



Arge Pharmazeutika



Code of Conduct for the Transportation of Medicinal Products in Austria

created by:

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&

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Disclaimer: In case of doubt, the German version prevails.
All terms referring to individuals are generic and refer to both genders.

Preamble

The following code represents a policy for the transporting of pharmaceutical products by pharmaceutical operations (manufacturers/distributors/wholesalers) in accordance with the 'Rules and Regulations for Pharmaceutical Enterprises' (AMBO). The main focus of this document is on the local transportation of finished medicinal products.

This document was prepared by the members of ARGE Pharmazeutika and Pharmig, and applies to products, which fall under the currently valid version of the 'Rules and Regulations for Pharmaceutical Enterprises' (later called only AMBO). In preparing this document, reference was made to the following international studies and/or guidelines: GDP Guidelines (94/ C63/03); Qualification versus validation and good cold chain management practices; ICH Q1A(R2); ICH Q7A (18 Chapter 10).

When dealing with pharmaceutical products, the logistics basically differentiate between micro-logistics (fine distribution) and macro-logistics (pallet transports and/or large shipments). These processes sometimes run under entirely different general conditions. If these conditions are relevant to the organization of transporting pharmaceutical drugs, this is referred to in the code.

A thorough product-related risk analysis, transport packaging and a storage temperature with various transport temperature ranges (2 to 30°C for the majority of the medicinal products to be transported) ensure that the quality is not negatively influenced in transports that last a maximum of 26 hours (24 hours for transport + 2 hours for acceptance by the recipient).

Handover to a customer/recipient either takes place personally or to clearly defined places within their realm of authority. The customer/recipient is responsible for proper storage and temperature conditions, since specific storage temperatures must again be clearly kept starting from this time. Keeping these storage conditions throughout the entire supply chain is a key requirement of the pharmaceutical manufacturer.

The responsibility of the sender ends upon handover to the customer.

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The relevant areas are described in detail below:

1. Procedure for qualification of transport process
2. Quality review
3. Commissioning and handover of products
4. Transport
5. Obligation when accepting products
6. Refrigerated products
7. Personnel
8. Hygiene
9. Transport training sessions
10. Returned goods procedure

Due to the great number of logistics possibilities for achieving the quality standards required by the AMBO, it must be assumed that this code of conduct only represents a rough guideline. Deviations can be made if necessary with use of an individual business shipping risk analysis and suitable qualification and documentation, as well as application of appropriate SOPs.

1 Procedure for qualification of transport process

General

Medicinal products, which must be stored at specific temperatures, are to be shipped in accordance with the results of a risk analysis with proper precautions.

The transport processes must be documented and categorized. The goal of the procedure is to provide proof and/or qualification that the defined temperature limits for transporting products are kept within the given environmental and ambient conditions.

- Define processes and materials used (e.g., packaging)
- Categorize processes (e.g., extraditing city, country, day, night, season)
- Define critical parameters
- Define parameter limit values and determine worst-case scenarios
- Define measurement methods
- Define measurement instruments
- Documentation of results
- Ensure reproducibility of results
- Use documented procedural instructions to ensure you keep parameter limit values established upon qualification
- Periodic evaluation of critical influencing variables and limit values

Measurements are taken using annually calibrated temperature monitors. If there is no calibration certificate for a monitor or a temperature indicator that is built in to the motor vehicle, these measurement devices must be comparably calibrated at least once per year. Any temperature deviations from the calibrated temperature monitors must be documented.

Verification occurs through measurement inside the transport container and/or packaging, and with suitable positioning of the temperature monitor in a storage area covering representative scenarios during the qualification. The length of transport is defined as loading time, travel time, any relocations in the shipper's transshipment centers, including unloading until takeover (transfer of risk).

Verification must be separately provided and documented for each relevant configuration. In order to ensure reproducibility, all results must be verified by several separate measurements.

Corresponding procedural and/or operating instructions must be drawn up from the data obtained in order to ensure that the defined parameters (e.g. transport period, packaging period) are actually kept.

