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Life Science in the era of pandemics

Making medical devices during a pandemic

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How has the coronavirus pandemic affected the risk profile of medical device manufacturing?

When countries with well-developed health systems scrambled to purchase life-saving ventilators at the start of the COVID-19 crisis it illustrated just how serious the pandemic would be. Working on a war footing, governments from Australia to China, Europe and the US asked the industry to produce ventilators and personal protective equipment at speed.

With stringent regulations here in Asia Pacific, the EU and the US relaxed to allow life-saving equipment to get to the frontline quickly, companies from gin distilleries to car manufacturers valiantly answered the call to make medical devices in an effort that embodied the community spirit of lockdown. Behind the scenes, however, managing the risks created by this unprecedented situation has been challenging.

The great pivot

"Some companies were perhaps a little naive as to what they were getting into," says Alex Forrest, Head of Life Sciences, Overseas General at Chubb. "They were running towards helping the war effort without really contemplating the potential consequences for their firms if they got things wrong."

Emergency Use Authorisations (EUAs) in the Asia Pacific region, such as Australia, China, Japan and South Korea have allowed anyone wanting to manufacture or market devices such as ventilators, personal protective equipment and COVID-19 tests to apply for temporary approval, bypassing the standard authorisation process, which can take up to a year depending on the product class. The EUAs apply for the period of the pandemic and for a company to market a device under an EUA a set of essential criteria specific to the type of device must still be met.

However, if a car manufacturer pivots to producing a ventilator, even using another company's design, they become the legal manufacturer of that product, with all the associated regulatory burdens, such as conducting market surveillance on the product for its entire lifespan and maintaining it regularly.

Renate Pochert, Senior Risk Engineer at Chubb, describes the journey of one coffee machine manufacturer that wanted to help. "They were asked by a big client in the US if they could produce ventilators and they got to the stage of asking for technical support from outside, but in the end the process was stopped because of the legal risk."

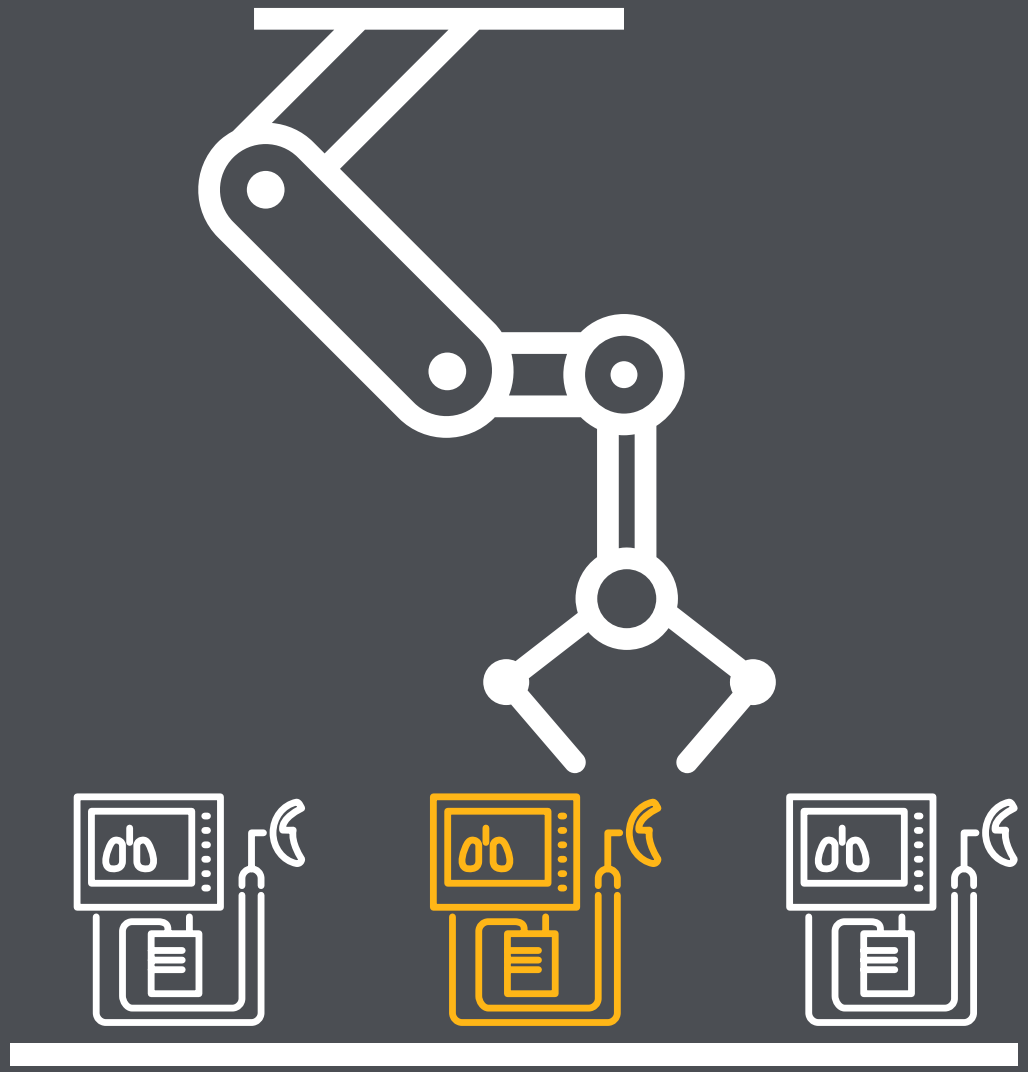
Emergency medical devices require a lot of commitment from manufacturers. Once the device has been produced the company must:

- Gain regulatory approval under an EUA

- Conduct market surveillance and warn users of any dangers

- Maintain the product

- Withdraw the device from the market after the pandemic



EUAs

only certify devices for emergency use – while the pandemic is ongoing

Off-label use

Even for established medical device manufacturers, remaining compliant with regulations during the pandemic has been challenging. “If a product is used off-label for something other than its intended use - such as a ventilator being used to treat two patients instead of one - liability could attach to the device manufacturer if they fail to take action. After production and sale, the producer still has the obligation to monitor their goods on the market. They need to warn users of dangers that were unknown until now,” explains Travis McIntosh, Life Science Specialist, Asia Pacific, Chubb.

Off-label use has been common during the pandemic. In some instances, the EUAs cover modifications to existing products. In the US, for example, the Food and Drug Administration (FDA) has authorised certain anaesthesia gas machines that have been modified for use as ventilators.

When doctors are working under these conditions and hospitals are stretched to breaking point, market surveillance is difficult. “You don’t really get any market surveillance in a pandemic. If you’re a manufacturer, good luck trying to ring up a hospital to understand what they’re doing with your products. They’re not interested in speaking to you at that point,” says Forrest.

Nonetheless, the onus remains on manufacturers to stay on top of the situation, and if the information is in the public domain or if they can see their competitors are having issues, then they have to react. That might involve putting information on their website or notifying the relevant medical product regulator, such as the National Medical Products Administration (NMPA) in China or the Ministry of Food and Drug Safety (MFDS) in South Korea, about correct usage.

In some cases manufacturers have advised doctors how best to adapt their devices for alternative uses. “It’s all about managing legitimate safety expectations,” explains Karishma Paroha, Senior Associate at law firm Kennedys. “It may be that the manufacturer adapted their own earlier design under emergency circumstances. As long as their warnings cover the expectation that there could be side-effects, they’re less likely to be at risk. It’s all about providing adequate warnings.”

The risk is ultimately that a patient sues a hospital, for example, after discovering they were put on a ventilator incorrectly, and the hospital’s defence is that the ventilator manufacturer didn’t provide them with proper training, the plaintiff could still go after the manufacturer, a particular concern in litigious markets like the US and Australia.

For established medical device manufacturers, market surveillance right now is a more stressful version of business as usual, but for a company that has pivoted to help in the fight against COVID-19, it can be more commitment and product liability than they bargained for in an area they are unfamiliar with.

A protracted emergency

From an underwriting perspective, one of the biggest concerns has been how to prevent the devices authorised under emergency laws from being used

3.5 million

Antibody test kits were ordered rapidly by the UK early in the crisis

The UK had to move so quickly to secure supplies that checks revealed the tests to be inaccurate only after money had been paid, leaving the country seeking a refund

X2

The number of Chinese test manufacturers has roughly doubled since February

during normal times. “The EUA relating to ventilators is for a fixed period and it’s very specifically for COVID-19 patients. Part of the authorisation comes with traceability so at the end of the crisis, if there is still stock out there, you need to know how you are going to get it back. You can order the hospital to destroy it, but you’ve got to make sure it’s not being used again,” says Forrest.

With the pandemic showing no sign of ebbing, many of these devices are remaining in hospital stores ready for the next surge. “Where emergency use devices are staying in the market for longer than originally planned, either in storage or in use, they must be checked and maintained at regular intervals,” adds McIntosh. “Both the manufacturer and the hospital must ensure the products remain authorised for use.”

For the full-time medical device manufacturers in Europe, as the eye of the storm passes for now, international markets are becoming more of an immediate concern. Brazil has been requesting ventilators, but European manufacturers may not be set up for getting authorisation in that territory, where the regulatory environment is complicated.

Testing times

Another major challenge during the crisis has been sourcing enough reliable COVID-19 testing kits. Governments have had to buy up vast supplies very quickly in order to secure the tools they need to contain outbreaks and get economies started again. While developing and getting approval for test kits is a relatively straightforward process, the unprecedented global demand for kits has caused problems. When the UK moved quickly to snap up antibody test kits early in the crisis, for example, it ordered 3.5 million units from China, only to discover during checks that they were not reliable.

