Follow That Car

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Amid the move towards multi-use, high-performance systems to protect payloads, temperature-controlled packaging for the life sciences industry is facing similar concerns to the automotive sector when considering disposal of end-of-life components and the environmental implications

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In recent years, temperature-controlled packaging systems have become more robust and complex in order to meet the expanding needs of global healthcare. This can partly be attributed to the well-documented 'patent cliff' phenomenon, where a number of blockbuster patents from pharmaceutical companies have expired, creating a loss of revenue for many of the world's leading drug manufacturers.

Coupled with the rise in generics and increased regulations leading to tougher approval of drugs, this has resulted in the development of bio-tech and biologics, because they are harder to manufacture and copy. Of course, they are also more expensive and unstable, so there is a further need for greater performance from temperature-controlled packaging systems to protect the higher-value assets.

Other contributing factors include: globalisation, as both individual and societal wealth grows; increased environmental and logistic demands to get the drugs to new markets, where typically infrastructure is poorer and temperature stresses are higher; and the need to reach and test on treatment-naïve patients, who have not been subjected to inoculations or other everyday drugs to combat illnesses.

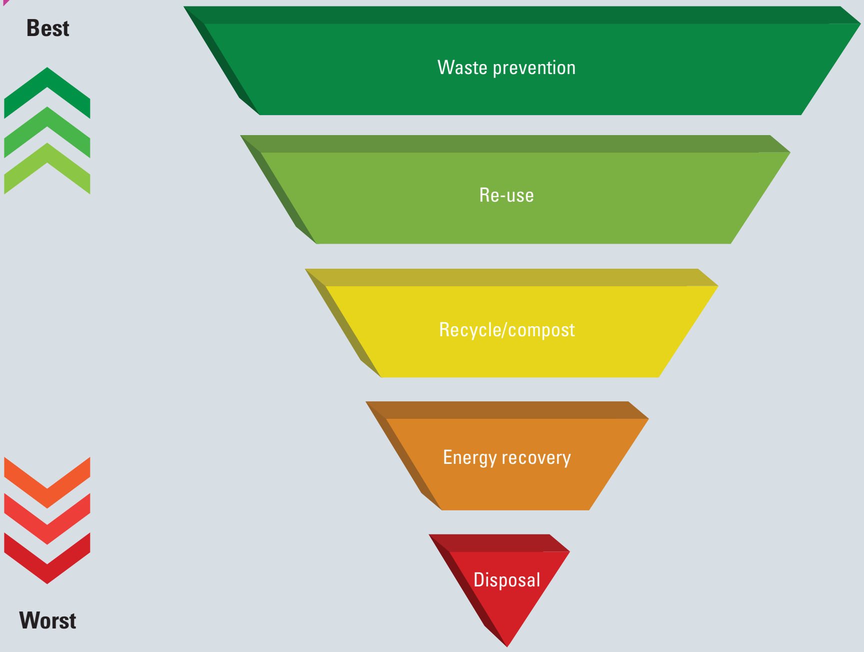
High-Performance Systems

Because of these issues, temperature-controlled packaging manufacturers are now required to create solutions that will transport a high-value, unstable payload further, for longer, with poorer infrastructure, in higher temperatures and with increased humidity. This means the traditional method of implementing single-use containers, which utilise either expanded polystyrene (EPS) or polyurethane and/or water-based gel packs, have been replaced with high-performance vacuum insulation panels (VIPs) and phase change material (PCM) systems.

VIPs are a form of thermal insulation consisting of a near gastight enclosure surrounding a rigid core, from which the air has been evacuated. PCMs are a typically organic hydrocarbon and inorganic salt solution, which absorbs and releases thermal energy during the process of melting and freezing. When a PCM freezes, it releases a large amount of energy, in the form of latent heat, at a relatively constant temperature.

These more robust, reusable containers offer pharma companies the performance they need in a lighter, smaller package. This provides a larger payload capacity versus total shipper weight, and is an essential advantage as the reduction in shipping cost helps offset the high cost of the materials used in constructing these solutions. The materials are much more durable, too, and can be designed to be multi-use, which multiplies affordability and sustainability, in turn reducing waste and associated disposal costs.

Figure 1: Packaging waste framework pyramid



Environmental Impact

PCMs address the limitations that water/ice has as a temperature control component. Water's freezing point is fixed at 0°C (32°F), but PCMs have been developed for use across a broad range of temperatures, from -40°C to more than 150°C, and they can store up to 14 times more heat per unit volume than water for the same application. This gives a much more stable payload temperature, while using less mass to do so.

