

PHARMACEUTICAL & MEDICAL Packaging NEWS

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PHARMABIO TRANSPORT: New Rules for Airport Cold Chain *A regulation addition promotes cold-chain cargo handling*

By David Vaczek

The airline industry's Perishable Cargo Regulations address the most difficult-to-predict segment of cold chain transport. The regulations support the pharmaceutical industry's need for control and visibility in this supply chain area by defining the critical points where lapses most often occur in airport logistics. They also lay out best practices for meeting regulatory agency requirements for temperature-sensitive products.

Chapter 17 specifies rules for healthcare cargo, saying that shippers and carriers should work together to develop a standard operational procedure (SOP).

"Pharmaceutical companies go to extraordinary lengths to protect product from environmental hazards, with very expensive packaging," says Kevin O'Donnell, director and chief technical advisor to industry, Tegrant Corp., ThermoSafe Brands (Arlington Heights, IL). "They over-engineer packaging, because they don't completely understand what happens after product is surrendered at the airports.

"The airline segment has long been identified as a weak link in the chain, with significant potential for mishandling and improper storage," O'Donnell adds. He worked with a cross-industry committee to write the regulation's additions. "Chapter 17 updates the handling for medicinal products. The regulations describe what the airlines can begin to do to understand the drug industry's needs for expediting freight in a safe and efficient manner."

Airlines that commit to handling medicinal products can offer value-added services and earn higher margins for the high-value cargo. Because healthcare products account for a small fraction of airline revenues, however, observers say the established guidance will dissuade some airlines from emphasizing the segment. "There will be carriers that feel this is way too involved for them," O'Donnell says.

Eric Raemdonck, manager, special cargo standards, International Air Transport Association (IATA; Montreal, Geneva), and secretary of IATA's Live Animals and Perishables Board (LAPB), says that "the air transport industry has a good understanding of the needs of the healthcare industry. It will increasingly serve this market, especially now that drug manufacturing is spread across several continents.

"Who else but the air industry can ensure rapid and efficient distribution such as in times of disease outbreaks?" Raemdonck

says. "For some airlines, [the new guidance] translates into offering customers specialized temperature management products and solutions, whereas for others the focus may be elsewhere in the cargo segment."

Stating that drug firms and airlines share responsibility for the proper handling of packages, Chapter 17 references the World Health Organizations' (Geneva) guide on good storage practices for drugs. The guide describes GMPs for proper personnel training, storage conditions, and labeling. Controlled conditions must be maintained in transport, with devices for monitoring temperature in transport advised.

Container labeling isn't mandatory, although the regulations note that "an industry-wide acceptance of standard labeling . . . that does not telegraph the contents of the packages would help expedite product movement [and] avoid improper storage." It would also provide "the best, safest, and surest means of communicating the time/temperature sensitivity of [healthcare] freight."

"Drug companies have approached labeling by writing special instructions for handling in the airway bill," says O'Donnell. "[But] the ground handlers on the ramp don't see the bill of landing or read the operating procedures. A lot of ground handling is outsourced. You have people working different shifts, for different airlines, for whom English may not be their first language."

Chapter 17 includes proposed label designs to indicate that container contents are time and temperature sensitive. At its semi-annual meeting in Montreal last October, LAPB voted to consider a more definitive labeling format. Packages may be labeled with a numbering scheme, with numbers representing containers' temperature requirements. "On this issue, no official decision has been made," says Raemdonck.

"These regulations will help the airlines understand what they are handling so they make the right decisions, such as when making a judgment call," says Eric Isom, manager of warehouse operations, Sentry Logistic Solutions (Indianapolis).

At the LAPB meeting, a Time and Temperature Task Force was approved to work with pharma on the regulations. "This Task Force is temporary in nature, and we encourage the healthcare industry to take advantage of this dedicated platform and delegate observers," Raemdonck says.

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