Building resilience into your life sciences supply chain

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The life sciences sector is heavily networked and more reliant on third parties than other industries. Knowing where your materials are and how this affects your capability to manufacture is essential.

With disruption increasing, our webinar on 23 March 2022 looked at the rising frequency and severity of external threats to the life sciences supply chain, how the insurance market is responding, and what you can do to mitigate your risks.

This review gives an overview of the key talking points and learnings from the webinar.

Session leader

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Speakers

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Supply chain risks affect life sciences every day

It's not uncommon for the simplest of drugs to have a complex supply chain, with 60-70 participants. No two supply chains are the same. The consequences of disruption can be severe, ultimately leading to delays in life-saving drugs reaching patients.

Risks can occur throughout the chain – from the upstream supply of raw materials, through manufacturing and packaging to downstream distribution and wholesale.

In a recent 48-hour period, all these threats to the life sciences global network took place:

- **A strike at a major airport hub**
- **A tornado near a pharma manufacturer**
- **A chlorine leak at a facility**
- **A product recall**
- **A lawsuit regarding theft of trade secrets**

Disruptions like these are common. Other destabilizing factors include natural disasters, the ongoing pandemic, cargo ships stuck in trade lanes, inflationary pressures, worker shortages, political unrest, cyber attacks, port shutdowns and materials shortages. These are all examples of the unprecedented uncertainty and systemic risk faced by the life sciences industry.

Whistlestop tour of the life sciences supply chain

The first upstream links in the pharmaceutical supply chain include companies that formulate active product ingredients from raw materials and reagents. Also upstream are third party suppliers of excipients and non-product suppliers of packaging.

From upstream, the supply chain moves to manufacturing. Suppliers involved at this stage include contract manufacturers and intermediaries such as distributors, contract warehouses and analytical testing labs.

Downstream takes the drugs through to packagers, fillers, labelers and on to wholesalers and finally to providers and patients. The whole system relies on transportation providers, freight forwarders and third party logistics companies in ocean, rail and trucking.

Upstream – supply side

Daniel Green, Property Broker, Direct & Facultative at WTW, detailed the cover available for non-damage business interruption.

Numerous non-damage events will have an impact on a company's activities with significant financial implications. These can include regulatory control of manufacturing licenses, sanctions and nationalization of IP.

Contingent Business Interruption (CBI)

CBI insurance reimburses a company for the costs of business interruption including lost profits and necessary continuing expenses as a result of disruption to a supplier.

Who needs CBI insurance?

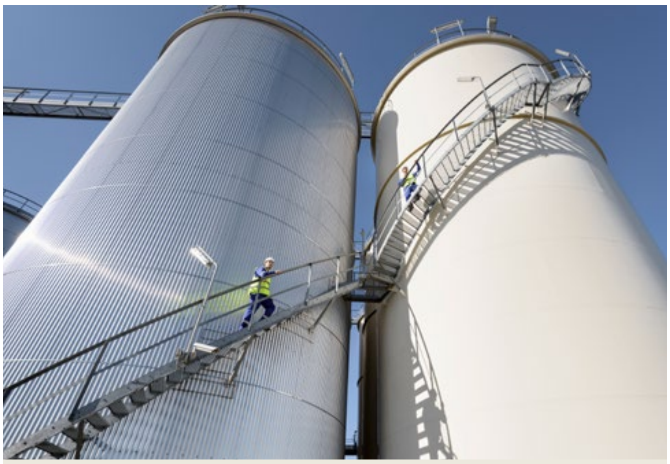
Global commerce and competition have increased the complexity of supply chains. Critical suppliers are located in many different countries, increasing potential vulnerabilities and creating new exposures. But even if all suppliers were local, life science businesses would still face contingent business interruption risks, so it's important to have a solid understanding of third party partners to minimize losses.

CBI insurance can be bought as an extension to the time element in property insurance. It usually covers a period of restoration – the time it should take to repair the damage and resume normal operations.

Additional coverage restrictions

It is important for organizations with complex global supply chains to identify potential cover restrictions. For example, some policies will only provide cover if you have a direct relationship with the supplier and not a supplier who is working for you indirectly through another supplier. This can leave gaps in cover if you have multi-tiered supply chains.

Up-to-date business continuity planning is essential so that exposures are accurately identified and the appropriate cover is in place.



CBI example:

A drug manufacturer on the U.S. East Coast insures an active ingredient from a tier 1 supplier in Japan. A natural disaster in Japan causes damage to the facility and halts supply of the product. The manufacturer loses income and customers as a result. CBI insurance covers the manufacturer for the business interruption costs that result from the lost supply.

