Transport of Medicinal Products

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Transportation Considerations

- Essential function for supplying safe, effective and good quality medicinal product to patients
- Responsibility for the product from receipt → delivery to the customer
- Transportation → extension of your warehouse
- Controls already in place from receipt to dispatch → continue as product leaves the warehouse
- Weak point – potential robbery
Transportation Planning

Controllable Factors

– Routes
– Delivery time
– Mode of transport
– Packaging

Uncontrollable Factors

– Traffic
– Weather
– Other delays
– Handling
Chapter 9 - Transportation

Responsibility of the supplying wholesale distributor to:

1. protect medicinal products against
   • breakage
   • adulteration
   • theft

2. maintain temperature conditions during transport

3. demonstrate that medicinal products have not been exposed to conditions that may compromise their quality and integrity
Overview

1. General Requirements
2. Containers, Packaging & Labelling
3. Cold Chain
4. Security
5. Outsourced Transportation Activities
1. General Requirements
Transportation (9.2)

• Maintain required storage conditions
• Report deviations to the distributor and customer
• SOP - temperature excursions
• Ensure vehicles and equipment are suitable for use and appropriately equipped to prevent exposure to conditions which could effect quality and integrity of packaging
• SOP - operation and maintenance of all vehicles and equipment
Transportation (9.2)

• Risk assess delivery routes to determine where temperature controls are required
• Maintain and calibrate temperature monitoring equipment
• Use dedicated vehicles, where possible
• Non–dedicated vehicles SOP – avoid product being compromised
Transportation (9.2)

Deliveries

• made to address on delivery note and into the care or premises of the consignee

• not left on alternative premises

• emergency deliveries outside of normal business hours - staff should be designated and SOPs available
2. Containers, packaging and labelling
Containers, packaging and labelling (9.3)

Medicinal Products should be transported in containers that:

• have no adverse effect on quality product

• offer adequate protection from external influences, including contamination

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Containers, packaging and labelling (9.3)

Selection of container and packaging should be based on:

- storage and transportation requirements of the medicinal products
- space required for the amount of medicines
- anticipated external temperature extremes
- estimated maximum time for transportation including transit storage at customs
- qualification status of the packaging
- validation status of the shipping containers
Containers, packaging and labelling (9.3)

Labelling requirements

• Container labels should:
  – include sufficient information on handling and storage requirements
  – include precautions to ensure that products are properly handled and secured at all times
  – enable identification of the contents and its source
3. Cold Chain
Products requiring special conditions (9.4)

- SOP - delivery process of temperature sensitive products and seasonal temperature variations control

- Qualified equipment should be used to ensure correct transport conditions are maintained between manufacture → wholesale distributor → customer
1. Temperature controlled vehicles

• Maintain and calibrate temperature monitoring equipment at regular intervals

• Perform temperature mapping under representative conditions and take into account seasonal variations

• Provide information to customers to demonstrate that products have complied with temperature storage conditions (if requested)
2. Cool packs in insulated boxes

• Locate such that product does not come into direct contact with the cool pack

• Train staff on SOP for assembly of insulated boxes, seasonal configurations and reuse of cool packs

• Implement a system to control the reuse of cool packs to ensure that incompletely cooled packs are not used in error

• Ensure adequate physical segregation between frozen and chilled ice packs
4. Security
Products requiring special conditions (9.4)

Controlled Drugs

- Maintain safe and secure supply chain
- Apply additional controls for delivery
- Implement a protocol for theft
Products requiring special conditions (9.4)

Highly active and radioactive materials

- Transported in safe, dedicated and secure containers and vehicles
- Relevant safety measures in accordance with international agreements and national legislation
5. Outsourced Activities - Transportation
Outsourced / Contract Transportation (9.2)

- Contract - include requirements of Chapter 7

- Inform transportation providers of the relevant transport conditions applicable to the consignment

- Transport route includes unloading, reloading or transit storage at a transportation hub, pay attention to
  - temperature monitoring
  - cleanliness
  - security of the immediate storage facilities

- Minimise the duration of temporary storage while awaiting the next stage of the transportation route
Chapter 7 - Outsourced Activities (7.1)

1. Correctly **defined**
2. **Agreed** by both parties
3. **Controlled** in order to avoid misunderstanding which could affect the integrity of the products

**How?** Written Contract
Chapter 7 - Outsourced Activities (7.2 & 7.3)

7.2 Responsibilities of the Contract Giver

7.3 Responsibilities of the Contract Acceptor
Responsibilities of the Contract Giver (7.2)

The contract giver remains responsible for the transport activities contracted out, at all times

The contract giver must:

• Assess the competence of the transportation provider
• Ensure the principles and guidelines of GDP are followed
• Perform an audit before commencement and whenever there's a change to the activities
• Define the audit frequency based on risk depending on the nature of the activities
• Provide all information necessary to carry out operations in accordance with specific product requirements and other relevant requirements
Responsibilities of the Contract Acceptor (7.3)

The transportation provider should:

• have adequate
  – premises
  – equipment
  – procedures
  – knowledge
  – experience
  – competent personnel

• refrain from any activity which may adversely affect the quality of products handled

• forward any information that can influence the quality of the product
Responsibilities of the Contract Acceptor (7.3)

The transportation provider should:

• not pass any of the contracted activities to a third party without approval

• audit the third party

• ensure that wholesale distribution information is made available in the same way as between the original contract giver and acceptor
WHY?

Transportation is an essential function in supplying safe, effective and good quality medicinal product to patients.
Next Steps

• Review your company’s current transportation arrangements
• Does your company outsource transportation?
• Does your company distribute products requiring special conditions?
• Are the required procedures in place?
Further Information

www.hpra.ie

• Guide to good distribution practice of medicinal products for human use

• Guide to control and monitoring of storage and transportation temperature conditions for medicinal products and active substances

• Guide to import and export licences and letters of no objection for controlled drugs
Thank you for listening

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