



TOWER
Cold Chain



White Paper

The total cost of shipping – Part 1

“The cost of shipping temperature-sensitive pharmaceuticals is not only the cost of the packaging plus the freight, but of many other related and often overlooked factors within the overall supply-chain”

The temperature-controlled supply-chain has seen much change in recent years. Since the release of the updated EU GDP Guidelines in 2013, manufacturers and wholesalers have had to look at their supply chains and consider whether products that may not have traditionally required temperature-control or monitoring might now need some form of protection, leading to inevitable cost increases. Meanwhile, many traditional ‘blockbuster’ drugs have come off-patent, opening up the market to manufacturers of cheaper generic products, resulting in a loss of overall market share and profitability.

Alongside these two significant changes to the market structure there is also the fact that new product pipelines are smaller, and that as a result there are fewer new compounds coming on to the market. One by-product has been an upsurge in merger and acquisition activity, with resultant pressure on cost structures.

The net effect is for pharmaceutical companies to seek greater operational efficiencies, and to look to reduce cost throughout the entire product lifecycle, from initial active pharmaceutical ingredient (API) manufacture through to administering the finished product to the patient.

Temperature-controlled packaging: the traditional approach

When considering which packaging solution to use, the supply-chain manager and the quality department, would in the past have used the following criteria:

- Product temperature requirements and any associated stability data
- Size of the product load to be shipped
- Type of product being shipped (and therefore the thermal mass)
- Value of the product
- Shipping duration
- Environmental conditions (temperature, sunlight, wind chill)
- Any available controls along the supply chain

These are the main factors that determine the acceptable level of risk, and thus influence whether to use a high-end active system, a passive system using higher-performing insulation and phasechange materials (PCMs), or a lower-cost passive shipping system.

Allowing for input from the quality department, the supply-chain manager's main focus would be the total cost of shipping. The main contributors to this are the temperature-controlled packaging (TCP) and the freight to ship the goods. Whilst the cost of the TCP should be fixed, the freight cost would depend on the weight and size of the TCP. Normally the carrier would review the actual weight of the goods (including the TCP) against the volumetric weight of the goods and charge the customer for the larger of the two. The volumetric weight is calculated using the external dimensions of the package. In metric, a standard method is to calculate the volume of the package in centimetres and then divide this by 6000, which will calculate a weight based on 166.69 kg/m³. The reason for this is cover against low-density, high-volume packages which could be unprofitable for the carrier

By adding together the cost of the TCP and the freight cost, the supply-chain manager will have a simple calculation to work out the cost-per-dose of shipping. This can then be used to evaluate different TCPs

However, this is only a fraction of the true total cost of shipping and other factors must be considered and calculated.



Figure 1 – Example of passive temperature-controlled packaging (TCP)

A holistic view

The traditional method described above only examines two very specific areas of the supply chain: the cost of the TCP and the associated costs of shipping the goods in the TCP as far as the destination point. To understand the total cost of shipping the goods there are many other influences that need to be considered (also see Figure 2)

TCP delivery costs

Transportation of the TCP from the manufacturer to the customer. It is likely that this cost is passed on to the customer and therefore it should be included in the cost of the TCP

TCP storage

Storage of the TCP packaging prior to use. Particularly for passive TCPs, it is unlikely that the packaging manufacturer will provide a just-in-time (JIT) service, so it will be necessary to carry stock. Whatever the size of the TCP solution it is probable that it will be high-volume, low-density, and therefore require a significant storage area, especially for cargo-sized solutions

PCM management

The PCM, whether water-based or otherwise, will need sufficient fridge and freezer capacity for conditioning, as well as sufficient time to allow the PCM to completely condition. The process will need to be verified to ensure that the PCMs are conditioned correctly every time

TCP preparation

The TCP must be prepared and packed according to approved standard operating procedures (SOPs). Depending on the size, construction type and configuration this can be a time-consuming and critical process. If the system is large (pallet-sized cargo) it is likely to be a six-piece panel solution. This will need to be built and the PCM placed inside. Some passive systems will have PCMs with two different temperature ranges. This adds complexity, with the risk of the PCM being placed in the wrong location