Manufacturing

Paul McLarnon, Corporate Development Director at Sedgwick Group, highlighted the most common issues that loss adjusters are facing, some of which are influenced by the pandemic and others that have been around for much longer.

Issue one: the inaccurate valuation of stock

There can be a gap between the amount that insurance will pay for stock, materials and trade, and the client's valuation of that stock – particularly where stock is valued by an in-house finance team with historic accounting conventions.

This can happen because valuations are loaded with net manufacturing costs of raw materials, variable overheads, and labor. It's also affected by price transfer mechanisms where goods move between territories. These factors can lead to an inflated sum insured globally for stock, which can cause disappointment at the time of a claim if the indemnity received does not match the client's valuation of stock and materials in trade.

To resolve the issue, adjusters work with insurers and brokers to understand stock costings and secure agreement in advance of a large loss. This removes the confusion at the time of a claim and means that payments can be processed quickly, and the sum insured represents the correct insurable amount.

Issue two: extended lead times

Due to the global pandemic, there can be significant delays to lead times on repair of machinery and replacement parts and this can affect business interruption cover. There has also been an increase in machinery replacement costs, leading to more insurers challenging the adequacy of global sums insured on machinery and plant.

A recurring issue is around underinsurance and average condition, which would serve to reduce the claim. The policy may be subject to an average/underinsurance condition. In some but not all cases, as long as the reinstatement value of machinery and contents is within 85% of the declared value at inception of the policy, there would be no underinsurance penalty. Some policies don't have this 85% condition and pro rata claim reduction can then be applied if there is any degree of underinsurance.

To resolve the issue, loss adjusters are identifying key territories where there is exposure to the issue of declared values which should represent the replacement cost of plant at the date of inception of the policy. An audit trail and evaluations are presented to insurers and used by brokers and risk managers to offer reassurance and support declared values.

Issue three: maximum indemnity period

The length of the maximum indemnity period is there to help businesses recover financial losses following an incident of physical damage. For example, a 24-month maximum indemnity period for a fire that occurred on 1 January 2022 will protect the business until 1 January 2024.

Clients are choosing periods of time that are inadequate for the coverage required. This has been exacerbated by the pandemic and subsequent protracted lead times for planning permission, certification, license confirmation and sourcing contractors to rebuild.

To resolve the issue, adjusters use time-focused scenario planning, showing the stages of recovery from day one to completion. This results in clients extending their indemnity periods and saves the business from encountering significant problems.

Downstream – logistics management

Charles McCammon, Team Leader Marine Risk Consulting & Claims Advocacy at WTW, explained the importance of mapping out specific risks in transportation and distribution, determining who is responsible and shifting risk along the supply chain.

At each node of the supply chain are various risks that require analyzing, mitigating and shifting. From the sourcing of raw materials, through manufacture, forwarding to distribution centers and on to the consumer, it is important to determine who is responsible for any losses along the chain.

Significant risk shifting takes place through the sales contract and should ensure that there are no gaps in coverage. The contract incoterms will identify when the risk of loss transfers between a seller and a buyer and who is responsible for insuring the goods in transit.

Marine cargo insurance solutions

Marine cargo insurance offers first party coverage as a pure property insurance product, but there are ways to enhance contracts to increase cover and provide some supply chain business interruption protection. For example, a valuation clause could include wording to insure goods and merchandise at landed cost plus a markup.

Marine cargo damage example:
Most carriers in the supply chain limit their liability to cargo damage. If a ship is travelling to the U.S., American rules allow the vessel owner to limit their liability to $500 per package. Goods within the global supply chain are often more highly valued than $500, so first party coverage is necessary in case of loss.

Understanding the opportunities to enhance coverage and protection requires a team of experts and access to relevant data. It is no longer acceptable to assume your business partners have supply chain coverage: greater diligence is required.

Accumulation clause

Marine cargo policies have specific accumulation clauses that limit the potential insurance for any exposure. The size of vessels has increased so suppliers are at risk of exceeding their contractual accumulation provision.

Warehouse forwarding clause

This area of marine policy can add protection to the supply chain when used to address cargo frustration, interruptions of supply chain, early termination of an insured voyage or similar events. The underwriter will allow extra expenses related to transporting the frustrated cargo to its destination.

