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Life Science Shipments

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Commercial insurance is one (perhaps the only) industry where the seller does not know the cost of goods sold until well after the purchase transaction. That is certainly the reason why underwriters have long practiced risk management, a term that since the financial crisis of the last decade seems to be included in everyone's lexicon.

There are several paths toward risk management but here we will discuss loss prevention (limiting the likelihood of loss/damage to goods in transit) and loss control (reducing the extent and impact of loss/damage should it occur).

While these may not be the most exciting operational functions, we are buoyed by the words of Peter Drucker, the management guru, - "The first duty of business is to survive. The guiding principle of business economics is NOT (our emphasis) the maximisation of profits. It is the avoidance of loss."

Due to some generally shared inherent characteristics, Life Science shipments represent a unique challenge to marine insurers that can be summarised by a few bullet points. They have:

- High per conveyance values
- High perishability
- High theft-attractiveness
- High regulatory oversight
- High total loss potential

This is not the ideal profile for any account yet alone a portfolio. How do insurers deal with these types of risk and, more importantly, how can shippers and other stakeholders (risk management is a team activity) assist them? There are numerous channel partners or links in today's complex, global supply chain as goods travel from origin to destination. Add to this the diversity within the Life Science sector with "Big Pharma" where there is an expectation of state-of-the-art processes and procedures to growing generic companies, small startups and even NGOs working on drug outreach to underdeveloped nations.

The various supply chain constituents may have differing objectives; ideally there will be more meshing than competing. With Life Science manufacturing continuing to shift its centres of excellence from established to emerging hubs, can we expect brick and mortar and "virtual" companies to outsource to contractors located in regions with less

established transport infrastructure potentially offsetting benefits due to a lagging time to market? Moreover, with geographical concentrations of production and the drive towards "leaning" of inventories, it appears as if single localised disruptions could wreak havoc.

Also, will transportation companies develop routing networks that maximise their asset deployment with transfers and in-transit handoffs that elevate the potential for cargo loss, damage and delays? Or will logistics schemes result from a more collaborative dialogue? These are a few of the things that can disturb a senior manager's quiet night sleep.

Each insurance company develops its own underwriting criteria ("special sauce") based on corporate directives, underwriting acumen and institutional knowledge which may well be influenced by "scar tissue" from past poor experience.

There are a number of factors to consider but typically due diligence focuses on the product, the trade lane(s), packaging, the conveyance, transportation providers and handling.

Product- There are raw materials, Active Pharmaceutical Ingredients (API) and finished goods and as we move upstream in the supply chain, the costs and thus values increase. They can range from innocuous chemical compounds to over-the-counter products to generics to the more "interesting" blockbuster drugs along with lifestyle and controlled substances. We need to consider their damageability whether it be due to breakage, spoilage, contamination, water contact as well as theft.

Packaging- For most goods being shipped protective packaging is disposable in the sense that if the carton or drum is damaged but the contents are unharmed, it is deemed to have done its job and can be simply discarded and replaced. That is not necessarily the case with Life Science shipments where breaching the integrity of even the exterior barrier will raise serious concerns.

Pre-shipment or transit testing of packaging can be a cost-effective way to ensure it is suitable to withstand the anticipated rigors of handling and transportation. Validation (or is qualification a more accurate term?) of passive cold chain packaging vis-à-vis the required temperature range and the expected transit duration (we suggest adding a 50% margin to account for delays such as extended Customs clearance), is another recommended best practice.

We believe all Life Science shipments have some degree (no pun intended) of intolerance to temperature excursions; therefore, ambient, controlled room, cold chain and frozen are discrete and meaningful delineations. For example, just because a bulk drug substance is considered ambient does not mean that it can be properly maintained in any prevailing climatic conditions.

All manufacturers should have temperature stability data, allowable deviations from prescribed norms, to enable them and their customers to determine if transit conditions have adversely affected their product's efficacy, stability or potency. This is also critically important to insurers as it can make the difference between a claim and loss-free delivery.

