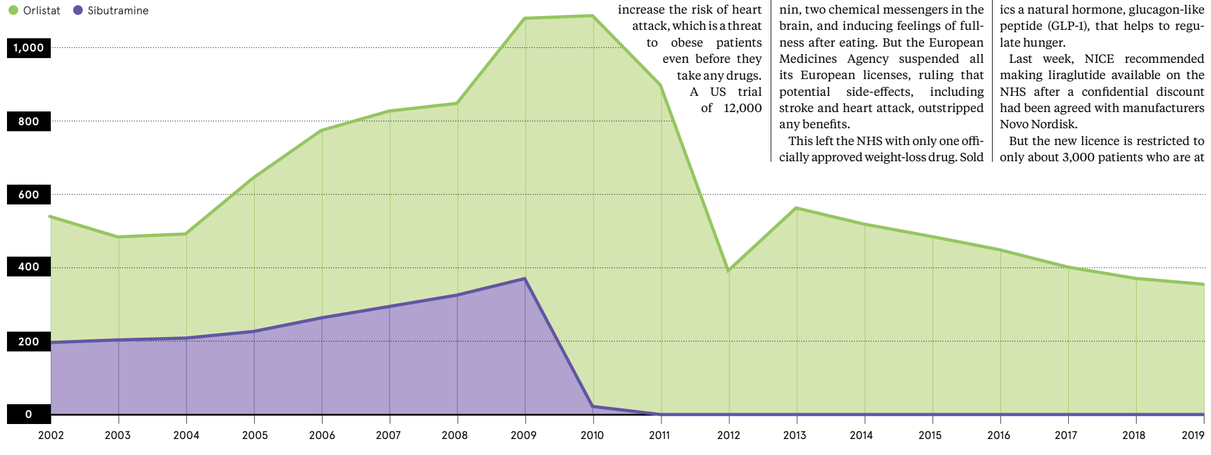
The Lancet medical journal reported in 2018 that patients taking tirzepatide lost significantly more weight than those taking just a GLP-1 drug alone. But it will take several years for tirzepatide to reach the market, if it is licensed. Clinical trials are due to end in 2024.

There is even the prospect of a triple-action therapy that could outmatch bariatric surgery, targeting GLP-1, GIP and glucagon, a hormone controlling blood sugar: this really could be the holy grail of weight-loss drugs.

There could be another major benefit to this holy grail. It could help to kill the booming market in unlicensed, dangerous and fake diet pills. *The Pharmaceutical Journal* recently reported that a pill known as DNP had killed a 21-year-old student. Widely available on the internet from sites which seem to be legitimate, DNP was first used on an industrial scale to make bombs. Almost certainly the student never knew that.

TOP WEIGHT LOSS DRUGS GO OUT OF FAVOUR

The number of prescription items for the treatment of obesity in England from 2002 to 2019 (in thousands)



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SOURCE: Rappuoli R. Pizza M et al. Vaccines, new opportunities for a new society. Global figure, proceedings of the national academy of sciences of the United States of America. 2014

Britain's Minister for the Cabinet Office, Michael Gove, wearing a face covering due to the COVID-19 pandemic, gestures as he passes an anti-Brexit demonstrator whilst exiting a 'Pret a Manger' coffee shop in London on November 30, 2020

BREXIT

What the future holds for pharma post-Brexit

As the end of transition looms, questions remain around what UK businesses can expect post-Brexit, no less for the pharmaceutical industry

James Gordon

In life there are many more questions than answers. It is a cliché, of course, but banality aside, it neatly summarises the general public's view of Brexit. Or, at least, it did until the coronavirus pandemic arrived on UK shores and forced Brexit off the front pages. Now however, with the transition period soon coming to an end, Brexit is once again dominating the headlines and is nearing the top of the prime minister's bulging in tray.

While a hard Brexit is a near certainty, the only point that really interests a Brexit-weary public is whether or not a last-minute deal or some sort can be struck. But for the UK pharmaceutical industry, a sector that generates £33.4 billion in revenue each year, many unanswered questions remain.

It is not yet clear, for instance, what effect Brexit will have on the UK life sciences sector, an industry that provides 63,000 jobs in the UK. What will it mean for global trade, supply chains and raw materials? Also what impact will Brexit have on regulations and patents for new medicines?