Expediting clause

An expediting clause can mitigate the physical loss or damage that might occur in transit. Underwriters will cover the cost of replacing or repairing the lost or damaged products and expedite the shipment. For instance, damaged products in Asia that were vital for a just-in-time manufacturing system could be replaced and expedited by air transport if needed.

Delay clause

Delay always has a significant impact on the supply chain, so it is important to understand the delay clause in a marine policy. This clause will extend coverage during a delay but there are time limits within which to notify the underwriter. With the recent Suez Canal closure causing massive delays, some coverage was found to lapse when a product was delayed over a certain amount of time.

Third party logistics pandemic best practice

Clients that have been successful in navigating pandemic-related supply chain disruption undertook these actions:

1. Identify risks using mapping software
2. Consistently mitigate risks through contractual shifts with logistics carriers
3. Develop insurance requirements for logistics providers, verifying the types and limits of insurance they have in place
4. Conduct investigations after losses to learn lessons and recommend corrective measures

Supply Chain Resilience

Frederick Gentile, Director of Risk Engagement at WTW, explores the types of supply chain vulnerabilities and what can be done to address them.

Building resilience has never been more important due to the threats faced by supply chains and this is only likely to increase in the future. To build effective resilience, we need to understand where the vulnerabilities lie:

Financial solvency – including supplier liquidity and credit record, plus the viability of the pharma sector from a supplier perspective.

Regulatory change – regulators are tightening the testing, security and environmental compliance of the pharma industry. We are likely to see further changes in packaging and labeling as we move to a patient-centric model. Governments around the world are encouraging drug companies to localize supply chains to increase resilience.

Data security – cyber crime is on the up and pharma operators are prime targets for confidentiality, integrity and data breaches.

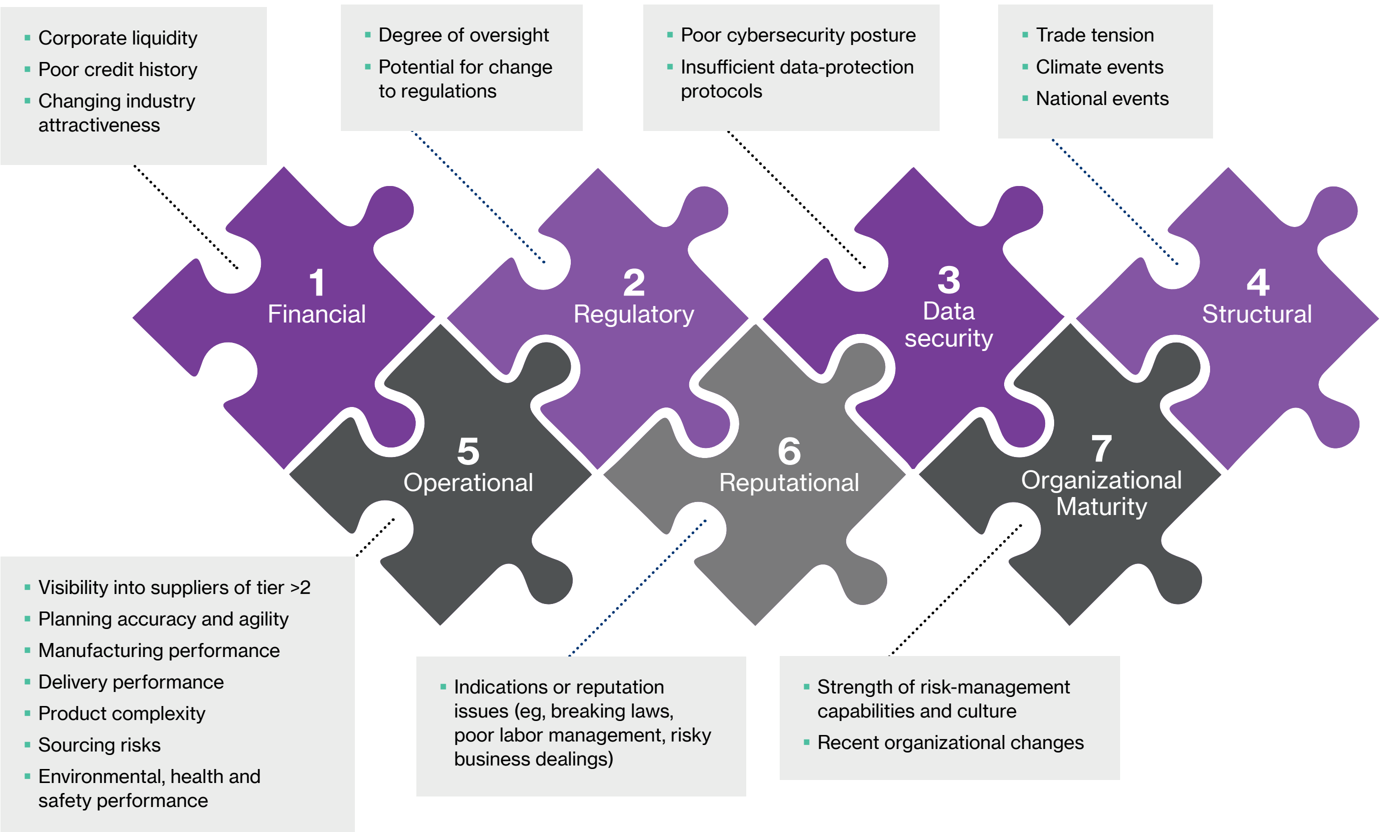
Structural factors – linked to climate events, geopolitics and major international events such as the COVID-19 pandemic. If a country like China, a leading supplier of basic raw materials and active pharmaceutical ingredients (APIs), changes trading and supply policies with partner countries, an intentional or unintentional reduction in supply would occur.

