Guidance for shippers, transport service providers and sub-contractors involved in the distribution of pharmaceutical products registered for storage between 2° and 8° Celsius

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1 Introduction

These documents provide guidance for **shippers** and **transport service providers** for the transportation of **pharmaceutical products** registered for storage between 2° and 8° C.

2 Purpose

The purpose of these documents is to ensure that the integrity of the cold chain for **pharmaceutical products** as conducted by **shippers**, **transport service providers** and their **sub-contractors** is maintained.

3 Scope

These documents apply to all transportation methods and to all parties involved in the **transportation** of **pharmaceutical products** that are registered for storage between 2° and 8° C and the related activities, such as, but not limited to:

3.1 **Preparing the goods for** transport;

3.2 Loading/unloading goods into **shipping equipment;**

3.3 Loading/unloading of shipping means;

3.4 Loading/unloading from one shipping equipment to another;

3.5 Receipt of goods;

3.6 Handling between transportation (e.g. airport transit, harbor transit).

4 Definitions

4.1 **Shipper:**
An individual or company who tenders **pharmaceutical products** for transportation.

4.2 Transport Service Provider:
Contracting party who mediates or executes the transportation of **pharmaceutical products** on behalf of the **shipper**.

4.3 Sub-Contractor:
An individual or company hired by the **transport service provider** to perform the actual shipment. The **shipper** and the **sub-contractor** do not necessarily have a contractual agreement.

4.4 Pharmaceutical Products:
Pharmaceutical products refer to those that are registered for storage between 2° and 8° C.

4.5 Transportation:
All activities from preparation for shipment up to the point of receiving at the final destination.

4.6 Transport Service Agreement:
A contractual agreement, which describes the legal, logistical, technical and quality terms or contractual arrangements between **shippers** and **transport service providers**.

5 Responsibilities: Shipper's Obligations

5.1 The **shipper** should have a **transport service agreement** with the **transport service provider**.

5.2 The **shipper** should audit the **transport service** provider on a predefined basis.

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5.3 The **shipper** should instruct the **transport service provider** on the characteristics of the **pharmaceutical product** and the handling requirements of the shipment.

5.4 Detailed instructions on transportation and handling conditions must be integrated into the shipping documents. Marks on the shipment should clearly indicate the temperature range within which the shipment must be handled.

5.5 **Transportation** of **pharmaceutical products** should be qualified to the extent possible. Where appropriate, and preferably if no transportation qualification has taken place, a continuous temperature monitoring system should be in place during **transportation**.

5.6 The **shipper** must ensure appropriate conditions for handover and subsequent handling of the **pharmaceutical products.**

6 Responsibilities: Transport Service Provider's Obligations

6.1 A quality management system should be in place at the transport service provider, covering topics such as, but not limited to:

6.1.1 GMP-/GDP-relevant processes need to be identified and described in standard procedures.

6.1.2 A procedure should be in place to identify the main functions of individuals, define roles and responsibilities and provide contact information in the case of a deviation. A list of relevant contact individuals should be maintained and readily available in the event of deviations.

6.1.3 Reference to available regulations on Good Distribution Practice (GDP);

6.1.4 Documentation control incl. tracking & tracing. Tracking & tracing documentation to have documented evidence throughout the transportation process should accompany shipments.

6.1.5 An adequate change control system should be in place. The shipper's approval should be obtained prior to changes potentially affecting GDP or product quality.

6.1.6 An adequate deviation management system including procedures for corrective actions should be in place.

6.1.7 Regular, periodic training of **transport service provider** personnel as well as **sub-contractor** personnel should be carried out. Training should be documented.

6.1.8 A designated individual within the transport service company should be responsible for quality management.

6.1.9 When sub-contracting takes place, the **transport service provider** should have a **transport service agreement** including quality requirements with all **sub-contractors** that correspond to the conditions specified in the **transport service agreement** between the **transport service provider** and the **shipper**.

6.1.10 The **transport service provider** should monitor the **sub-contractor** to the extent that:

- controlled conditions are applied throughout the **transportation**;
- the **sub-contractor** has suitable and adequate premises, installations and equipment such as, but not limited to cold storage areas, thermo trucks, pre-conditioned containers and vehicles, temperature monitoring systems in trucks and cold store areas. Monitoring equipment must be calibrated or validated where appropriate (e.g. cold rooms, trucks);
- an adequate quality management system is in place.

6.2 Specific aspects for transportation in vehicles/containers providing an active temperature controlled environment

6.2.1 Loading and clearance of vehicles should be carried out in an efficient manner especially when no insulated docking ramps are available and also when pharmaceutical products have to pass areas, which are not temperature controlled.

6.2.2 Vehicles/containers should be pre-conditioned (depending on weather conditions) to the required temperature (e.g. between 2° and 8° C) prior to loading.

6.2.3 Vehicles/containers should be equipped with a cooling/heating device as well as a calibrated temperature-monitoring device. Studies regarding temperature mapping in the commonly used load schemes should be performed. Alarms should be set in such a way that deviations to the required temperature can be identified and corrective measures be implemented upon request. Deviations from the requested temperature range should be recorded and communicated to the shipper.

6.3 Specifics aspects for active cooling systems

6.3.1 Handling of such containers/vehicles should be carried out according to the supplier's operating manuals.

6.3.2 The service provider's personnel should be familiar with the technology and how the units function. Through periodic training, personnel should be able to ensure proper handling of goods during all stages of the transportation process.

6.3.3 Systems in use must be in a good working order. Regular maintenance should be performed to ensure the containers are functioning correctly.

6.4 Specific aspects of passive cooling systems

6.4.1 Handling of such containers should be done according to the instructions given by the shipper.

6.4.2 Insulated boxes should not be opened and must be sent to the destination in the same manner as received from the shipper.

6.4.3 Insulated boxes should remain under controlled conditions as defined by the shipper. Exposure to extreme temperatures shall be avoided or minimized to the extent possible.

7 References

- Guidelines on good distribution practice of medicinal products for human use 94/C 63/03
- WHO-guide to good storage practices for pharmaceuticals
- Commission Directive 91/356/EEC
- WHO technical report series, No.908, 2003 Annex 9
- EU Directive 2001/83/EC