Taking the Heat Out of the Cold Chain – How Passive Packaging is Solving the Cost-compliance Conundrum

Market research analysts are forecasting that spend on global cold chain logistics will continue to rise between now and 2025, with increases of around 15% being predicted[1]. Not surprisingly, while key growth markets like China and India are the engine that's driving much of this rapid development, there is increased demand for pharmaceutical products in many new and emerging markets, as well as for perishable food products in the booming middle classes, where disposable incomes are rising.

The sheer acceleration and geographical diversity of this growth has generated a new era in regulatory compliance; as markets expand and regulatory requirements evolve, the global pharmaceutical industry strives to meet them, from both an internal and external perspective. Shipping pharmaceutical products is a no-error ball game – guidelines are there for a reason and need to be respected. But tightening them opens up a whole new scenario for pharmaceutical businesses. Companies needing to maintain their local or global cold chains for temperature-sensitive products in transit face a major issue balancing compliance with cost. So how do they go about achieving this in a more legislative environment?

Investment trends suggest that new and innovative solutions may be the answer. But to know what kind of solutions are needed, we must first determine the key hurdles to overcome when shipping temperature-sensitive products.

Meeting Compliance – Here, There and Everywhere

The scale and globality of the compliance landscape adds a degree of complication to the shipping process — various regional regulatory bodies need to be satisfied, not just one.

Recent years have seen the introduction of Good Distribution Practice (GDP) guidelines. These have been implemented in Europe and require pharmaceutical companies to transport their products at strict ship to 'label claim' temperatures; a label claim stating a required storage temperature of between +2°C to +8°C, means exactly that – no tolerance.

Conversely, the Food & Drugs Administration in North America often permits product transportation using known stability data. This would allow the same item to be shipped at temperatures anywhere between +1°C and +25°C, and still meet local regulatory compliance.

In Latin America, the cold chain regulatory framework is evolving and new rules are being imposed. But it is a fragmented mosaic with loose, longstanding practices varying across the region.

No matter where you turn, the same story unfolds: the issue of standardisation in the global cold chain environment is fraught with inconsistencies and potential stumbling blocks.

Tailoring Packaging for Products

The challenges don't stop there. Pharmaceutical companies need to juggle with an additional level of complexity when shipping products which have a storage and transport requirement.

Regulators now insist on adherence to control room temperature or CRT. Historically, these CRT products have been transported naked (or unprotected) at fluctuating and uncontrolled ambient shipping temperatures, shipped in nothing more than a cardboard box.

Not any more. Control is now required within a defined temperature range. This is further complicated by the broad definition of CRT –the exact temperature range can vary from product to product. Here are some of the possible variances you may encounter in meeting regulatory demand:

CHART: CRT temperature variances.

- +0°C to +40°C
- +1°C to +30°C
- +2°C to +25°C
- +15°C to +25°C
- +20°C to +25°C
- Do not freeze
- Store below +25°C

These groupings create a domino effect. Different temperature bands require different packaging systems for different transport modes — and the variations can be significant. Consequently, the materials required to provide the necessary levels of protection during transportation will be assessed on performance and shipping weight criteria. Ultimately, the type of packaging needed will impact any expenditure on freightage.

The Cost of Supply Chain Continuity

At a local level, pharmaceutical companies can still source temperature control packaging (TCP) systems which are adequate for in-country distribution. But widen your network boundaries and these TCP systems may often fall outside globally approved standards. This is driving pharmaceutical companies to seek out the perfect scenario: global TCP vendors who can provide both local supply and support while supplying a standardised range of TCP. On the face of it, this should be quite simple: select a vendor who will satisfy any transportation and regulatory need, and then ensure they can supply TCP systems or services in the specific regions and countries where they are required. But configuring a TCP solution to meet both local and global quality requirements gives rise to many other considerations – all of which have cost implications.