One expert who knows more than most is Professor Anand Menon, director of the UK in a Changing Europe think tank, who says Brexit has already hit the pharma industry with increased costs due to dealing with regulatory changes.

Coupled with UK pharma companies no longer being able to take advantage of European Union-funded research collaboration opportunities, such as the Horizon Europe programme, and the UK economy being hit by the worst recession in three centuries, the immediate future looks bleak. Alhough the government does recognise life sciences is a crucial sector for the UK's economic recovery.

"The only certainty right now is maximum uncertainty," says Menon. "A deal won't necessarily provide the UK life sciences sector with the clarity it so badly needs. The crucial issue for them is a mutual recognition agreement. If there is an implementation period, which has yet to be confirmed, it is likely this is when some of the major regulatory hurdles will be ironed out."

Dr Olga Gurgula, a specialist in life sciences and intellectual property (IP) law at Brunel University London, says the issue of divergence is one of the greatest regulatory barriers because it will "alter the way pharmaceutical companies do business".

When the Brexit transition period ends on January 1, 2021, UK-based companies will lose their status as EU marketing authorisation (MA) holders, which grants them approval to market a medicine in the EU, and therefore need to transfer their MA to a EU holder. This means pharma companies may need to carry out marketing authorisation twice, once in the UK and once in the EU, to ensure the product is certified for use in both territories.

"Being outside Europe's regulatory system will present a number of challenges, not just regarding marketing authorisation procedures, but also in relation to importation requirements, labelling and the sourcing of medicines. Medicinal products shipped from the UK to the EU will be subject to a raft of complex controls. Undoubtedly, the new rules will lead to delays and reduced access and supply, which could lead to higher prices," says Gurgula.

She also warns there will be changes to the rules of parallel trade. This, she says, "occurs when the IP rights in goods are 'exhausted' and the IP owner cannot stop a further distribution of these goods".

But what will this mean for UK-based pharma companies? Gurgula explains: "In the EU, there is an EU-wide exhaustion of IP rights. However, after January 1, 2021, the EU rules on IP exhaustion will no longer apply in respect of products placed on the UK market, meaning parallel traders will need the consent of the IP right holders to export such products to the EU."

Another challenge surrounds distribution of medicines in Northern Ireland after Brexit. Having reached an agreement in early-November, the UK and the EU have "agreed a phased process for implementing medicines regulation" until the end of next year. A joint statement by six bodies from the UK and EU pharma industry goes on to say both sides "must now use the next eight weeks to clarify the rules, which will apply in Northern Ireland from 2022".

But Menon is worried that the time frame is too short. "While the UK government and the EU have avoided a cliff-edge situation, neither has clarified what the new regime will look like from 2022 onwards. What is clear is that when the phased process ends, regularity divergence will kick in," he says.

Menon believes that while free trade agreements, "which reduce regulatory burdens when trading with other nations" would offer greater flexibility for pharma companies operating in the UK, he cautions that "the legacy of COVID should not be underestimated".

"There has been a lot of talk from politicians, though not UK politicians, that the pandemic has exposed flaws in complex global supply chains," he says. "Many who want greater protection are actively banging the drum for reshoring. If this happens, it could damage the business models of multinational pharmaceutical companies."

Supply chains aside, and regardless of whether or not there is a deal, there are no significant changes in the protection provided by patent laws, which means UK pharma companies can continue to apply for patents through the UK Intellectual Property Office, as well as in the European Patent Office. This is because the UK will remain part of the European Patent Convention (EPC).

Gurgula says: "The EPC is not a European instrument and therefore UK companies will still be able to file for a patent with the European Patent Office seeking protection in EPC member states, including the UK."

However, with the UK no longer part of the Unitary Patent System, there will be challenges for business, including UK-based life sciences companies, seeking patent protection of their inventions both in the EU and UK.

"In the EU, businesses will benefit from EU-wide patent protection under this system," says Gurgula. "However, in the UK, companies will only be able to protect their inventions by applying for national patents. The system, which was designed to ensure cost-savings and reduce the complexity of patent enforcement in multiple-jurisdictions, has now become less attractive without such a major market as the UK."

