Turbulent Times

The pharma cool chain is being reshaped by a need to reduce complexity, improve efficiency and trim costs. Two distinct developments are currently shaking up the sector: one involving a shift of business; the other a shift in technology

Alan Kennedy at PartnerSave

Image: © DuPont Protection Technologies

It was back in 1867 when Prime Minister Benjamin Disraeli said: "Change is inevitable. Change is constant". But although the Victorian era in the UK was one of great scientific and technological achievement, today's pace of change would be completely unrecognisable to someone from that time, such as Thomas Beecham, who opened Britain's first modern drugs factory in 1859.

In the modern era, technology, big data, competition, resource security, market forces, fiscal policies, demographics, regulatory developments, climate change and much more, exert huge pressures right across the pharma industry in both short and long timeframes. The distribution supply chain is no exception, and there are many drivers of change at work in today's fast-moving temperature-controlled logistics sector.

Embracing or adapting to these transformational forces invariably involves one common factor: the spending of money. And this, combined with the universal profit imperative of business, leads to the biggest change driver of all – the need to save costs. In a highly competitive world that is barely emerging from the worst economic recession in living memory, a large proportion of developments that are driving progress in both the pharmaceutical and freight industries have been motivated by a need to raise efficiency levels and improve the bottom line.

Load Displacement

'Modal shift' – the term used to describe the large-scale transfer of pharma freight from air to sea transport – is one of these cost-driven developments. AstraZeneca, for example, is reported to be pursuing a goal of a 70:30 air to sea freight ratio on a lane-by-lane basis, in a bid to reduce its costs and minimise temperature excursions.

"The modal shift we are witnessing moved from being an occasional aberration to a real trend following the impact of the global financial crisis in 2008," says Sebastiaan Scholte, Chief Executive Officer at Jan de Rijk Logistics and Chairman of the Cool Chain Association. "While the current flow is certainly more than a trickle, it is unlikely to become a tsunami wave.

Figure 1 (above): Handling delays on airport tarmac are an oft-cited weakness of air freight. Here, a Boeing 747-8 freighter is being loaded with pharma cargo at Findel Airport

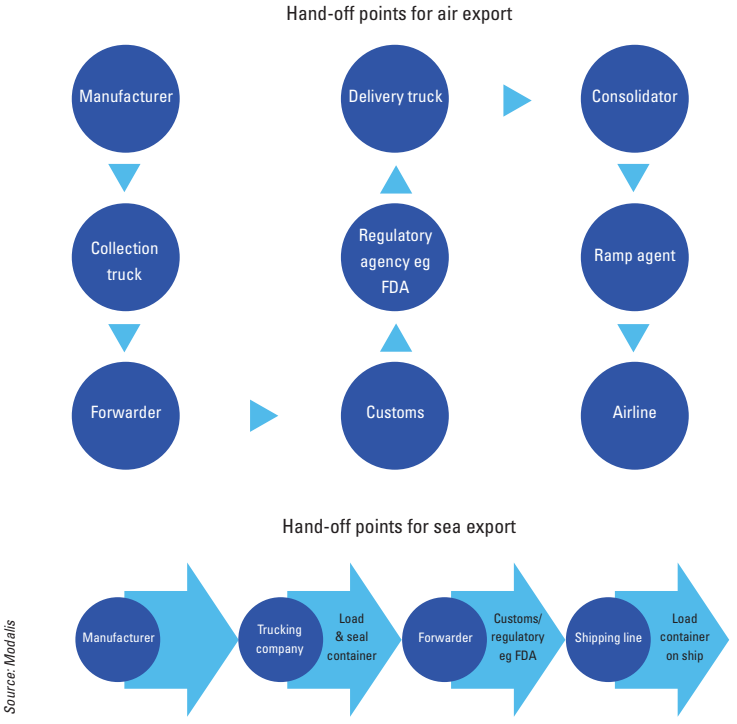
Some pharma freight is certainly suitable for ocean transport, but there will always be a need for speed and specialist pharma services. Air transport can also reduce the need for road haulage, minimise insurance premiums and reduce working capital. So, with the right cool chain partners and processes, it remains a very attractive solution."

