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Life science in the era of pandemics: two years on

The new normal in life science

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The new normal in life science

Two years into the pandemic, we consider its impact on the life science sector and how the risk landscape is evolving as the industry builds on the progress it has made

As the pandemic took hold in 2020, Chubb and Kennedys explored the emerging risks for a life science sector that was being tested to its limits in the report series *Life Science in the era of pandemics*. The sector faced many potential pitfalls early on as it balanced risk management with throwing everything it had at the virus on a global scale.

The stakes were high as trade-offs were made between best practice and pragmatism in clinical trials, emergency medical devices were produced in collaboration with other industries and overburdened supply chains tried to keep up with unprecedented demand for medical supplies.

Looking back at the past two years, the industry has, by and large, proved successful at managing the most significant risks faced. It has also demonstrated its capabilities during an extraordinary time; producing vaccines at record speed and rapidly delivering solutions - from telehealth to medical devices and genomic surveillance - that have helped us through this difficult period. Now the life science sector is building on that foundation to improve healthcare and preparedness for future pandemics, while continuing to battle COVID-19.

Evolving supply chains

The nuances of the life science supply chain have been scrutinised in detail on a global basis over the past two years. Unprecedented demand for personal protective equipment, medical devices, test kits and vaccines quickly revealed supply pinch points. Shortages of workers, raw materials and production capacity have all made the headlines.

But through all this disruption, the sector has shown itself to be incredibly resilient, according to Alex Forrest, Head of Life Sciences - Overseas General at Chubb. “It’s really impressive, actually, because many industry groups didn’t cope with the supply chain problems. Whereas in life sciences, we’ve spoken to many companies that said they had some issues, but they had enough contingency and resilience to absorb that interruption within their business. It’s an amazing testament to the life science industry and the fact that these companies operate in a very controlled and regulated environment. They are built to deal with these sorts of things.”

The industry is still taking lessons from the experience, according to Renate Pochert, Senior Risk Engineer at Chubb. “While the disruption had a manageable effect on our clients, they are looking at the supply chain in regard to business interruption,” she says. “One of the major concerns was that so many employees of the suppliers were ill. That’s not something a producer of life science products can influence, but they can ensure they have redundancies [excess capacity] in their system.”

Nearshoring or reshoring production capacity to be closer to home was a big theme when vaccine rollouts began. This idea has not gone away. “One of my clients is actively thinking of looking for new suppliers in Europe,” explains Pochert. “But it takes a long time because you have to look into the regulations, complete a recertification of the new supplier, notify the local authorities of changes and look at the raw materials or components they are delivering.”

Supply chain visibility

In the meantime, the focus has been on understanding existing supply chains and making them more resilient. “We’re seeing companies talk more about their supply chain visibility,” adds Forrest. “At a senior level, the supply chain was previously just something that they presumed was planned correctly. Now, though, there is real attention and focus at a senior level for clarity of the chain and how to protect their businesses against this risk.

“There are things they will likely do as a result, such as having more supply where necessary, or reshoring where necessary. However, the big activity right now is just getting visibility of the dependencies.”

Technology is part of the solution to greater supply chain visibility. “During the pandemic we have had greater reliance on technology, such as AI, robots and drones, and I think that’s something that’s going to be used increasingly to support the supply chain,” says Karishma Paroha, Legal Director, Kennedys.

Advanced analytics in particular can improve supply chain visibility. In 2019, pre-pandemic, management relied on people on the ground to explain any problems with production or distribution. Today, technology offers a deeper insight. “Because people have had to work from home, companies have rolled out advanced analytics systems, and the analytics have gotten to a stage where you can use them to understand what’s going on,” Forrest says. “That is resulting in improvements to quality management, quality analysis, and building on already robust Quality Management Systems (QMS).”

While human insight will always be vitally important, analytics can reduce the risk of human error and provide a broader, systems view of potential problems. “The quality manager might get very zoned in on something, but the tools are there to try and connect the dots that a person wouldn’t normally see,” he adds.

Technology comes with its own risk management issues, of course. Not the least of these is making sure that people within the organisation have the skills to use it effectively.

Managing telehealth progress

Telehealth usage surged during the pandemic in many developed economies and is now forming part of the new normal

Third-party product and service companies are providing the tools for telehealth, from e-consultations to wearables

One of the major risks for those businesses is their products not being used correctly. This puts the onus on life science companies to train medical staff

x38

US telehealth usage grew dramatically at the start of the pandemic

Modern slavery

Increased visibility in supply chains could help deal with another problem exacerbated by the pandemic, modern slavery. The pandemic increased the risk of forced labour in the supply chain because, early on, pressure was put on suppliers and their managers to keep producing, regardless of risk.