In-transit management

It should be considered whether intervention will be required during the shipment. All types of TCP, both active and passive, will have been qualified for a pre-defined period of time

Active systems run off an AC power source whilst stored in warehouse transit points, and rechargeable battery power while in transit, on the tarmac and on the aircraft. Whilst running on battery power they will have a finite period of running time dictated by the ambient conditions

Passive systems will have been qualified against a specific time-temperature ambient profile. If during the shipment there should be unexpected delays then decisions may have to be made as to what to do with the TCP. As such, it may be necessary to use the carrier's pharma-service to ensure adequate control within the supply chain

Receipt management

Upon receipt at destination, the TCP will need to be unloaded. As with the loading process, depending on the size and construction of the system, personnel will be required to complete this and there may also be a need to store the empty TCP and PCMs

TCP disposal or demounting

In the case of single-use or semi-reusable packaging it will be necessary for the receiving site to either dispose of the materials, or check and/or transport the systems for further use. Different countries have different legislation with respect to packaging materials and there could be meaningful costs associated with disposing/recycling of the insulation and PCMs, especially if materials have been used that are more challenging to dispose of or recycle

TCP qualification

The cost of qualifying the solution prior to use may also have to be considered. For some systems, particularly active and reusable passive solutions, the level of testing performed by the solution manufacturer may be sufficient to meet the requirements of the operational qualification (OQ) phase, as the solution will have been tested with the same configuration against an upper and lower temperature profile, stressing the performance capabilities of the system. The system can then be used immediately as part of the performance qualification (PQ) phase if this has been agreed with quality

However, many passive systems will have been tested against a simulated shipping route and this may not be representative of the shipper's circumstances and therefore additional testing may be required before the system is used in a 'live' situation. Also, if the system does not have an all-year-round packaging configuration, and uses different setups for winter and summer, then qualification will be required for both configurations at the appropriate time of year

Cost of compliance

There is another potential cost that is unlikely to be considered when analysing the cost of shipping, namely the cost of compliance. In the event that there is an issue in the supply chain that results in a temperature excursion then there are other hidden costs that may not immediately be assigned to the cost of shipping

In the event of a temperature excursion the product may have to be quarantined until a full investigation has been performed, to evaluate the impact on the product. This should include representation from the quality and supply-chain departments as a minimum, and may include other stakeholders in the process. As a minimum, the root cause should be ascertained with appropriate CAPA put in place to prevent reoccurrence, followed by a review of stability data to see if the product can be released for onward processing/use. In the event that the recorded temperatures have exceeded the allowable limits of the product, based on stability data, two possible outcomes would need to be considered: the first would be a significant impact on the product's shelf life with the need for additional controls to ensure that the product is either used in good time or, if the shelf life is reduced below the allowable limits of the destination country, the need to supply replacement product; in the worst case, the product might need to be destroyed. This would result in a number of challenges for the shipper, including

- Cost of the product loss
- Additional cost of replacing the product
- Potential reduction of supply in the market place until replacement product can be supplied
- Potential loss of reputation due to failure and inability to supply
- Loss of market position by allowing competition product to be used to replace lost product

These can lead to a significant cost to the shipper and though not a necessarily a direct cost of shipping, are a result of decisions made earlier in the process and part of the total cost of shipping

Sustainability

With an ever-increasing demand on the planet's resources, governments are working together to introduce legislation to reduce waste and limit carbon emissions. The use of temperature-controlled packaging solutions continues to increase and with it a need for companies to review the technologies that they use. Reusable solutions not only allow for the use of materials with significantly higher thermal performance capabilities but also allow for more robust materials, allowing for increased product lifecycle and a potential reduction on the environmental impact and ecological footprint



Figure 2 –A holistic view

The true cost of shipping

We therefore see that, when considering the choice of temperature-controlled packaging, it is not enough simply to consider the cost of the packaging and the freight costs

A complex and evolving market landscape means that the need for cost efficiency is paramount and, within pharma logistics, can only be achieved by taking a holistic view of the supply chain and evaluating all of the costs along the way

It may be the responsibility of different cost centres within an organisation to manage the costs for different parts of the supply chain but ultimately all of the cost falls to the same company

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