

# TURNING THE TIDE ON SHIPPING PHARMACEUTICALS

Advanced Phase Change Materials  
are the new game changer, lowering  
excursion rates and meeting compliance

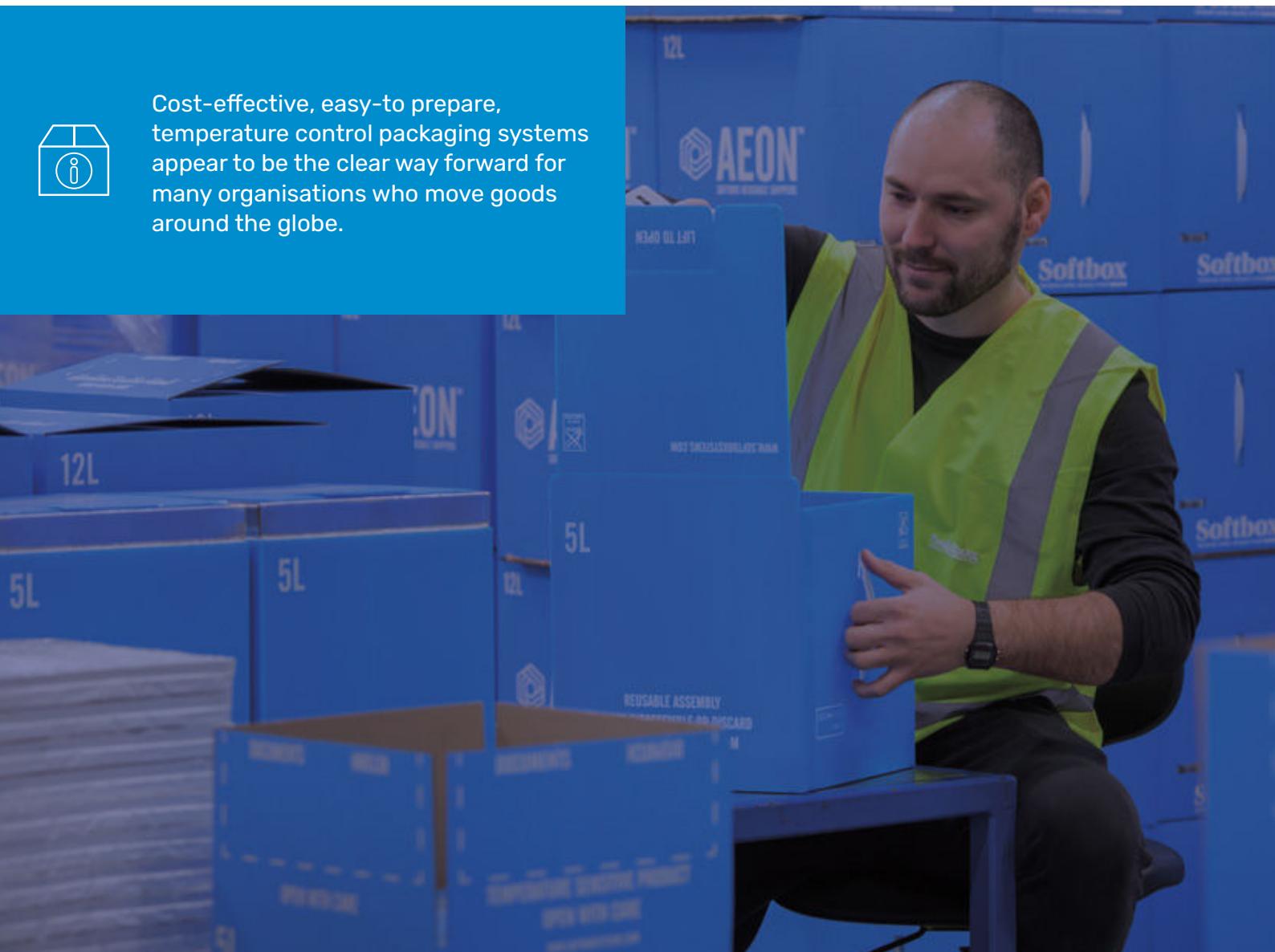
## Introduction

One of the most bone-chilling facts the Pharmaceutical industry now faces is that – according to IMS Health – losses associated with temperature excursions during transportation currently sit around the \$35 billion mark. Even for an industry that is projected to have sales of \$1.36 trillion dollars by 2019, that figure seems staggeringly high. The most alarming part? It's growing.

The usual suspects take their place at the top of the contributors list: product degradation due to incorrect shipping, scrapping as a result of logistics, and temperature-sensitivity damage due to a broken cold chain.