Currently, the conventional waste streams for traditional passive temperature-controlled packaging enables the disposal of corrugate outers and components within domestic waste – and these services are widely offered. EPS can also be recycled, and water-based PCMs drained and their packaging disposed of in regular waste streams.

However, while multi-use systems are more environmentally sustainable than their single-use counterparts, it is important to understand the disposal and recycling of these materials when they come to their end-of-life in the clinical cold chain. Due to the increased demand for PCMs in temperature-controlled packaging, the potential for PCMs to be introduced into the environment has increased; if not disposed of correctly, they can have a negative impact.

Need For Recycling

To comply with waste regulations, pharma companies are constantly aware of targets to be achieved for the recovery and recycling of packaging waste, such as those stipulated by the European Packaging Waste Directive 94/62/EC. But businesses bear responsibility for meeting these targets in different proportions, according to which activity they perform, thus putting the onus on packaging users. The following shows the activity obligations as a percentage:

- Manufacturing packaging raw materials – 6%
- Converting materials into packaging – 9%
- Using packaging to pack products or for filling with products – 37%
- Selling packaging (products contained in packaging) to the final consumer – 48%

In order to be environmentally sustainable, high-performance temperature-control packaging components such as PCMs need to be re-used effectively. Furthermore, when they reach their end-of-life in the clinical cold chain, after about five years, they need to be disposed of appropriately.

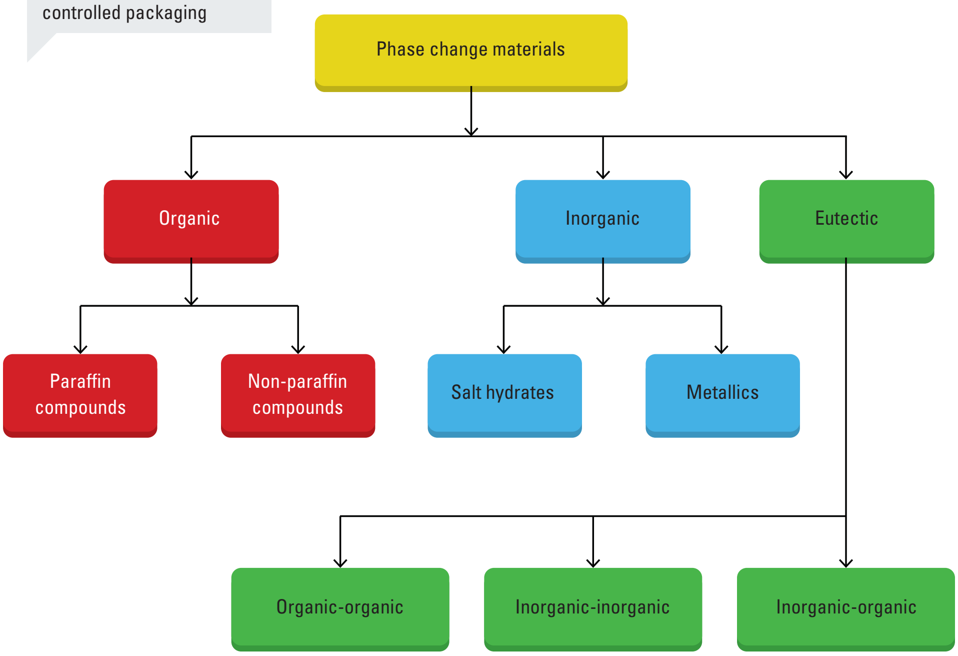
This prompts the question: how many people are actually aware of what is in their coolant? The term PCM itself is very broad, and as manufacturers distribute their best-performing PCMs, how many end-users still treat it as they would a water-based coolant by tipping it down the drain or throwing it in the bin? While some PCMs may be safe to drink, others are not; they can be environmentally damaging when put into landfill and are in fact classed as 'dangerous goods' by the United Nations.

PCMs are undoubtedly a greener solution because they are reusable, lighter and have a smaller carbon footprint by reducing the cost of distribution. But, when they reach their end-of-life, they need to be properly recycled to ensure they do not damage the environment.

Learning From Automotive

While not an industry that you would immediately pick to have similarities with life sciences, the automotive sector is also facing comparable environmental challenges. In particular, manufacturers are under pressure to produce environmentally sustainable cars, by switching from conventional combustion engines to hybrid or totally electric vehicles (EVs).

