

Turning up the Heat

As the temperature control regulatory framework evolves, the future of Latin American pharmaceutical logistics may be set to change

Alfredo Ratmiroff at Cold Tech Systems and Alex Vila at Tempack Packaging Solutions



Guaranteeing the integrity of time- and temperature-sensitive products during transportation has suddenly become one of the hottest topics in Latin America's pharmaceutical and logistics industries. Clinical trial medicines and specimens, vaccines, drugs, and other biologics all require reliable temperature control packaging methods if they are to consistently reach their destinations safely, securely, and in prime condition. From the moment they leave the manufacturing site until they reach the patient, these products need to be kept in controlled conditions typically between +2 to +8°C and +15 to +25°C.

Support operations in this cold chain are dedicated to upholding these parameters and are just as crucial as any element of the drug discovery process itself, but why, in recent times,

has industry dialogue started to centre around the area of logistics?

The New Social Order

Since the turn of the last millennium, the global pharma industry has been operating against a favourable backdrop based on an almost unprecedented economic phenomenon – high growth rates in emerging markets have catapulted 500 million people out of poverty. In Latin America, this gave rise to the biggest middle class in the region's history. While growth has steadied in the last five years, such a seismic shift in the region's social composition sent reverberations through industry and government, with most of the impact being positive.

The pharma sector has been a direct beneficiary of an enhanced social

spending capability. Sales have been fortified by a rise in income levels. Healthcare spend has moved beyond basic necessities, and, as governments seek to broaden generic drug access at reduced costs, the pharma chains have flourished. Between 2008 and 2016, Bolivia, Ecuador, Brazil, Argentina, and Chile all experienced sector growth rates above 5%, with Venezuela coming in at a whopping 22.6% (1). The trend for the decade is set to continue, with most estimates projecting growth of around 9% across the region versus 3% in mature markets.

Progressively minded pharma manufacturers continue to look to the region to fuel their growth results in a snowballing pharma supply chain that is wrestling with the Formula 1 racing equivalent of doing 0-60kmph in about half a second. Manufacturers

can scale supply to meet burgeoning demand, but, where logistics are concerned, the sheer magnitude of this expansion poses one big, basic question: can it be handled? The answer, as is so often the case in Latin America, is yes – and no. While progress and capability is being demonstrated on many fronts, some familiar challenges remain.

An Evolving Regulatory Network

Hitherto, local governments have had little concern with regard to how pharma companies should transport and deliver their temperature-sensitive products. Decisions relating to cold chain distribution were taken solely by the local Latin American pharma companies, but loose, longstanding practices are not viable if products are going to reach a whole new swathe of customers in pristine order. Where health is concerned, this is not just important – it is critical.

The good news is the cold chain regulatory framework in the region is evolving and rapidly accelerating the maturity of the pharma distribution arena. For example, the governments of Colombia and Mexico are now imposing new rules to ensure the cold chain is maintained door-to-door, and the pharma companies are being pushed to ensure compliance with local regulations.

However, not only are they falling in line, they are implementing Good Manufacturing Practice standards of their own and they are doing it everywhere. Irrespective of whether one is warehousing in Brussels, Boston, or Bogotá, the same internal rules relating to the cold chain are being applied. Does that mean Latin America, North America, and Europe all align? Not so fast.

The issue of standardisation in the global cold chain environment is fraught with stumbling blocks. One would be forgiven for thinking that compliance in the mature markets would operate in similar territory. However, in truth,

the differences can be quite stark. Good Distribution Practice guidelines in Europe ask companies to transport their products at strict ‘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 FDA in North America allows product transportation using known stability data. This would permit the same item to be shipped at temperatures anywhere between +1°C and +25°C and still meet local regulatory compliance. Throw in regulations on control room temperatures (which can have even more variation) and the picture is crystal clear: different regulatory bodies need to be satisfied – not just one – no matter which continent is being operated in. However, this is all just the tip of the iceberg where distribution across Latin America is concerned.

A Fragmented Regional Mosaic

Latin America is often referred to as a single entity, but, logistically, this is a region that operates without standardisation; country-specific challenges and shifting sands exist where regulations and governments are concerned.

Perhaps the most obvious obstacle to the movement of temperature-sensitive goods is the geographical size of the region (it is always worth reminding oneself that Buenos Aires is further away from Mexico City than London is from Mumbai). Longer distances mean greater fuel consumption with a need for multiple hubs or distribution centres, as well as coping with temperature variations in different climate zones.

None of this is helped by the fact that Latin American countries lag behind much of the world in infrastructure availability and quality (Panama is the highest-ranked country in the World Bank’s Global Logistics Performance Index, coming in at a modest 40th [2]). Rail networks are hampered by inefficiency and low maintenance.

Ports are running over their outlined capacity. Airports in certain locales have inadequate runways, preventing access for long-haul carriers. The result is that road transportation – which is considerably more expensive than rail or ship – is often the preferred method of haulage. Even then, challenges occur across borders.

