Airfreight Still Poses Major Obstacles for Temperature Sensitive Pharma Logistics

A staggering 35 billion US$ (31 billion €) per year are lost in the pharmaceutical industry due to temperature excursions. This number includes lost product costs as well as clinical trial and replacement costs.[1] 30 per cent of scrapped pharmaceuticals can be attributed to logistical issues, according to the World Health Organization and the Parenteral Drug Association. Every fourth dose of vaccines reaches its destination degraded because of incorrect shipping. With its CEIV Pharma certification, the international airline association IATA is trying to set standards and spread best practices, as booming pharma destinations such as ASEAN and Africa are still lagging behind in infrastructure and training to handle temperature-sensitive pharmaceuticals. However, even in the developed world, airfreight still faces enormous challenges.

By 2021, world sales of cold-chain drugs and of biologics such as vaccines and insulin products will likely top US$ 396 billion (€ 350 billion), in a global biopharma market exceeding US$ 1.47 trillion (€ 1.3 trillion). Despite the huge market, shipping pharmaceuticals across continents and climate zones has never been an exact science. Logistics is not conducted under laboratory conditions in a clean and controlled environment. It is more blue than white collar and will remain so, as different stakeholders from outside the pharma industry are involved, such as service providers for packaging, loading and handling of the products, as well as customs officials and distributors. It is a complex machinery and it only takes one element of the cold chain to fail in order to render the precious product inert. According to IATA estimations, 20 per cent of temperature-sensitive products are damaged during transportation due to a broken cold chain. Behind closed doors, pharmaceutical representatives and air cargo experts are conceding that there is a lack of standards, inadequate means of tracking and monitoring solutions in airfreight, as well as the problems with proof of debt, resulting in increased insurance premiums.

Precious Serum Rotting on the Apron

The need for more transparency in the supply chain and increasing cost pressure pose enormous challenges for the airfreight industry. By 2022, the international pharmaceutical market is expected to grow by an average of 6.3 % each year, and with it the logistics business, according to IATA. Many pharmaceutical products are highly temperature-sensitive and require a seamless cold chain. "You need the right people, IT systems, processes and technologies," said Martin Gouda, Partner at Buck Consultants at a recent workshop of the German Air Cargo Association (ACD) in Frankfurt. It is not only in emerging and developing countries that some of these elements are missing: industry insiders reported a delivery of serum from Europe to a medium-sized airport in USA weighing several tons, which literally rotted on the apron because no refrigerated warehouses were available at its destination. The entire shipment became unusable, resulting in millions in losses. It does not happen every day, but still too often. "We need a better dialogue between airfreight and pharmaceutical companies in order to achieve more transparency and an even more efficient symbiosis between the two sectors," said Prof. Christopher W. Stoller, President of the ACD.

Underestimating the challenges

Many pharma managers still underestimate the challenges of transporting their products across climate zones. It is not necessarily extreme weather conditions, like Arctic winters or Saharan summers, that pose a risk to temperature-sensitive pharmaceuticals: a pallet of unprotected product on an airport tarmac surrounded by an ambient temperature of ~70°F (21°C) can quickly reach temperatures above ~122°F (50°C) if it is not cooled actively. At that temperature, it is possible to fry an egg in 20 minutes. "The interfaces are often the problem. There are many routes where the infrastructure is simply missing and where active refrigerated containers are the only solution," said Andreas

Seitz, Managing Director of DoKaSch Temperature Solutions, a provider of actively temperature-controlled pharma containers, and an avid industry expert. A comprehensive lane risk assessment is usually comprised of risk assessment on identified critical control points, involved stakeholders, infrastructure, equipment, and operational and performance qualification of the equipment, plus the careful planning of all packaging, transport, storage, and handling steps. The type of container used for the mission is the most fundamental decision to be made – and the most decisive one.

A Key Question Is Active or Passive Container Solutions?