TCP vendors, of course, have their own challenges to overcome

when operating in a global market. For starters, sourcing raw materials needed for the construction of a TCP system is one thing; whether they will be uniformly available in all regions of the world is quite another. A temperature control packaging vendor may have to create product variants made from cost-effective, locally-sourced components if they are to ensure availability. It may be the only way of guaranteeing delivery to their pharmaceutical customers while still satisfying the regulatory requirements for temperature control.

Then there are the challenges associated with sourcing and deploying associated services. TCP vendors who are supporting global pharmaceutical and life sciences companies face challenges keeping pace with demand from the industry's emerging markets. Positioning products for distribution in any new region or local territory is a prerequisite for gaining traction. And should a new client be initially unable to justify the investment to produce TCP systems locally until there is critical mass, then vendors are typically requested to provide warehousing or storage.

Going Green: The Material Revolution

The utilisation of fully environmentally-friendly and cost-effective materials that can provide qualified temperature control for specific applications is a key goal of many pharmaceutical companies. There is a need to reach their own environmental benchmarks, as well as to meet the increasing demands of clinical investigators, retail outlets and patients.

Historically, many TCP systems adopted by the pharmaceutical industry have relied on the use of insulation materials constructed from expanded polystyrene and polyurethane foams. Although primarily designed for the simple 'ship and forget' distribution model, these materials are in fact considered recyclable.

The term recyclable is nonetheless open to interpretation. Yes, expanded polystyrene foam can be ground and reprocessed. But only into new polystyrene products. Polyurethane products such as panels, on the other hand, can be repurposed or upcycled into building materials. The systems required to accomplish this, however, are not always readily available. Dilemmas around disposal can develop, leading to complications when trying to meet local environmental regulations.

As such, many pharmaceutical companies with committed sustainability initiatives are looking for greener alternatives – ones that can be very simply recycled at all locations.

This has driven the need for new TCP systems that utilise environmentally-friendly insulation materials. The flip side? Greener products often come with limited application due to lower insulation values.

Naturally, there is a solution. At the opposite end of the spectrum are the high-performance TCP systems. Composed of materials such as vacuum insulation panels (VIPs) and phase change materials (PCMs), they come at a higher price, which often necessitates full re-use programmes to achieve sustainable cost-effectiveness.

Insulation materials	RECYCLE	UPCYCLE	FULL RE-USE
Paper	YES	YES	NO
Polystyrene foam	YES	YES	NO
VIPs & PCMs	YES	YES	YES

The Sweet Spot between Cost and Compliance

It is abundantly clear that creating passive packaging systems for the cold chain in a vibrant, developing and expectant world is not without its challenges. The top-line considerations are many and varied: end-user usability, safety standards, local and global compliance, control room temperature variances, sourcing materials, sustainability and recycling, warehousing, deployment, product positioning – they all play their part.

Add to this mix the fact that pharmaceutical companies are often challenged to reduce overall transportation costs, and some of the industry's most testing predicaments are being confronted head on. Many are now looking to new and innovative methods by which they can distribute their temperature-sensitive pharmaceutical products.

Re-use models which employ high-performance materials for consistent temperature control are gaining momentum – they are typically available via rental programmes. The challenge here, though, is one of supply and demand. Many of the reusable high-performance shippers that are currently available are difficult to reposition after use. This fact precipitates an expensive product repositioning service provision.

As such, there is an emerging requirement for affordable, reusable shipping systems that are available on a global basis and which can function in both temperature controlled (pharma freight) and uncontrolled freight services.