"At the same time, COVID-19 has also created an opportunity for companies to apply their improved supply chain knowledge in a modern slavery context," says Paroha "In a July 2021 report [by The Modern Slavery and Human Rights Policy and Evidence Centre], 80% of the managers surveyed believe that stronger legislation is needed to ensure better conformance with the Modern Slavery Act's reporting requirements."

Bedding in telehealth

Training is also an issue in telehealth, which is rapidly forming part of the new normal in many health systems around the world after widespread adoption during the worst of the pandemic. Analysis by McKinsey found that in the US, telehealth usage in February 2021 was 38 times greater than in February 2020. Dramatic upticks were also seen in other developed economies.

Third-party telehealth product and service companies are providing the enabling tools, such as software, wearable devices and diagnostics. "They need to be used correctly, so there is an onus on life science companies to train the doctors to do so," says Forrest. There are also risks around data integration and whether different systems are communicating as they should to inform doctors.

Data interoperability - as an example, making sure different systems can exchange information across organisational boundaries - has been a challenge for decades in the UK's National Health System. Layering telehealth on top creates additional issues.

"Because there are so many virtual participants in the healthcare system now, from general medical practitioners to psychiatrists, there is a risk that the various players within that ecosystem aren't able to exchange data properly," explains Paroha. "There is now a need for us to ensure better data integration and improved data flows in the virtual world so that there's a seamless patient experience rather than a fragmented one."

The long-term impact on clinical trials

Another great success during the pandemic was the speed at which vaccines were developed. "The concept of accelerated biotechnology, using mRNA technology, existed before the pandemic, but it has been catapulted forward," says Paroha. "The idea that we can produce vaccines and medicines within months rather than years is something new."

The vaccine trials proceeded in the full glare of the public spotlight. And people saw how different phases of the clinical trials were overlapped to expedite the process.

"We may have created a culture or an expectancy in society that trials will be very quick, which could result in public pressure on both regulators and producers to speed things up," says Forrest. "The public could say, 'Well, you managed a vaccine in a year, so why can't you produce this life-saving drug in two or three years, why do we need 10 years?'"

While quicker trials are great in theory, they might not be desirable on a widespread scale. "In the past, people have looked at speeding up clinical trials, but there were concerns over quality," Pochert explains.

Forrest agrees: "When you very quickly pile phases on top of each other, you're compressing your ability to see the full picture and spot any problems that might arise. It's a question of risk tolerance. Yes, you can get products to market in two or three years rather than 10, but you are increasing the risk that something slips through the net."

From a legal perspective, Paroha says we are not out of the woods yet on the compressed pandemic trials. "Given the fact that vaccines and treatment have been fast-tracked, there's a risk that side effects will emerge in the future. We don't have 10 years of data to inform us that nothing is going to happen. There are so many different versions of these vaccines, and in some jurisdiction somewhere there may be a vaccine that has long-term side effects."

There is already a low level of claims for vaccine-related side effects, which are test cases for the insurance and legal systems. "The pathway to compensation or damages is complex," says Forrest. "Some vaccine-related injuries have undoubtedly occurred but need validation first on the cause before it can be established whether a particular government, specific country compensation scheme or manufacturer insurance is the one to respond, or a mix of those."

Decentralised trials

Decentralised trials may be more likely to continue in the wake of the pandemic. Indeed, a record 1,300 drug trials with a virtual and/or decentralised component are expected to start in 2022, a 93% increase over 2020.

"I think contract research organisations (CROs) will continue to use a lot of distant monitoring as opposed to on-the-ground monitoring and auditing," says Forrest.

The safeguards and oversight of distant monitoring will need to evolve in step with the practice, though. "There have been well-publicised concerns, for example, arising out of one vaccine trial," says Forrest, referring to claims made by a whistle-blower at a CRO involved in the process. "It's an interesting window into what can potentially go wrong when we travel at such speed and the protections that need to be put in place."

Decentralising patients within trials (by recruiting them from multiple locations) has the potential to speed up the drug discovery process by over a year. But Forrest says this is still some way off. "I think the decentralised model is coming for patients, but there is a risk in totally unhooking from on-the-ground monitoring. There are patient safety concerns around making sure that doctors have informed patients properly and that consent is being sought correctly."