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It's hardly surprising then, that these kinds of figures have attracted the attention of industry CEOs, as well as serving as a springboard for new, increased regulatory control. So, with compliance standing as king, what steps are forward-thinking Pharma and Biopharma companies taking to ensure the safety, efficacy and quality of their products? And how is the condition of these products going to remain as stated within registration files, right the way through a shipment's journey?

### Battling the weather

If we take increasing demand as being perhaps the most credible yardstick, then cost-effective, easy-to-prepare, temperature control packaging (TCP) systems appear to be the clear way forward for many organisations who move goods around the globe. While the compliance process has played a part in driving this trend, there's another process that's supporting it: selection, simplification and qualification of TCP systems.

Traditionally, the water-based packaging systems used by the industry have required both local and regional qualifications. To ensure temperature control during shipping, this would often require the incorporation of seasonal pack-outs. While these systems are fit for purpose (they are designed to cope with a range of average ambient temperatures, ideal for temperate summer or winter shipping, with narrow fields of variation due to their material properties), their effectiveness can diminish when asked to function outside their stated profile. For example, should your company have a need to ship pharmaceuticals between let's say Germany and Australia, there is an obvious obstacle – you have winter in one location and summer in the other. Significant differences in seasonal temperatures can cause significant complications; it's not uncommon for excursion rates to reach around 30%.

As you may have experienced yourself, the challenges don't stop there. Historically, temperature control packaging providers have operated regionally, creating solutions for their immediate local markets. But as international trade diversifies and expands into the new, global growth markets of Asia, Europe, South America and Africa, a fresh challenge emerges – the need for higher-performing packaging systems suitable for all-year-round, local, regional and international shipping purposes. Couple this with the advent of Life Science companies taking a more global approach to packaging qualification and selection, and you come face-to-face with a quintessential problem-opportunity dynamic.

### The new, smart solution

To meet new requirements and keep pace with change, TCP providers are increasingly making use of progressive insulation packaging materials, such as Vacuum Insulation

Panels, as well as Phase Change Materials that freeze and thaw within the required temperature range for a particular product. The effect of combining these components is a game changer for the entire industry. Pharmaceutical companies can not only ship, but ship confidently.

While some of the latest cold chain packaging solutions offer the kind of increased thermal protection that businesses have been crying out for, they are now also much more robust. They are totally re-usable. And they are palpably smaller, potentially lowering the outlay in shipping costs. But what's given with one hand can be taken away with the other.

Higher performance inevitably comes at a higher price, both in packaging terms and through increased control of the phase change materials conditioning processes which are absolutely essential to ensuring product integrity (nothing is more critical in the shipping of pharmaceuticals). Thus far, it would seem that any initial financial outlays are being outweighed by the results. The fact that these elements have helped overcome global qualification requirements while significantly reducing the risk of temperature excursion during transit, is all-important. The pharmaceutical and biopharmaceutical companies are winning.

With availability of these new higher-performing temperature control packaging systems on the rise, we are now witnessing an increasing demand for more innovative products and services. Never has the choice of packaging system and its supplier been more crucial.



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### Creating the future

At Softbox, we're continually listening to what our customers are saying and evaluating what can be done. In particular, consignors of time - and temperature - sensitive products need to be evermore confident that the risk of excursion during transport is significantly minimised. Understandably, they're also looking to reduce packaging spend wherever possible. As their voices grow louder, a service provision model emerges.

This poses the question, how will increased and continual demand be met? Firstly, there are the raw materials to consider. Phase change materials are relatively new and operate by way of absorbing or generating heat as they change from liquid to solid states, or vice versa—at a pre-formulated temperature. Such materials are typically comprised of oils, salts, or paraffin. Although historically they have been difficult to source, demand seems to be fuelling change, with new supply chains emerging.

Where such precision is at play, quality is everything. These materials are vital to the ultimate performance of the new systems. And it's the global Biopharmaceutical manufacturers who find themselves spearheading the push for governance. Perhaps more than anybody else, they need a zero-tolerance approach to shipping temperature-sensitive products in extreme, uncontrolled conditions. They need the sustainability. And they need the industry standardisation. Therefore, careful investigation must be carried out into the material combinations and compositions of packaging systems, to guarantee the kind of suitability and efficacy that's required.

This has also been a catalyst for us at Softbox. It is the continued investment and innovation in product design which allows us to offer a total range of high-performance

temperature control packaging systems—one that has been recognised by our industry and made us a go-to vendor for the pharmaceutical industry.

Not only do we offer systems that incorporate vacuum panels and advanced phase change materials, but our products are both environmentally friendly and capable of true end-of-life recyclability. What's more, in a bid to make our high-performance solutions as affordable as possible, our next generation of TCPs are now being developed to work within defined rental programs, to ensure that cost-effective re-use is possible, irrespective of the volume and frequency of shipments.

