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Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User

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Last Mile: Guidance For Good Distribution Practices For Pharmaceutical Products To The End User Task Force

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1.0 Introduction

Medicinal products and devices requiring controlled temperature storage are subject to highly variable distribution environments. The manufacturer distributes in a well-controlled shipping lane that is routinely monitored for temperature excursions and is subject to uniform, stringent Good Distribution Practices (GDP). Conversely, shipping/distribution regulations vary widely from location to location, and uniform guidelines are lacking. This divergence has proved challenging for the pharmaceutical industry.

Good Distribution Practices are a natural extension of Good Manufacturing Practices, Good Clinical Practices and Good Laboratory Practices, among other requirements for manufacturers of medicinal products and devices. Regulations and guidance for each different custodian in the supply chain can vary by country, state and province. For example:

- The United States Pharmacopeia (USP) Chapter <1079> Good Storage and Shipping Practices offers guidance and procedures on maintaining pharmaceutical integrity throughout the supply chain to the patient.
- The World Health Organization (WHO) provides *Good Distribution Practices for Pharmaceutical Products* (WHO Technical Report Series, No. 937, 2006, Annex 5).
- The European Union issued *Guidelines on Good Distribution Practice of Medicinal Products for Human Use* (94.C 83/03) and Council Directive on the *Wholesale Distribution of Medicinal Products for Human Use* (EEC 9225).
- Canada developed *Guidelines for Temperature Control of Drug Products during Storage and Transportation* (Guide 0069). Additional guidance has been prepared in Ireland, Singapore, Brazil and Austria.
- *PDA Technical Report No. 39, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment* (TR-39) provides global and industry perspectives with further documentation of quality systems.
- Argentina passed Law # 26492, *Regulación de la cadena de frío de los medicamentos*, requiring all pharmaceutical products for human or veterinary use containing temperature-sensitive active ingredients to have a temperature indicator attached by the manufacturer to verify that the cold chain for the product has not broken when it is received by the consumer.

"Last mile" is an often-used logistical term, and in the shipping of pharmaceutical products, is considered to start from the manufacturing facility handoff to the wholesaler or pharmacy and continue to delivery to the end user. This may include thousands of miles or the last few feet until the product is administered. The "last mile" to the point of patient administration can prove difficult to manage. Health care professionals, patients and most retailers are, by and large, unaware of the challenges experienced during the "last mile." Invariably, detailed and practical knowledge and information related to any product excursions beyond compendial ranges are unknown or unavailable to the end user.

This guidance document serves to complement the information provided in TR-39 by going beyond manufacturer-focused issues and addressing those issues specifically encountered within the "last mile."

1.1 Purpose

The purpose of this document is to provide guidance to all involved in the "last mile" regarding the proper handling and storage of controlled-temperature medicinal products and devices.