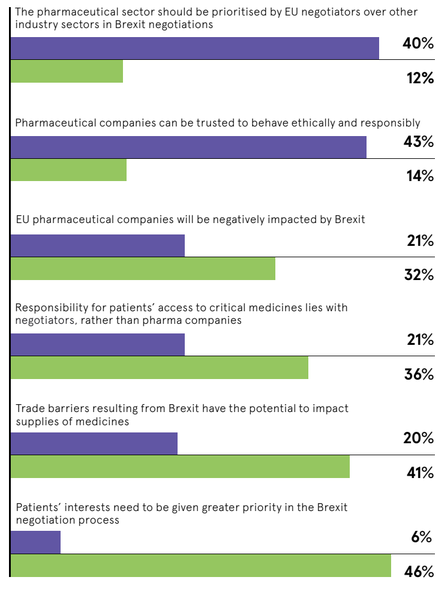
But she points out there is an upside to Brexit too. "Leaving the EU may present the UK with a once-in-a-generation opportunity to reconsider the whole system of pharmaceutical innovation, moving from the proprietary system based on strong IP protection, which stifles innovation, to a model of open innovation. That would unshackle and empower researchers to innovate and make game-changing new discoveries like those we have just witnessed."

Forged in the crucible of Brexit, this would represent a huge leap forward, not just for pharma, but the whole world.

> **While the UK government and the EU have avoided a cliff-edge situation, neither has clarified what the new regime will look like from 2022**

PHARMA WORRIES AROUND BREXIT ARE OF LONGSTANDING

In 2018, EU influencers (including MEPs and EU staff) were asked about their attitudes towards Brexit and the pharmaceutical industry, covering issues which remain up in the air



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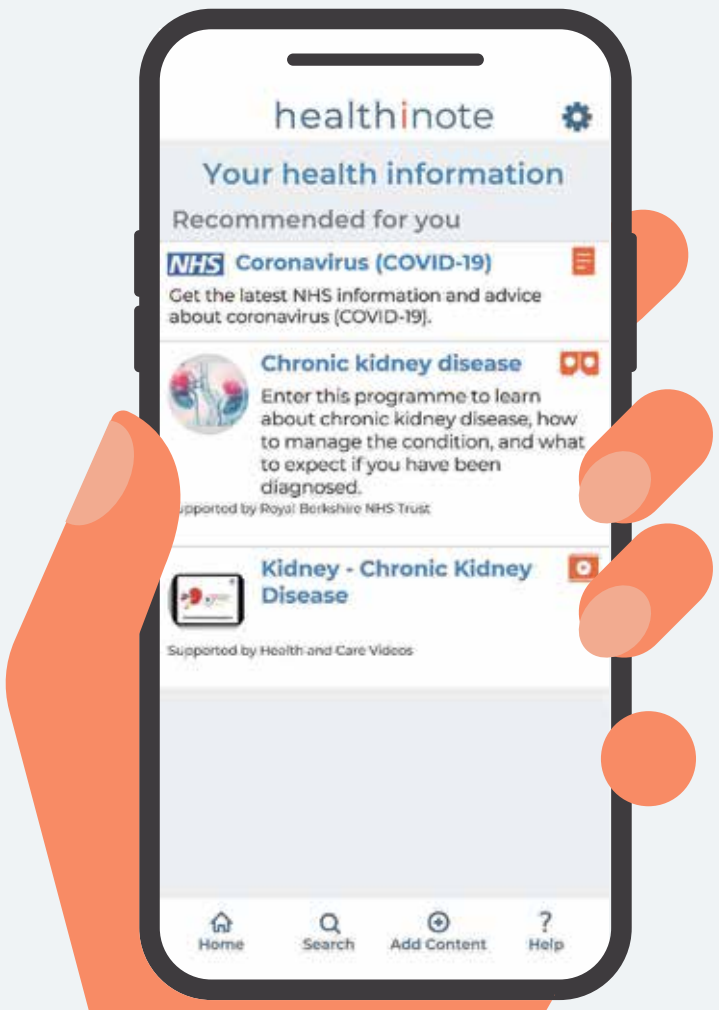

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