Chapter 6

1. Transportation

The shipments are managed by the logistic provider, who has the responsibility to protect the pharmaceutical products from breakage and theft and to ensure the maintenance of the temperature within the established limits during the transportation.

The basic rules of the transportation are:

- **Medicines should be maintained at the required storage conditions which are established by the manufacturer or written in the transport documentation**
- **In case of deviation during the transportation, it should be reported to the contract giver or the consignee of the affected pharmaceutical products**
- **There should be applied procedures for the maintenance of all vehicles and equipment involved in the distribution process**
- **Risk assessment during the transportation of pharmaceutical products should be performed in advance**
- **Dedicated vehicles and equipment for the shipment of pharmaceutical products should be used; if it is not possible, segregation procedures should be in place to ensure the quality of the products.**

2. Containers, Packaging and Labeling

Medicinal products have to be transported in packagings which can not affect the quality of such products. The selection of containers and packagings should be based on the storage and transportation requirements of the medicinal products as well as the space required, the external temperature and the estimated maximum time for transportation.

A **label** is attached on each container in order to provide information about the **correct handling of the product** and **precautions** to ensure that the products are properly handled during the whole logistic chain.

3. Products requiring special condition

The logistic provider should maintain a **secure supply chain** for the delivery of products which require special conditions such as narcotics or psychotropic substances. **Radioactive pharmaceutical products** should be transported in dedicated and safe containers and vehicles. **Temperature sensitive products** require the use of qualified equipment such as **thermal packaging** or temperature-controlled vehicles, in order to ensure correct transport conditions.

4. Packaging

There are many different types of packagings designed to keep the internal product at a specified temperature within a defined period of time.

They can be defined as:

-**Active package**: they can warm up or cool down the internal temperature. They have an insulated exterior shell and they function through a **mechanism of energy distribution**.

- Passive package: they are made of insulated materials and consist of components and materials which keep the contents of the package at a specified temperature for a defined period of transportation; there is no mechanical system in them. Internal temperatures are maintained by **cooling elements** which consist of many types of liquids which solidify at different temperatures: this liquids are named **Phase Change Material**. Passive package have default autonomy so the delivery to the final costumer should occur as soon as possible.

Passive Package can be further defined as:

- **Disposable insulated containers**: they are mainly designed for single use but they can be reused in whole or in part, depending on the conditions of the material. They are usually made of:

  -Low density polyethylene

  -Expanded polystyrene

  -Polyurethane

  -Vacuum Insulated Panels

  -Or a combination of these materials.

  Then, they are enclosed in an outer box of paper.

- **Reusable or durable insulated containers**: they consist of an outer shell of laminated **material like fiberglass or molded rigid plastic**. The insulation is incorporated into the container panel. Durable containers are intended for **multiple uses**.

5. Temperature monitoring during transportation

A **data logger** is an electronic device which records the temperature during the transportation; it also provides a document showing any temperature excursions. It is put inside or outside the packaging.