Perceived Deficiencies

A significant factor behind the drift from air to sea freight rests in some of the claimed deficiencies of air transportation, which are said to be causing pharma shippers to seek quality and consistency improvements elsewhere. Exponents of sea freight maintain that there is a lower risk of temperature excursions and less physical handling of product. Containers tend to remain sealed from point of origin, physical customs checks are rare and, when they do happen, they are generally conducted under controlled conditions.

Speaking at the Cool Chain 2015 Conference in Frankfurt, Mark Edwards, Managing Director at logistics consultancy Modalis and former Global Freight and Compliance Manager for Actavis, explained that the problem principally relates to the much larger number of hand-off points that are used in air freight transportation (see Figure 2). One global pharma company cited by Edwards has been able to introduce temperature controls across its entire supply chain, for no extra cost, by switching the bulk of its distribution from specialist air services to sea freight, using active reefer containers. Another global shipper using a daily air freight service, but beset with frequent customs delays, was able to shift to sea freight with minimal effect on lead times. The firm's customs issues are now sorted out en route, while it enjoys cost savings of more than 80%.

Figure 2: Hand-off points for air freight transportation are far greater than for sea export



Source: Modalis

All At Sea?

However, it is not all plain sailing for the sea freight industry. While the visible cost savings of sea freight versus air freight can be of an order of three to ten times greater, the real-life situation is much more complex. Apart from its unsuitability for low stability products, other factors restricting the growth in sea freight include insurance restrictions, its inapplicability to many far-inland locations, the difficulties of implementing continuous shipment tracking, and the tying up of valuable capital for extended periods of time.

"High-value pharma inventories tied up in transit absorb huge amounts of cash which could be better utilised elsewhere, including improved cool chain facilities and management," said one conference delegate. "Reducing shipment times nearly always reduces overall costs and improves customer service."

In any case, the degree of transfer from air to sea is a contentious issue. Many pundits dismiss the apparent shift that occurred in the immediate aftermath of the global economic downturn in 2008 as a temporary phenomenon. Others point towards a more permanent and continually growing trend. Some observers even argue that no such shift has taken place, with both air and sea freight volumes having been affected by the downturn. However, figures from reliable sources consistently point to a continuous trend, suggesting that the impact of falling fuel costs, and the recent growth of premium pharma air freight services, have yet to be fully realised.

Right for the Job

Moving forwards, the need to create value from generics and the accelerating growth in the biopharma sector are two

Figure 3: Pharma products need protection from solar exposure during airport transfers

Image: © DuPont Protection Technologies

factors that will strongly influence the air-sea divide over the next few years. High volume and relatively low-value generic products will naturally gravitate towards economical sea routes, while complex biologics will almost invariably require the speed and on-time certainty of air freight.

"Reports of a 7% decrease in air freight pharma volumes compared to sea freight must be viewed within the context of an overall rising market," says Scholte. "It's a classic 'horses for courses' scenario. Sea freight undoubtedly offers a more controlled shipping environment for some products, but to paraphrase the immortal words of humourist Mark Twain, the rumours surrounding the death of pharma air freight are being greatly exaggerated."

Figure 4: The air cargo industry needs to embrace modern practices if it is to recover market share from sea freight

Image: © DuPont Protection Technologies

Intelligence Embedded

These days the dictum "every business is a digital business" applies as much to pharma and logistics as to any other areas of business. Many of the big transformations and innovations currently under way in the field of pharma distribution have their roots in the information revolution. Cool chain performance measurement, pharma shipment tracking, e-freight transactions, product serialisation and transport route profiling are just some of the advancements that are dependent on the accurate collection, analysis, exchange and interpretation of information. For example, the successful implementation of a universal certification model – such as the International Air Transport Association's Centre of Excellence for Independent Validators – are wholly dependent on the ability to collect, interpret and process accurate digital data, in order to develop the standardised procedures and processes that will ensure a safe and dependable cool chain.

Good Distribution Practice (GDP) requirements generally state that pharmaceutical products must be shipped according to the storage conditions as per the package label, and that all temperature excursions should be recorded and reported. Requirements like these are translating into a stellar rate of growth for the data-logging market: a field where new technologies, and even some potentially disruptive innovations, are emerging at a rapid pace.

Digital Explosion

The explosion in digital monitoring of medical shipments and benefits of real- and near-time data acquisition have already revolutionised the pharma cool chain by facilitating more controlled transportation and reducing wastage costs. Dynamic temperature monitoring using the latest data-logging devices can be instrumental in controlling storage and transit conditions throughout the cool chain. Invaluable for temperature mapping exercises, it can also be life-saving in determining the temperature implications of unanticipated events, including flight delays, equipment breakdown and extreme weather.