Figure 2: Families of PCMs used within temperature-controlled packaging



Just as reusable temperature-controlled packaging systems are powered by PCMs, electric vehicles are powered by extremely large batteries. These batteries now contain more and more exotic and precious metals that require invasive mining at a high cost, both financially and environmentally. Once used, they cannot be disposed of in landfill, as they cause environmental damage in pure form.

A large number of EV and hybrid owners chose these cars because of the reduction in greenhouse gases when in use, but both manufacturers and owners should be fully aware of the environmental impact and disposal/recycling needs of these products and components at end-of-life.

Right Infrastructure

In the automotive industry, rising oil prices, plus the demand for lower costs and increased efficiency, have led the trend towards automotive electrification such as hybrids and EVs. In fact, the global EV charger market is forecast to grow from more than one million units in 2014 to 12.7 million in 2020 (1).

However, with this growing popularity, the global demand for lithium is increasing, too.

Recycling and re-using these lithium-ion batteries is a hot topic in the automotive industry, as there are concerns around the supply and availability of the raw materials for battery production. As such, manufacturers are considering how to use these batteries in other applications and recycle them (2).

With this in mind, it appears that the challenge both industries have to overcome is the need to put the right infrastructure in place to make sure materials are safely recovered and recycled so they do not go on to damage the environment: and this needs to start with education.

Second Life?

For the automotive sector, the EU currently demands that 95% of a car is recycled. The End of Life Vehicle (ELV) Directive 2000/53/EC requires the manufacturer to detail provisions laid out for vehicle collection for proper recycling, as well as the number of vehicles due for recycling per year, based on production.

A lithium-based battery can last from 5 to 20 years and still retain 80% of its charge (3). Therefore, once the battery has come to the end of its life as a car battery, it can have a valuable 'second life'. Examples include back-up power for computers and medical equipment, or electrical grid storage, which would go hand-in-hand with renewable power, like wind or solar. Alternatively, the battery's components can be broken down to make new batteries.

Currently in the life sciences industry, there are no programmes in place specifically for the use, recycling and disposal of PCMs. So perhaps we need to take note of what the automotive sector is doing, and recreate a similar process – led by the temperature-controlled packaging manufacturers – to ensure PCMs are recycled properly and effectively, and do not harm the environment.

Questions that need to be answered include: how easy is it to get PCMs to a recycling centre; how easy is it to return

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them to the original manufacturer; can the coolant be put in the post and sent back; and how are they recycled?

Product Return

As pharmaceutical distribution is a highly quality-driven environment, it would not be suitable to recover every PCM to be re-sold into new products for the pharma industry; there would not be the right batch control, or traceability of where the PCM has been or the treatment it has undergone. However, they could potentially be used to create coolants for other industries, such as food or flowers, or adopted into other uses – for instance, building materials to help control or regulate room temperatures.

One of the main challenges faced by temperature-controlled packaging manufacturers is knowing where their product is in order to get it back to recycle it. Within the automotive industry, the UK government has stated that an ELV collection site must be within a 10-mile radius of 75% of owners and within 30 miles of the remainder – making it easier for manufacturers to recycle products. In addition, cars across Europe are licensed, so manufacturers can understand where they are, and with a user licence and address available, vehicles can be tracked down. Temperature-controlled packaging manufacturers would have to trace PCMs across the logistics network, and then find out where they have been and for how long. This would require manufacturers to track the number produced, where they were sold, and provide an easy route to return them.

Future Trends

With temperature-controlled packaging solutions responding to new technology and industry requirements, manufacturers need to change the way they think about packaging, its full lifecycle and how it is disposed of. Environmental legislation will continue to move in its current direction, increasing pressure on pharmaceutical distribution, as will the need to develop and deliver medication in a cost-effective way.

As seen in the automotive industry, consumers are becoming more conscious of where their car has come from and the environmental impact it will have in the long term. This trend is also translating to other sectors, such as food and clothes. It will not be long before patients start to ask the same questions surrounding the production and distribution of their medication.

While the onus is on the packaging user, it is the drug producer and distributor's responsibility to ensure the safe and proper disposal of packaging waste, according to local directives. The first step of the process must start with the temperature-controlled packaging manufacturers to educate them about new materials and not hide the facts with cloudy language.

In essence, designing a sustainable packaging solution is only solving the first half of the problem. The other half is ensuring products are utilised to their full potential, and can be re-used beyond their working life in new applications – before they end up buried in landfill, where they will lie unused and potentially hazardous for a long time.

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About the author

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