2 Quality review

Transport routes must be periodically checked for the defined and qualified transport categories. The results of this evaluation must be documented and stored. If a certain route cannot be assigned to any available categories, this must be separately qualified and documented.

The validity of the verification procedure for the revealed influence factors must be checked at appropriate and defined intervals.

In addition, a random testing type method must be used to make regular checks to ensure that defined processes and defined temperature ranges and transport period are kept. The results must be documented. Deviations from the specified temperature ranges must be justified as per the procedures described in the company quality assurance system and/or as part of the ongoing improvement process, and counter-checked using appropriate measures. In case of deviations, an information obligation is defined in the quality agreement concluded with the carrier.

Regular internal quality audits (self inspections) during the year also ensure that procedures and processes are actually kept. Internal audits must be properly recorded. The results and any consequent measures will thus ensure an ongoing improvement process.

3 Commissioning and handover of products

The commissioning process is defined as the sum of activities from removal from the storage shelf to preparation for shipping, including packaging. Since commissioning takes place at storage temperature, no special verification procedures or precautions are required to transport products stored below room temperature.

If transfer of the products does not take place at a controlled room temperature, the sender must ensure that the products remain within the standard temperature range of 2-30°C and qualify a time span until the specified transfer of risk. The products shall be provided in such a manner that it can be assumed that the loading time will be as short as possible.

If a product cannot be delivered within the standard temperature range of 2-30°C, the sender is obligated to report this to the recipient.

With delivery, the time segment from commissioning to departure of the product is also a part of the qualification process of the deliverer.

If a pharmaceutical product is transferred to an Austrian pharmaceutical trader who is subject to the Pharmaceutical Drug Law and thus the AMBO, it can be assumed that the drug shall be transported using AMBO criteria and is monitored by the Federal Agency for Safety and Health Care (BASG), and thus transported under the qualifying conditions. The sender is responsible for qualification of the transport.

If a third party carrier transports on behalf of a manufacturer or wholesaler, this transport is also subject to individual business operation qualification and the transfer of products takes place according to the operation's individual SOPs (Standard Operating Procedures).

Attention should be paid to specifics of commissioning and transferring refrigerated products → see section 6 "Refrigerated products".

4 Transport

Transport of the products takes place at the standard temperature range of 2-30°. This also includes short time handling in hubs or carrier warehouses. In case of conventional shipping conditions, this standard temperature range of 2-30°C cannot be guaranteed year-round without procedures, or technical assistance.

For this reason, individual transport processes must be classified, and measures defined as to how 2-30°C can be maintained year-round under various outside temperatures, and qualified as follows.

The shipper or your own transporter must keep adequate statistically representative temperature measurements of loading rooms and transshipment areas. Measurement equipment must be annually calibrated or the like. Evaluation of the transport temperature must be documented per type of means of transport and transshipment hub.

In the following, suggested sample measures to ensure keeping the standard temperature range of 2-30°C are listed, which however, depending on the basic logistic conditions, are not mandatory:

- When accepting the product, the target temperature of the cargo compartment is already in the standard temperature range (2-30°C) so that the target temperature is maintained with quick loading.
- Loading/unloading of the means of transport carrying the product must take place as quickly as possible. The cargo compartment must not be open for longer than is absolutely necessary, especially when there is no ramp with side weather protection or strip curtains. This must be specified in writing in the instructions for use and must be documented.
- The product cannot be stored outside, even for a short time. This must be specified in writing in the instructions for use and must be documented. If sorting is required, the product must be sorted into standing special cargo compartments, which are not exposed to the outside temperature without air conditioning!
- Small transportation vehicles must be properly isolated in the loading area, not have any windows in the back, and must have an active heating system and adequately active air conditioning if it appears that the qualification of delivery or the transport temperature makes this necessary (long delivery trips, etc.).
- The dominant and current cargo compartment temperature during the trip shall be displayed to the driver on the dashboard. The sensors and their function must be checked at least once annually using a reference measurement.

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- There is an SOP describing how you can be certain to keep the qualified conditions. Sample tests using a data-logger are controlled and documented. The carriers quality system describes standard monitoring.