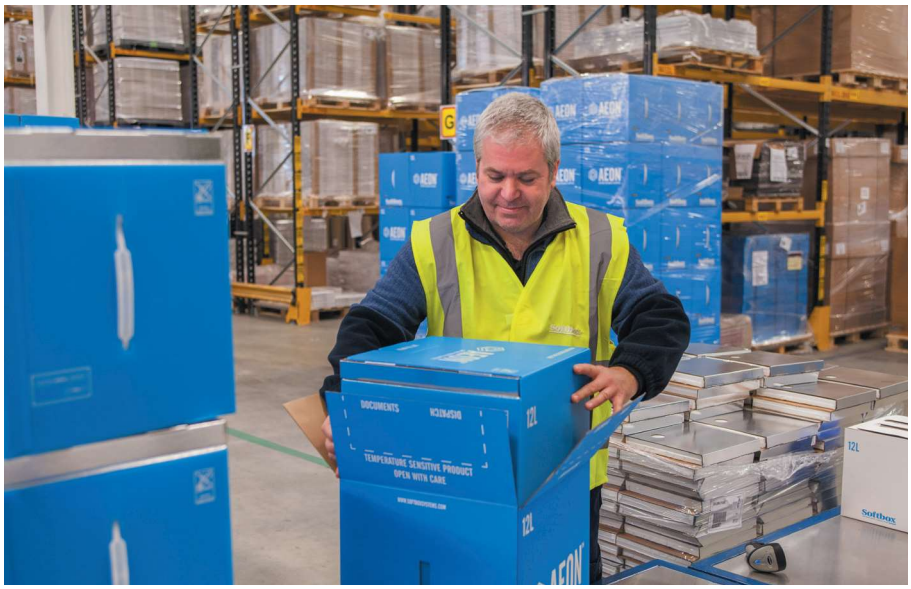
The Innovation Impact

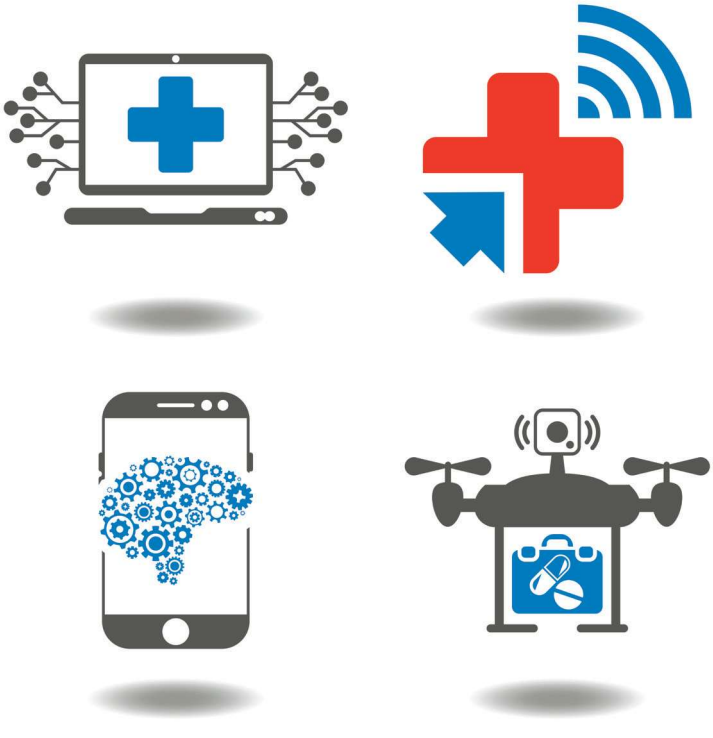
Innovation may be leading companies to evaluate the use of alternative materials, but it is also driving investigation into the application of emerging technologies that can leverage the materialisation of the Internet of Things (IoT).

Smart technologies are prompting the development of connected healthcare systems that can fundamentally change how pharmaceutical company supply chains operate. The capability is now available to allow interaction with patients who receive and use medicines, potentially streamlining processes and improving communication at all levels.

The combination of new materials and IoT could help to bring about change in traditional cold chain distribution, with the cloud and the internet forming a new frontier for packaging manufacturers. According to Smithers Pira, IoT packaging that uses embedded technology to gather real-time intelligence and deliver messages on products or their environments will grow at a staggering 18% per year, reaching almost $2.2 billion (£1.5 billion) by 2021[2].

Effective maintenance of the cold chain for temperature-sensitive products in transit will only be assured by embracing the different kinds of innovation that are breaking new ground in the sector. They can bring an unprecedented level of transparency to shippers, brand owners and customers alike. And should closer collaboration be forged between all the relevant parties, the expectations around what it means to ship pharmaceuticals can not only be met, but exceeded.





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