Data availability and accuracy, frequency of readings, and absence of human error are a few of the advantages of using data loggers. But they have also been associated with some disadvantages: high capital cost, complicated data retrieval, unwieldy dimensions, a need for specialist equipment and, often, a requirement for user training. However, these drawbacks are quickly receding as technology improves.

Although minuscule temperature loggers using a variety of transmission devices have been around a few years, only recently has the combination of new phone technology, dedicated smartphone software (apps) and contactless near-field communications (NFC) been brought together for a huge leap in functionality, ease of use and cost savings. This latest 'techno-fusion' has resulted in the creation of an affordable data collection platform based on simple credit card-sized data loggers that require neither dedicated data readers nor an expensive back-office infrastructure.

Single-Use Technology

At the Cool Chain 2015 Conference, Transposafe Systems Holland BV – part of the international Brady Corporation – was demonstrating a new device that has these attributes, with the additional advantage of being single-use. "The pharma industry has embraced disposable technologies for many years, from disposable personal protective equipment to disposable production systems," says Dennis Koolmees, General Manager at Transposafe. "Now it has

Image: © Transposafe Systems BV

Figure 5: The latest 'credit card' data loggers have a disposable future

single-use data loggers which, when used with cloud services, open up a new paradigm in affordable cool chain control."

The logistics of managing, maintaining, re-calibrating and re-using conventional electronic data loggers can make them an expensive and inflexible option. Not so with the new-generation 'intelligent' labels, according to Koolmees: "With this technology, there is no need to open the pharma packaging, there is no need for a computer, there is no reliance on USB or proprietary connections to access the data, no size or weight issues, no return-to-base headaches and, of course, there are no product write-downs, or 'shrinkage', of expensive logger stock."

Loggers such as Transposafe's NFC device can be configured to communicate with a free Android app, with the resulting time-stamped data files sent via e-mail, Bluetooth, Wi-Fi or to the cloud for analysis. Units are powered by a self-contained long-life battery with a shelf-life of one year and a typical operating life of around five days (dependent on the selected frequency of sampling). The labels use non-volatile memory for data storage, meaning that data will not be lost if the power fails. They record within a temperature-envelope of -30° to +60°C, can be user-branded, and come pre-calibrated with a 12-month guarantee. Most importantly, from a security and GDP perspective, all loggers have a unique code that is linked to each shipment.

Smaller and Smarter

Another benefit of this disposable technology is the ease with which it can be embedded directly into cool chain containers and packaging. "The logger can be used standalone or directly incorporated into passive temperature protection products to provide an integrated solution," adds Koolmees. "This immediately transforms an inert package into an intelligent control instrument, adding huge functionality and user value."

One company that is actively looking at the possibility of using miniature NFC data loggers in a cool chain product is DuPont™, manufacturers of the Tyvek® range of air cargo covers. "We are currently looking at a 'smart-cover' concept where, by embedding low-cost data monitors, we can provide additional shipment security, real-time temperature monitoring and the high number of data points necessary for the development of viable cool chain modelling and simulations," stated former Manager of Business Development at DuPont Protection Technologies, Malik Zeniti, earlier this year. "This would be seen as the next evolutionary step."

Stimulating Change

It is such ideas and technologies that the pharma cool chain must embrace as it seeks to make the adjustments necessary for survival in a brave new world of heightened competition, lean organisations, pressurised healthcare budgets, rapid technical progress, changing customer demands and an ever-tightening regulatory environment. The common denominator remains one of reducing costs, and only those cool chain organisations that are able to juggle continuous improvement with greater efficiency will be equipped to survive the increasing pressures on profit.

Find out more at FlyPharma

To get the latest on this topic and hear more from PartnerSave's Alan Kennedy, book your place at the FlyPharma Conference on 9-10 September.

Alan will be presenting on why he believes pharma needs a big shake-up in his session 'Old Habits Die Hard'. Mark Edwards at Modalis and Malik Zeniti of Cluster for Logistics, Luxembourg (formerly at DuPont), will also be taking part in the event. Visit www.flypharmaconference.com for further details.

About the author

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