Inclusive research

One review of major genomics studies found that 88% of the recorded genomes came from people of predominantly European descent. And researchers have found that the results from such studies are not as relevant to people with non-European ancestry

With genomics playing such a vital role in the response to COVID-19, shedding light on how it interacts with our immune system and why some people are affected more than others, lack of diversity in datasets creates health inequalities

Greater diversity in reference data should be a priority going forward to ensure the benefits of genomics are evenly spread

ACE2

People with fewer ACE2 receptors may be less susceptible to the virus

Genomics still has more to offer

Genomics has also grown in profile over the course of the pandemic, forming the backbone of the surveillance for new variants. But we are arguably yet to see the full potential of genomics in this pandemic.

Research is ongoing into how COVID-19 interacts with the human body, fuelled by the knowledge we have gained in genomics. “Some people will be stuck in isolation for two weeks with their families who have COVID, but won’t get it themselves, and then others will catch COVID instantly,” says Paroha. “Through the field of ‘host genomics’, which studies how individual biological features respond to emerging diseases, we should soon start to anticipate how different genetic make-ups will respond to the virus.”

One possible contribution is that ACE2 receptors have a role to play in giving the virus access to the body. “Genetically, the number of ACE2 receptors that we have varies from person to person. So, if you’ve got fewer ACE2 receptors in your respiratory system and your upper throat, it’s harder for the virus to get in,” says Forrest. “Four or five years from now, you may actually have a test that shows whether you’re genetically a high or low risk because of this.”

The impact of this would be the ability to channel treatments such as antiviral drugs to where the need is greatest.

“Our generation had to take our experience out of this pandemic, which was a new situation, and I don’t think the development stops here,” says Pochert. “This pandemic pushed biotech development and researchers very intensively, and it’s now in everybody’s minds. We can now look deeper into genomics and gather more knowledge before the next pandemic comes along.”

Ensuring that research is inclusive will be vitally important. “One of the lessons from the pandemic is that there’s not enough diverse genomic data, so we’re not able to anticipate the genetic differences of the full diversity of the population, and why people of colour and with disabilities may have been more affected by COVID-19. We’ve not got to the bottom of that yet,” says Paroha. “Greater diversity in data should be a priority going forward.”

Mitigating human error in medical devices

From ventilators to the quality of PPE and diagnostic tests, medical devices have been a source of anxiety throughout the pandemic. But despite the irregular circumstances, one of the biggest challenges producers have faced is very ordinary - managing rapid expansion.

“There’s huge pressure to produce volumes that we’ve not really seen before, and that is more likely to lead to human error,” says Forrest, discussing the pitfalls of manufacturers asking people to work longer hours. “We have seen significant recalls and heavy costs from those. But that’s part and parcel of the regulated life sciences industry. If demand grows 10 times over night, that is going to strain any company, no matter what you do.”

Pochert adds: “It is always difficult when you interrupt routine in the life sciences, because they are so specialist and strictly regulated. If you lose any employees, some steps can’t be done or have to be done by others who are not trained properly, which is a concern.”

Key takeaways

- **Supply chain visibility** is now a key focus at c-level, enabled by technology
- **Decentralised trials** could be here to stay but decentralising patient recruitment is still a way off
- **Genomic research** still has a lot more to offer during this pandemic
- **Research needs to be more inclusive** to ensure the benefits of genomics are enjoyed by all
- **Fostering innovation** in the context of remote working is the next challenge

Knowing how to expand safely in this highly regulated sector is therefore an important risk management strategy for medical device companies. "You almost need a plan in place to say, if we suddenly needed to increase our capacity by 30%, what is the human plan, the operational plan and the physical plan?" Forrest explains.

Where next?

The life science sector has shown what it is capable of. It has responded to the call from governments and health services around the world for more medical devices, more knowledge to fight the virus with, more software and tools to provide healthcare at a social distance, and targeted vaccines and medicines. And for the most part, the strong systems and leadership in this highly regulated sector have enabled this to happen safely. Many risks have been navigated with care and experience.

"What has come out of the pandemic at an overarching level is a huge interest in life sciences," says Forrest. "That should encourage capital to flow in and provide the resources and money to the industry to push ahead with solving some other problems."

Figuring out how that product ideation works in the new normal is the next challenge. "We are well positioned, we've got a great foundation, but are companies still designed to be innovative and drive forward some of those product developments?" asks Forrest, referring to new remote working models. "We might be fine, but I think the internal structures of companies still need to be strong enough to foster innovation."

The pandemic is by no means over and continues to create huge challenges that will test the sector. But in many ways the life science industry is far stronger now and better prepared than ever to cope with whatever comes next.

Click here to read the other reports in this series, *Life Science in the era of pandemics*

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