Active containers are equipped with redundant electrical heating and cooling systems. They are regarded as the "premium cars" of the pharma transport chain, used for vaccines and other high-value pharmaceuticals. Other products are also shipped in passive containers, where the internal temperature is maintained by utilising cool packs. The significant difference between both solutions is that passive containers are very limited in their runtime. Once the limit is reached, the internal temperatures cannot be contained. Active containers, however, can easily be recharged anywhere, allowing an unlimited time of operation. Most of the drugs that are shipped with active containers need to be transported at a specific temperature level that has to be guaranteed the whole time, according to Seitz. Local weather, logistic processes, warehouse capabilities, aircraft ops can change at short notice. A passive packaging solution is just as good as the logistic process planning is, with all uncertainties of a global supply chain. The problem with cool packs is that the performance and the runtime of the container depend on the surrounding conditions. If the actual ambient temperatures deviate too much from the expected temperatures, the anticipated runtime is significantly reduced, posing a potential threat to the freight. If, for example, a 2°C to 8°C shipment is exposed to ambient temperatures of -20°C in a North American winter, deviations are very likely.

Challenges for Pharma Logistics Managers Remain

Even in our uncertain times, the growth of "high value" trade growth is likely to continue. Pharma is the third largest product group to contribute to global trade in value. Trade of pharma topped growth rates with an average increase of 11% over the last 13 years. The US and Europe are still the main

origins of pharma in air trade, but India and China are expanding their market share with their large markets. 43% of pharma transports by air consists of products of more than US$150 (€132) per kg in value, such as vaccines and other biopharmaceuticals. Lower value pharmaceuticals are being shipped by ocean to the continent of destination. However, for many time- and temperature-sensitive pharmaceuticals, transport by air remains the only option. “You have to look at each transport route separately,” said Seitz. “On lanes in which every step, from origin via the hub to the destination, is controlled and the transport duration is within the runtime of passive solution, then these types of containers might be sufficient. However, a lane validation is still necessary, due to a great deal of factors that influence the transportation. Electric/air-conditioned containers, on the other hand, work for an unlimited period of time in any climatic situation. Only one global qualification is necessary.

Certification as Key for Setting Standards

With its CEIV-Pharma certifications[2], the International Air Transport Association (IATA) wants to standardise processes and the training of employees in pharmaceutical logistics. IATA’s Time & Temperature Working Group (TTWG) develops and maintains standards for the procedures, documentation, cargo handling, packaging and acceptance of goods from the healthcare sector. "The problems often do not occur during the actual air transport, but on the apron or in the warehouse. Here we want to implement uniform standards for pharmaceutical products throughout the entire transport chain," said Beverly Seebach, Cargo Manager Europe at IATA. Airline cargo handlers have been identified as the weakest element of the supply chain, and this is where IATA is pushing for improved standard operating procedures and best practices. The programme was designed to target airlines, ground handling companies, freight forwarders, road transport companies, distributors and airports. Also regulatory officials at customs are posing risks for the products, as they might be unaware of its value and its sensitivity to temperature excursions. The main objective of the CEIV programme is to enhance industry readiness to deal with growing expectations from pharmaceutical corporations. With its Center of Excellence for Independent Validators (CEIV), IATA is auditing the complete supply chain from trucking companies to ground handlers, warehouses, airports and airlines. Training the staff is essential in order to set the standards and to improve awareness and overall quality of transports of pharmaceuticals. Ultimately, only certified logistics providers with effective sets of standard operating procedures should be allowed to transport pharmaceutical products, but this is still a long way to go.

REFERENCES

1. World Health Organization (WHO); Parenteral Drug Associate(PDA); worldpharmaceuticals.net; other industry estimates; quoted in: www.cargosense.com/cold-chain-shipping-loss-in-pharmaceuticals.html
2. https://www.iata.org/whatwedo/cargo/pharma/Documents/ceiv-pharma-specifications.pdf
3. https://www.iata.org/whatwedo/cargo/pharma/Pages/index.aspx

Thomas Rheinfeld

Thomas Rheinfeld is a Munich-based technology writer, public speaker and business consultant. He is covering issues regarding IoT/Industry 4.0, future mobility as well as RnD in pharmaceutics. Most recently he spent three years in China to investigate cutting edge technologies developed or implemented there.