

Turbulent Times

The Pharma coolchain is being reshaped by a need to reduce complexity, improve efficiency and trim costs. Alan Kennedy reports on two different developments that are shaking up the sector; one involving a shift of business, the other a shift in technology.



It was back in 1867 when the prime minister Benjamin Disraeli said "Change is inevitable. Change is constant". But although the Victorian era in the United Kingdom was one of great scientific and technological achievement, today's pace of change would be completely unrecognisable to someone from the Victorian era 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 are exerting huge pressures right across the pharma industry in both short and long time frames. 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 the 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 trends. Astra Zeneca, for example, are reported to be pursuing a goal of a 70:30 sea to air freight ratio on a lane-by-lane basis in a bid to reduce their costs and minimise temperature excursions.



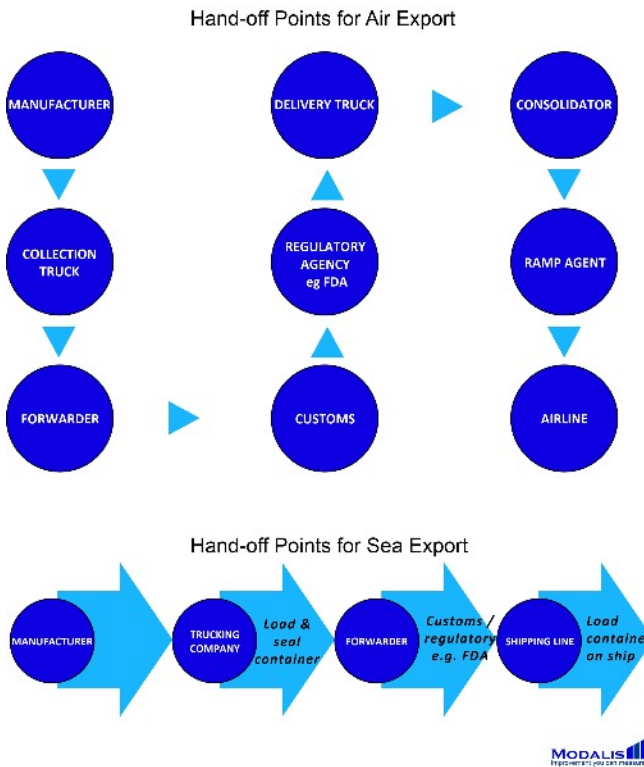
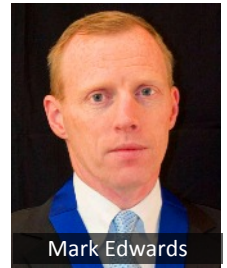
"The modal shift we are witnessing moved from being an occasional aberration to a real trend following the impact of the global Global Financial Crisis in 2008," says Sebastiaan Scholte, CEO at Jan de Rijk Logistics and Chairman of the Cool Chain Association. "While the current flow is certainly more than a trickle, it is unlikely to become a tsunami wave. "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 coolchain partners and processes it remains a very attractive solution."

PERCEIVED DEFICIENCIES

A significant factor behind the drift from air freight 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 that there is less physical handling of product. Containers tend to remain sealed from point of origin, physical customs checks are rare and when they happen they are generally conducted under controlled conditions.

Speaking at the Coolchain 2015 Conference in Frankfurt, Mark Edwards, Managing Director at logistics consultant Modalis and former Global Freight & Compliance Manager for Actavis, explained that the



problem principally relates to the much greater number of hand-off points that are used in air freight transportation (see diagram). 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 shift to sea freight with minimal effect on lead times. The company's customs issues are now sorted out en-route while it enjoys cost savings of more than 80%.

PLAIN SAILING

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 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 coolchain 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 shift from air to sea is a contentious issue. Many pundits argue that the shift that was apparent in the immediate aftermath of the global downturn in 2008 was largely a temporary phenomenon. Others point towards a more permanent and continually growing trend. Some observers argue that no such shift has taken place with both sea and air freight volumes having been affected by the economic

downturn. However, most figures from reliable sources consistently suggest a continuous trend although the impact of falling fuel costs and the recent growth of premium pharma airfreight services have yet to be felt.

HORSES FOR COURSES

Going forwards, the need to create value from generics and the accelerating growth in the bio-pharma sector are two of the 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 whilst complex biologics will almost invariably require the speed and on-time certainty of air freight.

“Reports of a 7% decrease in airfreight pharma volumes compared to sea freight be 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 humorist Mark Twain, the rumours surrounding the death of pharma air freight are being greatly exaggerated.”



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 pharmaceutical distribution have their roots in the information revolution. Cool chain performance measurement, pharma shipment tracking, e-freight transactions, product serialization 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 IATA CEIV Pharma is 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.

GDP requirements generally state that pharma 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 quickening pace.



DIGITAL EXPLOSION

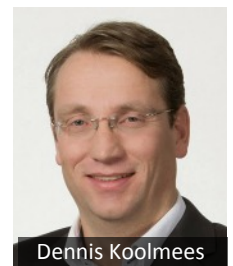
The explosion in the digital monitoring of medical shipments and the benefits of real- and near-time data acquisition have already revolutionised the pharma coolchain by facilitating more controlled transportation and reducing wastage costs. Dynamic temperature monitoring using the latest data-logging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

Data availability, data accuracy, frequency of readings, and absence of human error are some of the advantages of using data loggers. But they have also been associated with some disadvantages including 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 but it is only now that a combination of new phone technology, dedicated smartphone software ("apps") and contactless near field communications (NFC) have 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 dataloggers that don't require dedicated data readers and are not dependent on expensive back-office infrastructure.

SINGLE-USE

At the Coolchain 2015 Conference, Dutch company Transposafe Systems BV, part of the international Brady Corporation, were demonstrating a new device that not only has these attributes but with the added advantage of being single-use. "The pharma industry has embraced disposable technologies for many years, from disposable PPE to disposable production systems," says Dennis Koolmees, General Manager at Transposafe. "Now it has single-use data loggers which, when used with cloud services, opens 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. No so with the new generation



'intelligent' labels according to Koolmees: "With Transposafe® NFC 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."

The Transposafe® logger communicates with a free Android App and the resulting time-stamped data files can be sent via mail, bluetooth, wifi or to the cloud for analysis. The units are powered by a self-contained long-life battery which has a shelf-life of 1-year and a typical operating life of around 5 days (dependent on the selected frequency of sampling). The labels use non-volatile memory for data storage which means that the 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 and with a 12-month guarantee. Most importantly from a security and GDP point of view, all loggers have a unique code that is linked to each shipment.

Another benefit of this disposable technology is the ease with which it can be embedded directly into coolchain containers and packaging. "The logger can be used standalone or directly incorporated into passive temperature protection products to provide an integrated solution" say 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 coolchain 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 coolchain modelling and simulations," says Malik Zeniti, manager of business development at DuPont Protection Technologies in Luxembourg. "We see this as the next evolutionary step."



STIMULATING CHANGE

It is such ideas and technologies that the pharma coolchain 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 coolchain organisations that are able to juggle continuous improvement with greater efficiency will be equipped to survive the increasing pressures on profit.