

PHARMACEUTICAL & MEDICAL Packaging NEWS

THE PACKAGING MAGAZINE FOR THE HEALTHCARE

PHARMABIO TRANSPORT: Keeping an Eye on the Cold Chain

By John Conroy

A 2001 forecast by LEK Consulting predicted the life sciences segment of the pharmaceutical industry will grow at a compound annual growth rate (CAGR) of 12 percent through 2007, with the temperature-controlled portion of the segment estimated to grow at a CAGR of 22 percent during the same period, says Angelos Orfanos, vice president, Americas, life sciences and healthcare for DHL (Plantation, FL). A more recent forecast by DPWN Inhouse Consulting estimates an industry CAGR of 6.6 percent through 2012, he notes.

In addition, 39 percent of all life sciences products were forecast to be temperature-controlled drugs by 2007, with the remaining 61 percent dry, non-controlled products. In 2001, those figures were 15 percent for the former category and 85 percent for the latter. Temperature-controlled products can include those kept at the controlled room temperature (CRT) of 15° to 25°C, Orfanos says.

"The whole concept of maintaining temperature during transport is a huge part of the industry, and it's going to grow," says Eric Isom, manager of warehouse operations for Sentry Logistic Solutions (Indianapolis). The 3PL distributor operates a foreign trade zone that allows international pharmaceutical and biotech clients to bypass importation regulations such as "customs, paperwork, dues, and tariffs," he says.

With this in mind, regulators worldwide have expanded the definition of a temperature-controlled product, Orfanos says. While historical cold chain temperatures range between 2° and 8° C, the industry has recently seen "an evolution to the 15° to 20° C range." Considered room temperature, this range "has evolved in regulators' minds as a controlled-temperature zone" referred to as temperate or ambient, he notes.

The expanded definition of temperature-controlled product has led many countries to pass laws mandating that manu-

facturers ensure that drugs are kept in the range stated on the label, according to Orfanos. "If you're going to ship it from Point A to Point B you need to maintain [the product's] efficacy," he says. "Regulators around the world have taken the label designations and said, "Okay, fine, but now you've got to meet that requirement."

And if you don't? "A product could potentially be delayed in reaching its destination, requiring analysis or, in the worst case, being deemed spoiled," Orfanos says. Spoilage could occur when a combined accumulated range of temperature excursion reaches a certain length of time deemed unacceptable by the manufacturer's quality assurance department.

"The whole concept of maintaining temperature during transport is a huge part of the industry, and it's going to grow."

—Eric Isom
Manager of Warehouse Operations
Sentry Logistic Solutions

"A number of regulatory and standards-based guidance documents have been published over the last two years," says Henry Ames, director of strategic marketing for Sensitech (Beverly, MA), which specializes in cold chain solutions for monitoring

temperature-sensitive products from the beginning to the end of the supply line. These include the November 2005 publication of USP <1079>, the general guidance document covering good storage and shipping practices by the U.S. Pharmacopeia. Other documents addressing product efficacy and patient safety include Technical Report 39 ("Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment," revised in 2007), by the Parenteral Drug Association, as well as regulatory publications from Canada, Ireland, and other countries.

Increased cold-chain traffic keeps pharmaceutical and medical supplies in stock, and lets doctors treat their patients. Regulations keep those shipments up to par, saving lives in the process.