CHUBB®

Life Science in the era of pandemics

Part 5: Lessons from the supply chain

Kennedys

CHUBB®

Kennedys

Contributors

Alex Forrest
Head of Life Sciences - Overseas General, Chubb

Keith Gallois
Senior Risk Engineer and Life Sciences Industry Practitioner, Chubb

Peter Kelderman
Marine Risk Management Leader for Continental Europe, Chubb

Cece Liu
Underwriting Manager, Life Science, Chubb

Christopher Chatfield
Partner, Kennedys

Karishma Paroha
Senior Associate, Kennedys

Joanna Manthorpe
Corporate Affairs Lawyer, Kennedys

Lessons from the supply chain

The vulnerabilities of the life science supply chain are at the forefront of everyone's minds, but, behind the headlines, how is the pandemic affecting attitudes to risk?

At the start of the pandemic the global supply chain was tested as governments around the world urgently tried to buy personal protective equipment (PPE), test kits and other medical devices. This revealed pinch points, with production clustered in certain areas of the world, leaving the supply chain vulnerable to shocks, and governments at the mercy of global free markets in a time of crisis.

"Factories in Malaysia, which manufactures 65% of the world's supply of medical gloves, suffered a lengthy lockdown following infection outbreaks, resulting in a global shortage," explains Keith Gallois, Senior Risk Engineer and Life Sciences Industry Practitioner, Chubb.

The free market quickly corrected some of the initial problems. "To serve the global needs around PPE in such a short period of time - and a lot of that extra capacity came out of Asia through new companies - I thought was quite elastic and quite impressive," says Alex Forrest, Head of Life Sciences - Overseas General, Chubb.

High-stakes cargo

Attention is now fixed anxiously on vaccines, which in many countries represent the best exit strategy from lockdowns. The most high-profile vaccine supply chain issues have centered on the capacity of manufacturers to produce to agreed timelines.

"Manufacturers are trying to rewire their production sites to upscale. It's not always a smooth journey in terms of scaling up production, sometimes it goes down a bit before you can go up and that can lead to complaints from whoever is trying to source those vaccines," explains Forrest.

With so many lives and economies at stake, tensions have run high over fulfilment timelines, demonstrating the importance of clear contracts. "Countries threatening to sue manufacturers is instructive about when you're promising to deliver something. A financial liability or contractual liability is a key risk to plants during this last stage. It's all about the contracts."

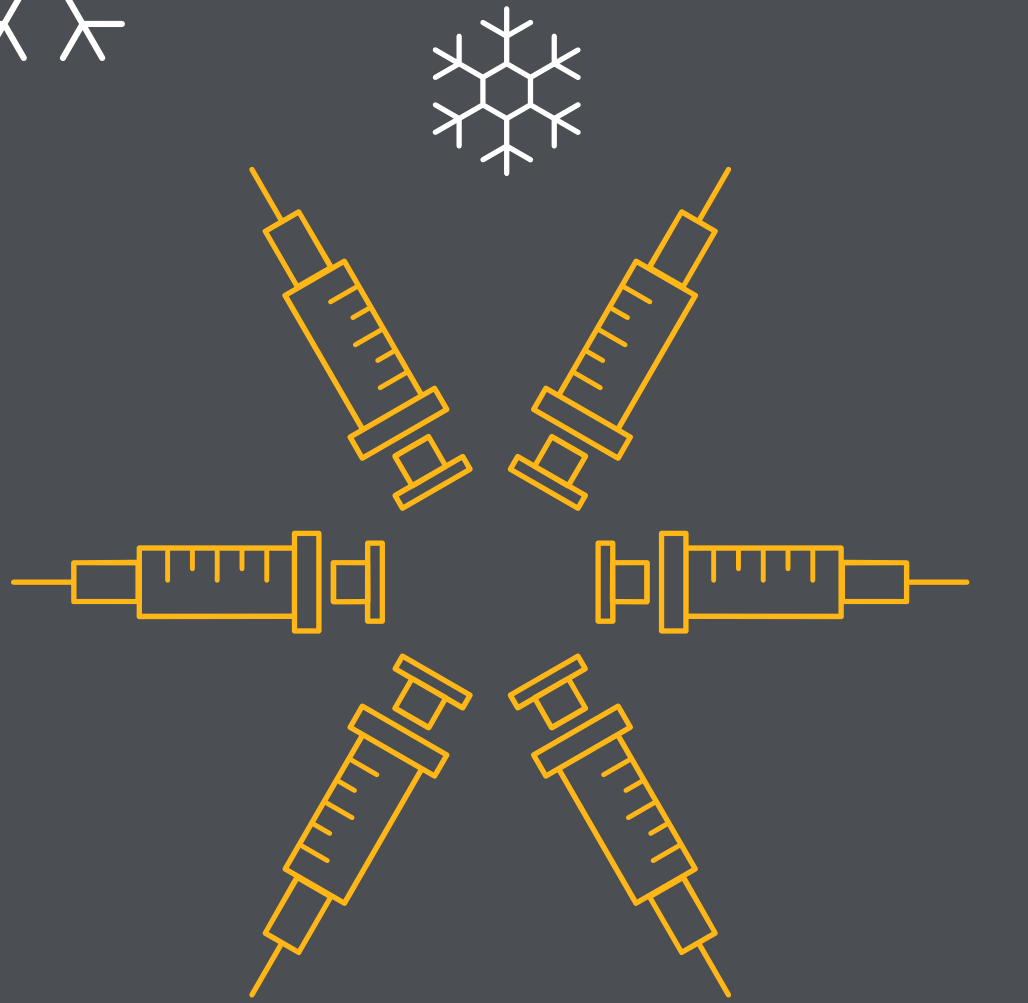
Looking beyond the headlines, the downstream supply chain is now where some of the most significant risks reside.