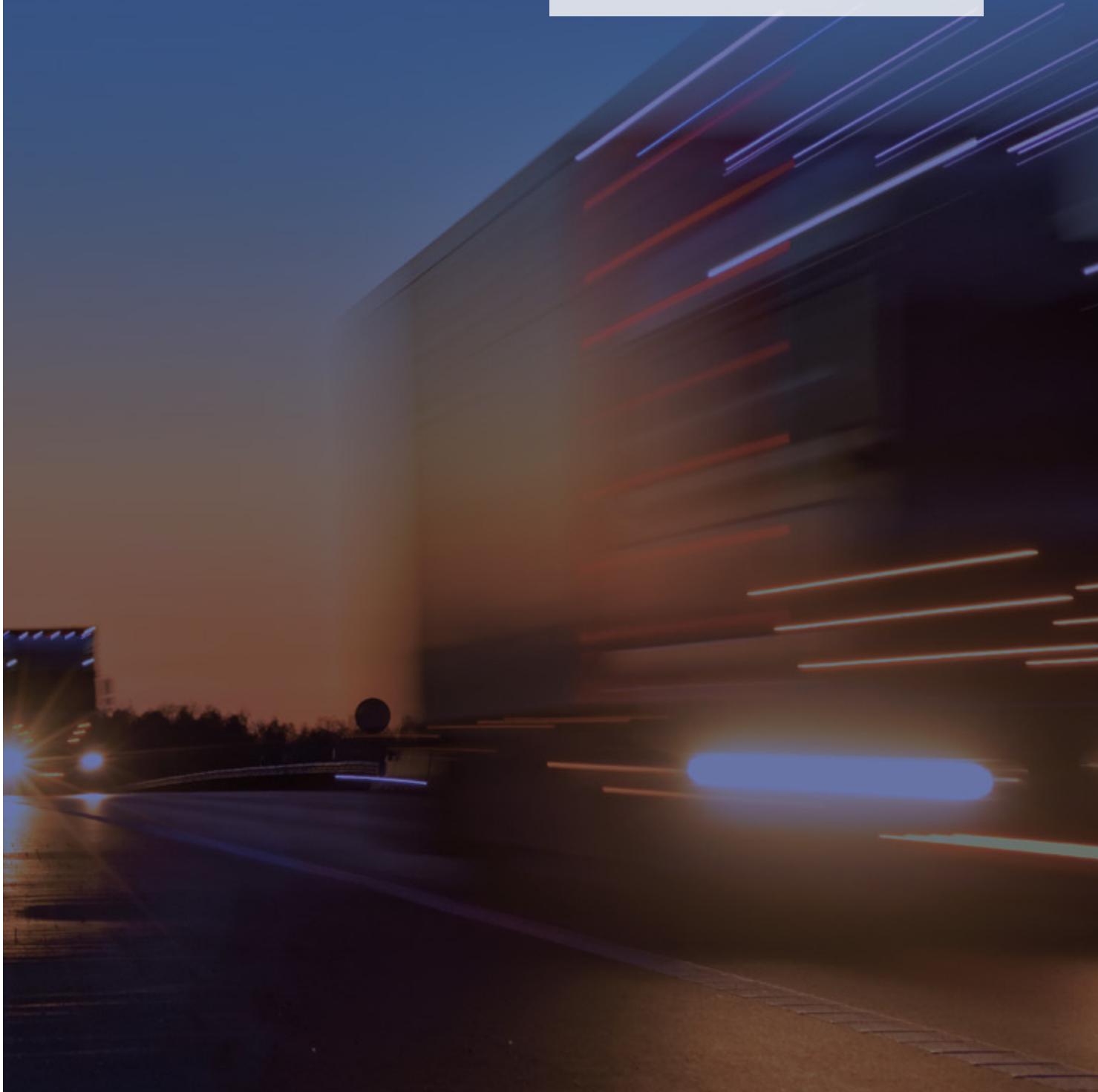
Softbox is an award-winning temperature control packaging innovator that has been designing and producing high-performance, passive temperature control packaging systems for over 20 years. We offer consistent quality to our global clients and have long-standing partnerships with the world's leading pharmaceutical, clinical research, biotech and logistics companies. We apply innovative thinking to overcome the challenges that our clients face in managing the Cold Chain when shipping temperature-sensitive, clinical trial and commercialised products.





## About the Author

**Clive Bryant** is Global Product and Marketing Director at Softbox and has more than 30 years' experience of global cold chain and clinical trial logistics. Formerly head of Life sciences at DHL, Clive has been involved in developing innovative customer solutions that ensure cold chain maintenance and regulatory compliance.



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