Operational factors – supplier visibility at tier 2 and beyond, maintaining manufacturing and delivery performance and product complexity adds another layer of vulnerability.

Reputation – poor labor management, breaking laws and infringement of ESG requirements are key risks. In 2019, Novum Pharma suffered considerable reputational damage after changing its pricing policy for a skin cream product and subsequently went bankrupt.

Organizational maturity – how mature is the risk management process and are organization structure changes reflected there? How frequently are risks reviewed? A level of maturity is required to properly understand supply chain risks in order to mitigate them.

Figure 1: **7 areas to examine for supply-chain vulnerabilities**
This graphic shows a model for assessing where vulnerabilities lie within the supply chain



Source: Foster T, Patel P and Skiba K, McKinsey and Company – https://www.mckinsey.com/industries/life-sciences/our-insights/four-ways-pharma-companies-can-make-their-supply-chains-more-resilient

Four key actions to address vulnerabilities and add value

1. **Add supply chain risk and resilience to the executive agenda:** This should be embedded in the organization's strategic planning and execution, with structured governance to ensure that decisions are made and acted on at the correct level and the right time. This can be associated with existing functional business risk assessments which already exist in management team meetings and is the ideal vehicle to aid resilience. To work best, each unit must have risk identification and analysis tools, trained capabilities and expertise. Alternatively, create a chartered risk committee, a defined group that is accountable for assessing and managing all supply chain risk across the company, also requiring strong analytical capabilities and tools.
2. **Routine stress testing and assessment:** Use scenario planning and simulation modeling to quantify the impacts and mitigate the effects of risks. During the COVID-19 pandemic, a leading pharma organization used a digital twin simulation to understand the impact of production slowdowns and shutdowns on the supply of patient medication. Also consider red teaming whereby an internal group is tasked with providing an outside challenger approach to policies and processes. An external consultant can provide this service but an internal team understands the business thoroughly. The red team can explore how the organization would deal with a macro event or global disruption.
3. **Reduce exposure to shocks:** Relying on a single source for critical components and raw materials creates vulnerability, as can depending on multiple suppliers located in the same area, so it is wise to expand the network of suppliers. Developing a balance between just-in-time and just-in-case inventory levels and bolstering physical assets to withstand climate events and provide support to distressed essential suppliers is prudent.
4. **End-to-end visibility and transparency:** To address the challenge of external threats such as cyber attack and ESG scrutiny, organizations should introduce a robust and agile supply chain mapping capability software tool. This will allow a better understanding of the relationships and flows in the supply chain with live event tracking and the ability to be proactive to events, assess the risks and reduce exposure and operational delays.

WTW tools and competencies

WTW has an experienced team of experts with the tools and competencies to help clients understand their supply chain vulnerabilities and align their production with financial risk. Our products such as global peril diagnostics for mapping and monitoring, provide an early warning system to gather relevant data and assist with mitigation of supply chain risks.

About WTW

At WTW (NASDAQ: WTW), we provide data-driven, insight-led solutions in the areas of people, risk and capital. Leveraging the global view and local expertise of our colleagues serving 140 countries and markets, we help you sharpen your strategy, enhance organizational resilience, motivate your workforce and maximize performance. Working shoulder to shoulder with you, we uncover opportunities for sustainable success — and provide perspective that moves you. Learn more at wtwco.com.

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