-70°C

With some vaccines needing to be stored at very cold temperatures, the pressure is on within the supply chain. If consistent temperatures are not maintained when drugs are transported it can lead to batches being thrown away

Problems can occur when:

- Several different methods are used to record shipment temperatures
- There is ambiguity over what counts as a ‘movement’ when a product comes out of deep freeze
- Temperature increases are caused by doors frequently being opened in warehouses



EU GDP

requirements mean distributors must track the conditions within which goods are shipped

"The biggest risk is that the vaccines are not transported in the way they should be," explains Peter Kelderman, Marine Risk Management Leader for Continental Europe, Chubb. "We have a lot of obstacles within the industry at the moment. If you look at deep-freeze products - the vaccines which should be transported at minus 70 degrees - the capacity is not always available."

Losses associated with deep freeze products tend to be concentrated in the last mile. "If you look at the transport organised from factories to the main hub, that is organised very well, and also the storage facilities are very good, but then you have the last mile to the final doctors, there you have big issues if you look at temperature control and that is frequently not taken into account," explains Kelderman.

Although the last mile is where problems more commonly occur, issues at warehouses have a bigger impact. "If you look at quantities and values, then of course the last mile is always the smallest bit and the bigger failures you have are in the main warehouses," says Kelderman.

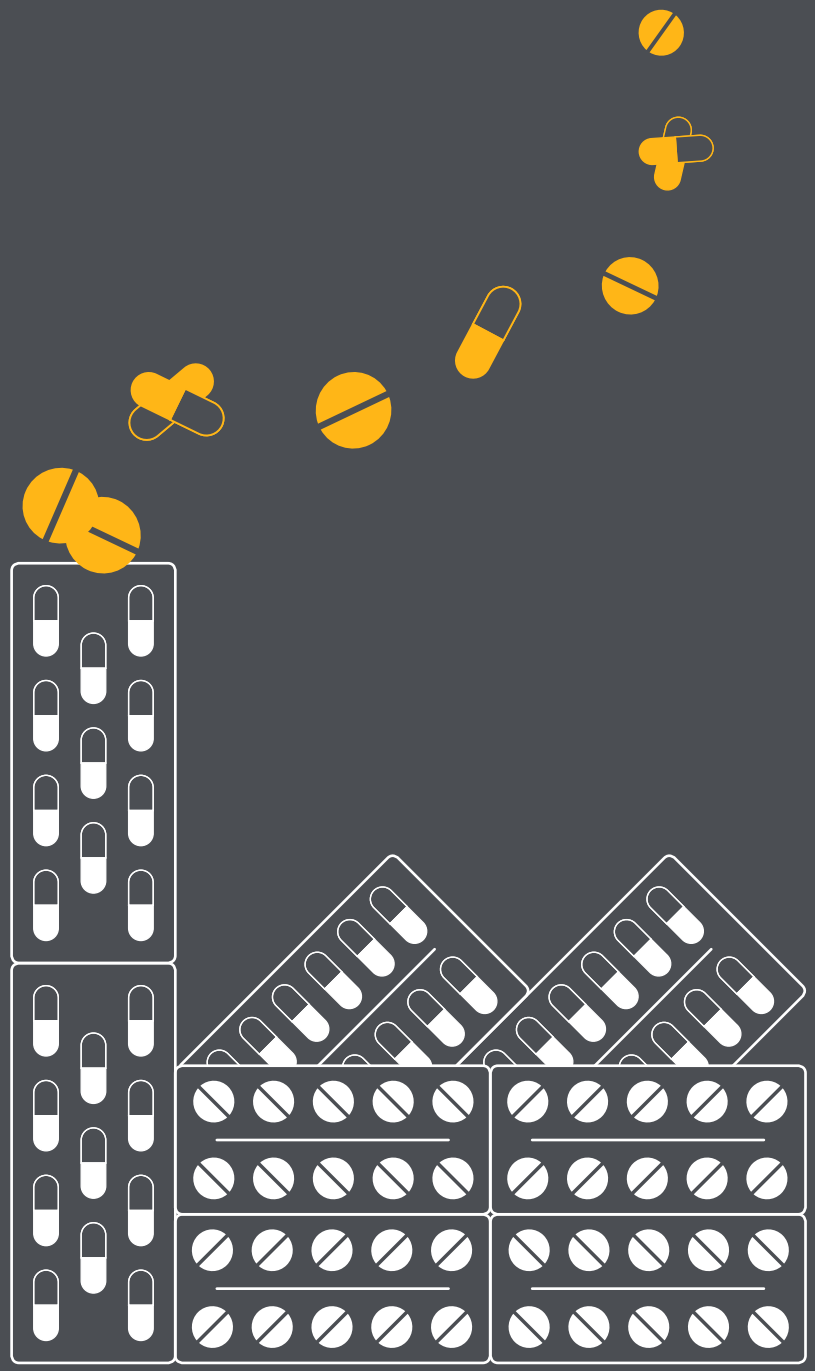
Claims arise when a consignment of pharmaceutical products falls outside set parameters during transit or storage. "Distributors have to be able to show the parameters within which medicines are being carried as part of the EU's Good Distribution Practice (GDP) requirements," explains Christopher Chatfield, Partner, Kennedys. "Temperature is the one everybody's focusing on but there are all sorts of other parameters. For example, vibration and humidity."

