



# Chill Pill

As temperature control packaging companies develop solutions that answer tighter regulations governing wide-stability products, Clive Bryant, global product and marketing director for Softbox Systems, looks at the challenges they must face.

It seems almost inconceivable in a sector so often lauded for its innovation and progress, that pharmaceutical companies could be left wanting for a low-cost, rudimentary parcel shipper that protects temperature-sensitive products below 30°C. But here we stand.

It would be jumping the gun to apportion blame and put packaging companies in the firing line. Their focus has typically been on developing solutions to answer increasing regulatory pressure that is being applied elsewhere in the cold chain sector. What is abundantly evident is that we are in the throes of a temperature compliance era that has accelerated in tandem with regulatory demand and industry growth. Next up: wide-stability guidelines.

USP general chapter and ICH quality guidelines cover Good Distribution Practices for the storage and transportation of pharmaceuticals products. The guidelines involve a number of temperature ranges such as 2-8°C, 15-25°C, 20-25°C and 2-30°C. Where a storage temperature is stated on a product label, it would need to be shipped under controlled and monitored conditions.

#### COMPLIANCE GOES FURTHER — AND WIDER

Although there are different interpretations of what constitutes

CRT, Good Manufacturing Practice compliance refers to it as the customary working environment temperature of 20°C to 25°C. Excursions between 15°C and 30°C that are experienced in pharmacies, hospitals, warehouses and during shipping are also acceptable.

The aim, however, according to a US Pharmacopeia CRT Range Expansion stimuli article, is to “standardise the definition of CRT to remove uncertainty and promote long-term value to industry.” This includes a revision of the guidelines that take into account and permit ranges supported by stability data, for example ‘store below 30°C.’

Regulators are now seeking assurances from manufacturers not only on the quality, safety and efficacy of products throughout their shelf lives, but also during the shipping process to the end customer.

Is this an issue for pharmaceutical companies? Not exactly. Together with their packaging allies, they have a habit of stepping up to the mark. But it certainly presents a challenge, particularly when trying to find cost-effective packaging solutions. Falling into the wide-stability category are lower cost products such as over-the-counter medicines and routinely dispensed prescription products. Pharmaceutical companies, along with pharmacies, dispensing

doctors and clinical trials companies can be left scratching their heads as to what level of thermal protection they should use when shipping label-claim products.

#### INVISIBLE, UNTIL NOW

So how has all this slipped under the radar? The reasons abound. But we have to acknowledge that it's easy to get lost in the noise of a saturated space. The rapid rise of the emerging markets, the geographical diversity of growth, an ageing population, the ascent of biologics, and an era of transparency and security have all been contributing factors in pushing the compliance machine into overdrive. It was perhaps only a matter of time before legislation was tightened in the wide-stability category. Without being subject to the more stringent regulations that have befallen other temperature-sensitive pharmaceuticals, historically it may have been deemed safe to ship such medications naked or in simple cardboard shipping boxes, perhaps in a vague expectation that they will reach their destinations in good condition and within their storage label claim. The hour for guarantees, however, is perhaps upon us.

#### RELIABLE, AFFORDABLE AND RECYCLABLE, PLEASE

The capability and materials are there to produce a workable

solution and this has now been seasoned with intent. But in truth, it's only half the battle. When you look at the volumes involved, it's not hard to understand why the world's leading pharmaceutical companies are all asking the same question: “How much do I have to pay for a basic, simple-to-use, wide-stability shipper?” As the packaging innovators rally to offer a low-cost compliance remedy, they must be mindful; the real agenda comes with a further twist.

#### ENTER THE ENVIRONMENT.

The pharmaceutical sector has taken a leadership position in the sustainability movement with commitments to eliminating waste, re-use and recycling. While leading temperature control packaging (TCP) companies are mirroring this, there is some ambivalence where the term “recycling” is concerned. Expanded polystyrene foams, for example, can only be ground and reprocessed into new polystyrene products, effectively recycling them. Alternatively, polyurethane products such as insulation panels can be repurposed or upcycled into building materials — but programmes are not always readily available, leading to challenges in disposal. These can be further complicated by regulations that increasingly require imported packaging to be re-exported to avoid local disposal or recycling.

Performance TCP systems that employ vacuum insulation panels and phase change materials offer a greener alternative, when linked to full re-use programmes which help to achieve sustainable cost-effectiveness.

But as welfare wins over waste, there's an increasing need for 100% kerbside recycling. This allows materials to be picked up in containers acceptable to, or prescribed by, local municipalities.

#### A NEXT-GENERATION SOLUTION IS OUT THERE

In the quest for a panacea that satisfies all the criteria, there are some encouraging early signs. Thermaflute-type insulation could have a pivotal role to play. This cardboard material is used to create effective insulation layers, replacing traditional methods. It is a game changer. And it would allow consignors of temperature-sensitive pharmaceuticals to comfortably meet regulatory compliance without impacting on the environment.

What's more, expectant pharmaceutical partners will be anticipating features inherent in traditional shippers that save on costs, like ease of assembly and a flat-packed design that maximises storage space.

Naturally, whatever TCP systems materialise from this undertaking, they will have to be qualified to recognised industry standards and rigorously tested to uphold the wide-stability temperature range for pre-defined shipping durations.

The lower cost, totally recyclable, rudimentary shipper that performs with complete reliability for wide-stability products is poised to see the light of day, no doubt in different configurations. Start your engines, ladies and gentlemen. The race is on.



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