STEPHENSON HARWOOD

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Shipping COVID-19 vaccines

The global pharma market is said to be worth $1.3 trillion, composed of patented and generic medications of all kinds.

Some, like vaccines, have "active pharmaceutical ingredients" which mean that they are perishable and often require specific storage and carriage conditions.

The global supply chain is complex with multiple actors. The biggest challenges it faces are matching supply to demand, maintaining complete batch traceability to protect public health and brand confidence, safely moving cargo between modes and the differing distribution methods employed in different territories.

In general terms the supply chain moves ingredients to a manufacturing site from which medicinal drugs are shipped in large quantities under controlled conditions as containerised cargo to distributors in the receiving country where they may be repackaged. In the detail, the nature of the logistics is governed by the type of medicine being shipped and the way that it will reach the patient.

The pharma supply chain is not regarded within the industry as ideally configured. Commentators typically point to the lack of data enabled solutions and transparency, lag times in ports and distribution centres and uncertain links between supply and demand.

That last point was exemplified in the UK at the start of the first UK lockdown in March. A surge in demand for anti-inflammatory and analgesic drugs soon led to acute shortages as the supply chain failed to cope.

The same could have happened to prescription medications but fortuitously stockpiles had previously been enlarged to cater for a “no deal” Brexit and the shock was absorbed by this buffer stock.

The COVID-19 pandemic has until now been characterised by the lack of an effective vaccine. Given the huge economic damage incurred so far (the effects in the US alone are estimated at $16 trillion) producing and distributing an effective vaccine has been of supreme importance to political leaders. About 30 vaccines are in the testing pipeline worldwide with a few ready to be rolled out pending regulatory approval.

A novel characteristic of these new vaccines is the lower than usual storage and carriage temperatures.

The usual temperature range for other vaccines is between -4 and -40 C. One COVID-19 vaccine requires -80C to stay viable and others ship at -50C.

The World Health Organisation estimates that 50% of all vaccine shipped loses effectiveness due to failures in temperature control, logistical delays or damage during shipment.

COVID-19 vaccines will stress existing cold chain logistics, and there will be little public tolerance for large scale losses.

The challenge for shippers, carriers and distributors will be to overcome the existing internal friction in the global supply chain whilst at the same time coping with a higher demand for a material shipped under conditions for which there is little or no prior experience or equipment.

There are several obvious developing choke points affecting multi modal cold chain logistics. They are increased congestion at ports and terminals caused by the global economy braking sharply and now accelerating more gently and the reduction in capacity on liner routes following the downturn in trade.

Regionally, Brexit will inevitably cause delays for both imports and exports brought about by an increased administrative burden. The increasing use of sanctions and regional conflict further complicates the movement of medical cargo from the developed to the developing world.

The dramatic reduction in scheduled passenger flights, long and short haul, takes out capacity for the rapid shipment of smaller consignments of high value perishables.

The demand to be met is likely to be a requirement to move billions of individual doses of vaccine from a relatively small number of manufacturing sites to anywhere and everywhere over the next 18 months.

Because of the value of the cargo, vaccines are shipped in smaller lots to a maximum cash value per unit, typically $50m which equates to about 150,000 doses. That means every sailing will have COVID-19 vaccine aboard in several reefer units.

Moving containerised cargo by sea involves multiple actors, all of whom are interlinked by a suite of contractual agreements that transfer and distribute risk and liability.

The carrier enjoys limitation of their liability by statute or convention, which is often incorporated into the contract of carriage but others, such as terminal operators, do not. All parties seek to transfer their balance sheet risk to insurance in one form or another generating an environment of claim and counter claim post loss.

Vaccine cargo can be shipped on standard terms such as Hague or Hague-Visby rules. However, because the unit value of pharma cargo is high the shipper will almost certainly have insured their goods in transit on a global insurance programme fronted by a major broker and placed in a mature market, typically London.

These cargo policies typically contain a "Control Of Damaged Goods" clause. This effectively removes any scope for adjustment or recovery for underwriters following damage to or the theft of a consignment.

Although vaccines can survive for a period out of the normal temperature range, that information is never divulged to the carrier and the CDG Clause allows the shipper to take custody of and then destroy a damaged batch and present a claim for the insured value.

In the case of theft, particularly of active pharmaceutical ingredients, the loss can extend to the recall of an entire production batch.

The CDG Clause, from the shipper’s perspective, is necessary for three reasons. It protects the shipper's brand reputation by preventing soiled or damaged goods from entering the distribution chain. It ensures regulatory compliance with, for example, the European Medicines Agency Good Distribution Practice. It prevents medicines from falling into the "black market" which undermines public health and the financial position of the manufacturer.

Sometimes vaccines are shipped in transit packaging and repacked by the receiving distributor for placement into pharmacies. The new packaging is shipped as cargo and is treated (apart from unit value) as if it were pharmacological cargo for the purposes of the CDG Clause.

The distribution of COVID-19 vaccines is already attracting the attention of politicians and regulators. In the UK a minister has been appointed to oversee a vaccination programme. There are always risks inherent in the transportation of goods by sea which are only fully understood within the industry. The industry should prepare itself for more intense scrutiny and hostile commentary when the inevitable happens.

The nature of the inevitable legal disputes post loss will not change that much. We might see state intervention in salvage operations to force the release of a cargo otherwise held by salvors by way of a lien in the absence of a salvage bond.

We might see the insurance market respond with harder pricing or carve outs for COVID-19 vaccine cargoes.

Without data driven insight, insurers of ports and terminals will not see sudden accumulations of risk as containers of valuable vaccine dwell in port and compete for a finite number of reefer points. This will cause a silent increase in unpriced exposure, a real risk for cargo underwriters.

This logistical effort is going to be needed at a time of uncertainty in the container market. The original lockdown had a dramatic effect on capacity, causing vessel layups, blanked sailings and displaced boxes which severely disrupted what was already a heavily interconnected and interdependent operation.

Economies around the world are now partially awakening at different times and at different rates

causing further stress on terminal capacity and throughput.

As an example, very recently MSC had to invoke clause 19 of its Bill of Lading and Sea Waybill terms and conditions, diverting reefer containers away from Chinese ports that had run out of reefer points. These shipments are being disrupted and delayed.

All of this begs the question as to whether the existing pharma supply chain will successfully ingest COVID-19 vaccines, or if at the state level some form of intervention and capacity building will occur particularly for products with unusual carriage requirements.

Roderick Johnson FNI
Marine director
T: +44 20 7809 2287
E:roderick.johnson@shlegal.com

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