Another GDP parameter involves the number of times a consignment is moved. "For one of the vaccines, you can only move the product four times within the cold chain before it's used," explains Karishma Paroha, Senior Associate, Kennedys.

Differences of opinion

Things can and do go wrong with monitoring these parameters even at the best of times. "Tracking is often an issue," says Chatfield. "With temperature tracking in particular we'll often find that the pharma company and the freight forwarder keep their own records and the two often don't match. Sometimes they have different methods of setting the equipment used to measure the products in transit, sometimes they put a thermometer within the box, so it doesn't have the same exposure to temperature variations as a thermometer on the outside. And inevitably there are times where the product has to come out of deep freeze in order to be moved. Whether that qualifies as one of your movement times or not is a matter of some discussion because that can be a very short time."

Pharmaceutical products not being stored or transported within the correct parameters is a big source of claims. "We've seen these issues with, for example, flu jab distribution, where we've had temperature differences between the manufacturer, the purchaser and the freight forwarder. We often have it with warehousing as well. If you put a thermometer just by the door and somebody keeps opening the door, the product at the back of the warehouse may be okay, but the thermometer by the door will be measuring



Diversifying supply chains

From governments to corporates, the importance of a diversified supply chain has been a big lesson of the pandemic

But this idea raises questions, such as:

- How will states incentivise life science manufacturers to nearshore?
- What impact will more suppliers have on the number of quality control systems required?
- If production becomes more localised, could governments increasingly commandeer factories during a crisis?

API production is one area of the pharma supply chain that may be diversified

temperature increases as people walk in and out. It results in large quantities of products being thrown out sometimes," says Chatfield.

Liability for losses in transit can become contentious when the research and development costs of pharmaceutical products are factored into the value of the shipment. "We have an ongoing argument a lot of the time about research and development costs and whether they should be recovered as part of the liability of the freight forwarder," says Chatfield. "It may cost very little to make the product, but if you add the research and development costs into the value, then the product costs go up quite considerably."

This can have a knock-on impact on the costs of movement, which right now are already very high due to shortages of shipping containers.

However, during the pandemic some governments are taking on liability for the final phase of vaccine distribution. "In the UK, we've got the Army looking after that final step of distribution," says Forrest. "Pfizer send the vaccine across from Belgium into a distribution holding site and after that it has nothing to do with them, it's up to the UK government to figure out how to move the product through the country. The same has occurred with Israel, distribution has been done through a slightly non-traditional chain."

"In the future, we could see technology used to overcome some of these distribution challenges, such as drones for delivery into remote regions and blockchain for real-time traceability of products," says Paroha. "I think the use of drones for delivery will be fast tracked," adds Joanna Manthorpe, Corporate Affairs Lawyer, Kennedys. "The UK government is really looking to these tech companies to enable them to be more efficient in the future."

The state's role in supply chains

The pandemic has been a wake-up call for governments when it comes to health security. With various countries limiting exports of products from drugs to PPE, the tension between national priorities and globalised free markets has become abundantly clear.