Cold chain functionality differs greatly throughout the region with countries having their own political, legal, and regulatory frameworks. Each has distinctive customs and tax laws, bilateral agreements, and tariffs. Consequently, the movement of goods can be subject to label, package size, or case capacity changes that adhere to local regulations. Clearance procedures also vary; while Panama and Chile might be pioneering efficacy, waiting periods for countries like Brazil or Peru necessitate proper storage requirements. Even in the face of such apparent complexity, the majority of cold chain failures still come from human error, with many executives citing training as the biggest barrier to improving temperature control supply.

The Future Looks Positively Passive

The kind of resilience one might need to negotiate the region’s cold chain may appear similar to the prospect of scaling the Andes. Thankfully, the landscape is changing. In recent years, new innovations in temperature-sensitive packaging, transportation, and warehousing have all contributed to a more progressive outlook. Perhaps the biggest potential shift – and certainly the trend that is showing clear signs of emergence – is the move from active to passive systems. Essentially, this is a preference for transporting products using shippers or systems with a whole range of special boxes as opposed to temperature-controlled systems in transport vehicles.

To meet new requirements, temperature-control packaging providers are increasingly making use of progressive insulation packaging materials, such as

vacuum insulation panels (VIPs), as well as phase change materials (PCMs) that freeze and thaw within the required temperature range for a product. The effect of combining these components is a game changer for the entire industry. They are providing clients with reliable protection for their products during transit against challenging ambient temperatures and the risks present with numerous participants in the cold chain. Compliance can be met and excursion rates lowered, so pharma companies cannot only ship, but do so confidently. Further to this, smaller packaging systems (parcel shippers) are being displaced by pallet shippers because of the growing demand for higher payload systems across the board. The improved logistic efficiency through cargo consolidation and the lower labour costs are too much for customers to pass up.

Better Materials, Better Options

Customers can choose to send goods in a package that is disposable and designed for one-time usage or opt for either a reusable or multi-use version. Historically, single-use packaging is manufactured from cost-effective thermal installation materials such as expanded polystyrene and polyurethane. These are then coupled with PCMs like water or water gel compositions.

On the other hand, reusable cold chain packaging has always been designed with more robustness in mind with increased thermal protection. These shippers are commonly composed of progressive, environmentally friendly insulation materials (VIPs and advanced PCMs) that achieve sustainable cost-effectiveness. When combined, the components result in a high-performance and reusable shipping system. With autonomies of between 96 and 120 hours guaranteed for both +2 to +8°C and +15 to +25°C brackets, a growing range of PCMs ensure temperature ranges that are increasingly precise for extended transit times. Therefore, regional distribution lanes can replace refrigerated containers

with their lower overall cost per use and the expensive air freight option can be replaced with more viable ground transport.

The benefits of moving from active to passive systems (or parcel to pallet shippers) may seem pretty clear cut, but the transition still faces some of the regional obstacles outlined to date.

Recalibrating the Cold Chain

While they are beacons to a more functional future, technology and innovation alone will not be enough to completely iron out the issues that face cold chain distribution in Latin America. The heat is on for healthcare companies to deliver on safety, efficiency, and customisation, no matter what the handicaps. What else can be done?

As pharma companies throw a global blanket over quality standardisation, the pressure for greater performance in the entire region's supply chain continues to crank up – and trickle down – to the domestic markets. This is encouraging supply chain strategies to be developed with a significant local footprint at their core, allowing them to meet the increasing demand for local production, inventory, and technical support, or to overcome import quotas or satisfy the requirements of local tax and duty regimes. Equally essential to success is the need for integration and collaboration among all cold supply chain parties. Strategies for proactive intervention, breaking down silos, and leveraging best practices can help businesses protect cold chain products, customer relationships, and bottom lines. With so much on the table, it is hardly surprising that cost forms a crucial part of cold chain discussions; regulatory reform and changing reimbursement models will ensure it stays there. Companies can work with their third-party logistics providers to look at implementing methods that will minimise financial outlay.

The foundations for a safer, smarter, and more regulated future are already in place, and the reinvention era is well underway. New options are breeding new opportunities. Should the next two decades witness the same kind of strides that have been made in the last two, then Latin America will have the kind of innovative cold chain it needs to meet all its ambient and logistic challenges.

References:

1. Visit: www.statista.com/statistics/809813/pharma-industry-compound-annual-growth-rate-latam
2. Visit: ipi.worldbank.org/international/global/2016

About the authors



Alfredo N Ratmiroff is the General Manager at ColdTech Systems (a Softbox company) in Latin America and has over 15 years'

experience in logistics across several industries, with eight years in the pharma cold chain. During his career, Alfredo has held several management roles in well-established Latin American companies and has helped many market-leading companies ensure cold chain maintenance and regulatory compliance.

Email: aratmiroff@coldtechsystems.com



Alex Vila is the General Manager at Tempack Packaging Solutions (a Softbox company) and has more than 20 years' experience in the

field of temperature-control packaging for the pharma and biotechnology industries. Alex's global vision and clear commitment to international expansion led him to convert a local company into a multinational company, with offices across Europe and Latin America.

Email: avila@tempack.com