Having the stability data is essentially valueless without a reliable temperature history throughout the transit period, defined as from the time the product is packed until it is received at final destination. There are a number of temperature indicators available on the market. Not all temperature acquisition devices are created equally. Chemical/visual indicator models are inexpensive and easy to use and understand, but they come with one major drawback- they are single event types designed to trigger outside a pre-set temperature range but they provide no information on how high or low, and as importantly, for how long the temperature reached. Therefore, they render the stability data useless.

Dataloggers are far more effective and are, in fact, the de facto industry standard. The number and placement are not random choices but serious considerations. Using multiple devices, another safety factor if you will, is prudent but they should be positioned so they capture temperature representative of actual conditions. Think about positioning it/them close to the geometric centre of the load or about one-third in from the doors but away from the direct path of airflow. If the device is placed inside the actual packaging, then it should be as close to the product as practical but not touching the phase change material (dry ice or gel pack).

Rather than endorse one device or model over another, shippers should select one that meets these criteria - records continuously and within the temperature parameters of the product; is National Institute of Standards and Technology (NIST) validated within an 1° Celsius accuracy; is Federal Aviation Administration (FAA)/European Aviation Safety Agency (EASA) compliant if transported by air; has customisable alarm settings; is water resistance and has an appropriate battery life.

Technology has also given us monitors that provide real-time indications allowing for successful escalation and response processes.

The products have to be transported in an air cargo hold, truck/trailer or an ocean container. Optimally, the conveyance has been thermally mapped to determine the “hot spots” and there should always be a thorough inspection prior to loading to ensure it is clean, dry, free from odours and fully suitable. The cartons, drums or pallets also must be appropriately stowed as there are clear differences between cold chain (staggered to create viable airways) and frozen (in a block formation to keep the cold in).

Once the shipments leave origin they are in the care, custody and control of transportation providers and intermediaries. While shippers cannot realistically be there at every touch point along the supply chain, they can stand influence behavior of cargo handlers and transport personnel through clear and precise instructions. Marks on the packaging (Keep Frozen, Do NOT Freeze, This End Up, Fragile, etc.) and notations on shipping documents are opportunities for the shipper to communication requirements. In the United States, the Fahrenheit temperature scale is used while the rest of the world employs Celsius and this divergence can create confusion and cause costly losses. One solution is to indicate the temperature range in both. There is a flip side here. Shippers should give the name and 24/7 telephone number for an employee that has both the technical expertise and decision-making authority to respond to an emergency in-transit situation.

One final piece in the puzzle is carrier selection; choosing a transportation partner, perhaps, the single most important decision a shipper can make. Insurers take the view of the “Faithful Servant” parable that can be expressed colloquially as “to whom much is given; much will be required.” Entrusted with, in most instances, valuable and life-saving drugs, they have to be your greatest loss prevention ally. Shippers should seek out specialists that focus in this niche, with the experience, staff, equipment, worldwide network and added value services that align with their needs.

Are beneficial cargo owners spending on countermeasures such as boots on the ground route analyses or Cloud-based telematics solutions based on value of the shipment or the risk? Is a USD 20 million shipment moving between well-defined and known facilities in the United States or Europe of more concern than a USD 2 million load transiting across Brazil? Insurers and supply chain security consultancies can provide actionable intelligence from their global and individual country threat assessments.

The insurance risk-taking mechanism works best (providing a complete and competitively priced programme) when the insurer fully understands a company’s business and supply chain practices. As English philosopher Francis Bacon wrote “Ipsa scientia potestas est” knowledge is power as opposed to another contemporary saw Hic Sunt Dracones (Here Be Dragons) in which medieval cartographers will advise mariners to be aware of dragons signifying the end of undiscovered areas, truly uncharted waters.

Therefore the goal for both insurers and Life Science companies should not only be full disclosure but also shared risk and vision since loss-free shipments are the embodiment of a win-win proposition.

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