How governments attempt to mitigate health security risks has a direct impact on corporate supply chains. "We've seen a couple of examples, one in Australia, where a company has been set up to produce PPE domestically with their sole client being the government. There you're seeing a country trying to wean itself off supply from outside its national borders," says Forrest. "In the US, we've seen the government essentially commandeer a private company's production space for vaccines. That manufacturer, which was producing other drugs for other companies, had to tell their clients that they could no longer do it."

These examples reflect a trend towards states wanting to manage health security more closely. "We're seeing

that desire to control the supply chain start to edge back into national governments' viewpoints. That doesn't mean they're suddenly going to produce everything, but it does mean going from maybe 80% outsourced to only 60% outsourced," says Forrest, referring to the whole life science ecosystem from track and trace software to medical equipment and drugs.

How to bring production of life science products closer to home will be a big question for governments as the dust settles on this pandemic. "I can absolutely see huge incentives being given to companies to try and recentre some production into specific territories, and then governments can commandeer that production if needed," says Forrest.

To what extent health security is organised regionally will also be interesting to see after the crisis. Economically, it makes sense for individual countries to specialise in different areas, but that carries risk. "Germany is very good at diagnostics and machinery; the UK is very good at vaccines; and other countries are very good at manufacturing medicines. Economically, such specialised hubs make sense. However, when the pandemic struck, it highlighted the deficiencies in the capabilities of some countries due to such specialisation," explains Chatfield.

Corporate risk mitigation strategies

For life science companies, the risks posed to their supply chains by government interventions, lockdowns and competition for resources has put diversification firmly on the agenda. "Corporations are having to make sure that they don't have all of their eggs in one basket. Before COVID, something would have to go really wrong to lose your supplier - there would be great resilience within a single supplier. Now we're seeing a number of companies look to actively have two or three different suppliers supplying the same thing," says Forrest.

Diversification does, however, raise compliance costs. "If you're using two or three other suppliers for a component piece, what's the impact of that on quality control systems?" asks Gallois. "Using multiple suppliers can only increase the workload of the Quality teams, with every component from every supplier requiring some sort of quality check."

A focus on local supply is also a big theme in corporate risk mitigation efforts. However, this too can have a price impact.

Increasing inventories is another long-term strategy being considered. "Eventually we could see more raw material stored closer to the manufacturer, and more finished goods kept at locations that are closer to the marketplace," explains Gallois.

Kelderman believes we will see a mixture of these mitigation strategies. "I think that there will be a shift in the supply chain from globalisation to more localisation. I think that in future there will be more and more production of key products in the countries themselves, and also more domestic storage."

Key takeaways

- **Tensions over vaccine supply** timelines emphasise the importance of drafting clear contracts
- **Claims arise when pharma products** fall outside of set parameters, such as temperature limits, during transit
- **If a shipment's value includes R&D** costs, liability can become contentious
- **From governments to corporates,** diversification of suppliers and nearshoring is being discussed

To discover more contact

Alex Forrest
Head of Life Sciences - Overseas General, Chubb
aforrest@chubb.com

Keith Gallois
Senior Risk Engineer and Life Sciences Industry Practitioner, Chubb
kgallois@chubb.com

Karishma Paroha
Senior Associate, Kennedys
karishma.paroha@kennedyslaw.com

Cece Liu, Underwriting Manager, Life Science, Chubb Asia sees active pharmaceutical ingredients (APIs) as one area where a reframed supplier chain will be a priority. "China and India are the world's biggest suppliers of APIs. Discussion of reshoring API and other intermediate production to the US and Europe is taking place, with the purpose of reducing dependency on the major supplier nations. Large pharmaceutical companies are looking to either establish local manufacturing capacity or potentially to replace it with capacity from elsewhere, perhaps Thailand or Malaysia. Supply chain challenges, however, still remain for the post-COVID world. Change cannot take place very fast. China and India will still retain their position in the supply chain for APIs/intermediate products, but the pandemic definitely will urge the re-deployment of the chain."

Lasting legacy

Long after the life science supply chain is no longer at the forefront of everyone's minds, the pandemic will still be making its presence felt. "There is undoubtedly some big pharma scepticism among the general public, but I think the life science industry as a whole has come out very well in its ability to rapidly develop vaccines, in its ability to run clinical trials very quickly, to try and understand treatments, and from the medical device side as well. The industry has been able to provide what's needed generally," says Forrest.

"I think there's going to be a lot more acceptance of needing to invest in the industry, be it clinical trials or manufacturing, to have good quality production of life science products. I think the industry will come out of this relatively well," concludes Forrest.

For the full series on Life Science in the era of pandemics, click here.

Chubb. Insured.℠

UK7969-WA 03/21