Forrest says the reason for faulty tests is not so much the design but the quality management process when there is so much pressure on the supply chain. “Fundamentally the science of the tests would have been sound. There are a variety of reasons the tests could have gone wrong but they’re on the quality production side. It’s about the ability to put the test together with good quality reagents that are not defective and to make sure the test isn’t contaminated in some way, or that shipping doesn’t affect the test in some way.”

Pochert adds: “A lot of the in vitro diagnostic tests that didn’t work are from China.” This is something the authorities have picked up on, such that companies producing COVID-19 tests, even under the EUAs, must declare where the component parts come from.

The quality management issues coming out of China are a result of companies attempting to respond quickly to urgent calls for test kits. “In China there are something like 20 test manufacturers and I believe around 50% of them started since February 2020,” explains Forrest. “The issues are indicative of those newer start-ups not quite having that tried and tested production set-up. That’s just a general risk during pandemics - that you’re starting to move too quickly and you’re starting to move before you’re ready. The traditional diagnostic manufacturers have just done what they always do and have done it very well.”

E&O

liability is one of the biggest risks in relation to faulty test kits

From a risk management point of view, it is hard to prove causality for bodily injury claims resulting from faulty tests. Although Paroha adds: “We’re living in two parallel worlds in terms of liability and causation here. During the peak of lockdown, with people being tested after spending two months at home, causation was easier to figure out. But with lockdown easing, and if we are all on the move, then figuring out whether a test is right or wrong is a lot harder.”

For now, Forrest’s main concern with diagnostic tests is professional indemnity. “If a government bought millions of tests that all turned out to be faulty they would have a recourse against the manufacturer. It’s the errors and omissions (E&O) risk that we get concerned about and the knock-on financial impact of what’s produced being faulty.”

The outer reaches of the supply chain

As reputable companies reach out further into the global supply chain in order to fulfil large orders of ventilators, diagnostic tests and personal protective equipment, the risk of counterfeiting, diversion or fraud increases. Forrest thinks the risk goes up as you move down the list of product classes. “Regulators and health services will try and quality check batches of ventilators before use given the life dependant nature of the product, and they will try to use them in a consistent way. In contrast, things like personal protective equipment can be just as problematic because less attention is paid, even where there are complexities like the barriers that need to be woven into the textiles.”

Stories of equipment failing checks are not all bad, however, as they show that governments are testing whether what they have purchased has been made to the right standards.

Socialising risk during a crisis

In some countries governments have been directly shouldering some of the risks, providing an interesting case study into risk management during pandemics. In order to encourage companies to pivot into producing essential equipment, some governments have indemnified manufacturers against product liability claims.

The UK Government, for example, issued two Crown indemnities covering Rapidly Manufactured Ventilator Systems (RMVSs) intended to treat COVID-19 patients. The first indemnifies the third-party intellectual property rights for the designers and the contract manufacturers of the RMVSs. The second indemnifies the product liability for the same stakeholders. Government correspondence describes the indemnities as essential for the emergency provision of ventilators produced at pace.

Paroha thinks the role of governments in managing risk could expand further in the aftermath of the crisis. “There may be a discussion in Europe in the future about no-fault compensation schemes for

Key takeaways

- **Companies producing medical** devices under EUAs become the legal manufacturers of those products
- **Market surveillance is more** challenging now but still necessary
- **Devices produced under EUAs** must be traced and taken off the market after the pandemic
- **Pressures on the supply chain** have resulted in sub-standard products, but checks are being done
- **Given the urgent situation, some** governments are stepping in to indemnify manufacturers

To discover more, contact

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people adversely affected by these medical devices and other medical products such as vaccines," she says. This would involve governments operating a payment scheme, which offers a fixed lump sum to all victims who meet a certain set of criteria.

Pandemic side-effects

At a regulatory level, one immediate impact of the pandemic has been the delay of the new EU Medical Devices Regulation, which has been pushed back a year to 26 May 2021 by The European Parliament. The delay enables manufacturers of medical devices to focus on producing the equipment needed to fight COVID-19.

A second, longer-term effect of the crisis could be increasing automation within the production process, as companies react to social distancing requirements and look to cut costs. "Countries like India had to rely more on automated technologies to get the PPE and ventilators made during the worst of the crisis. It is a trend that I think will continue in the future, but that will come with its own risks," says Paroha.

Taking stock

A herculean effort has been required of medical device manufacturers during the pandemic and consumer companies pivoting to lend a hand have shown courage given the risks involved. For specialist manufacturers, the desire to answer calls for help may not have created new risks, but it has raised the stakes, with the global supply chain under strain as production ramps up and fresh regulatory complexities become apparent.

Indeed, even when COVID-19 eventually goes into retreat, the industry will still have its work cut out ensuring the equipment built during an emergency is not used when healthcare systems resume normal service.

As we reflect on the performance of the medical devices market during this pandemic, one long-term lesson is clear - regulators and industry can achieve great things if they work together. "There is usually a bit of healthy antagonism between the regulator and producer. This crisis is showing that industry can work in harmony with the regulator quite effectively," concludes Forrest.

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