The wholesaler must directly send the transport containers point to point from the wholesale warehouse to the authorized buyer. This means that in this case there is no forwarding via several hubs; the products are therefore not exposed to changing climatic conditions.

If sorting is required, the product must be sorted into standing WABs (swap cargo bodies), which are not exposed to the outside temperature without air conditioning!

In accordance with the AMBO, the pharmaceutical wholesaler is obligated to set up a quality assurance system so that distribution takes place exactly according to the quality standards, which assure perfect condition of the medicinal products during transport and storage. The shipper must also set up a quality assurance system for any activities transferred to him. This especially includes the following:

- Identification label of the product/ license plate number of the transport unit must not be lost.
- The product cannot contaminate other products or materials, or be contaminated by the same.
- Precautions must be taken against expiry, damage and theft
- Pest control: precaution against an infestation, especially from rodents and insects.
- Documented cleaning of means of transport and reloading points
- Goods must be secured from access by unauthorized persons.

All employees involved in transporting the products must be instructed in the specifics of transporting pharmaceutical drugs and hazardous goods. These training sessions must be documented in writing. For this purpose, the details described under section 9 "Transport training sessions" must be heeded.

The transport company and the driver must be familiar with the class of goods and/or the goods to be transported. Unloading is only permitted with the consent of authorized and trained persons.

Training documents, quality assurance documents and any other documentation must be stored for five years as per the AMBO.

For third party transports, the company must periodically provide the orderer with a signed up-to-date file or digital data carrier containing the relevant documentation.

On the shipping documents must legibly recorded:

- Time of pickup
- Time of delivery at the recipient
- Licence number of the drawing vehicle
- Name of the driver at the pickup and delivery

Deviating logistics forms between the sender and recipient must be separately agreed upon, qualified and documented.

It must be ensured that the products are found in suitable shipment containers or transport packaging, which provides necessary protection from mechanical forces during transportation and reloading.

For each transport, the party carrying out the transport must document the following:

- Tour (designation, number or similar for identification)
- Date of transport
- Time of handover of the products
- Driver
- Vehicle license plate
- Place of unloading/place of loading

This documentation must also be archived.

In order to minimize potential risks during delivery, a simple manual must be found in the vehicle in which the action to be taken upon possible technical defects, accident, absence of recipient, breakage of goods, etc., is described and a standardized course of action is provided for the driver. These instructions on how to proceed should be the result of a risk analysis of the delivery process.

5 Obligation when accepting products

The sender is principally responsible for arranging suitable transport. This transport must correspond to the fundamentals of qualification of packaging and the transport temperature range. The recipient is obligated to inform the orderer of any obvious deviations from the qualification parameters.

6 Refrigerated products

This section deals with the logistical specifics for products, which are to be stored and transported under refrigeration conditions, i.e., between 2-8°C.

If the unloading/commissioning and packaging of products is done at standard storage temperatures (15 – 25°C), the products must be immediately removed from the refrigeration area after unloading.

If refrigerated products are transported within standard transport temperatures (2-30°C) with a designated shipment container, the sender must provide proof that the packaging used for the refrigerated products will not exceed the target temperature range inside the refrigeration container for 26 hours during the period of transport at the specified ambient conditions (2-30°C). There may only be a maximum of 26 hours between product acceptance at the manufacturer/distributor/wholesaler and

transferring the product to the customer so that the goods can be stored at the defined refrigeration warehouse area within a period of 26 hours. The length of commissioning, the packaging process, and the storage period until acceptance by the shipper must not be included in the above cited 26 hours. This means that the product must remain within the prescribed temperature conditions when using a 24-hour delivery service and a maximum 2-hour storage period.

The recipient shall regulate keeping of the maximum 2-hour storage period by means of a SOP.

If delivery of the product takes place by means of a temperature-controlled vehicle without its own refrigerated shipment packaging within the temperature range of 2-8°C, it must be possible for the recipient to take over the quality assured goods as quickly as possible so that they can be checked for completeness and finally delivered to the provided for storage areas (refrigerated warehouse).

Refrigerated goods must be labeled as such on the shipping document so that acceptance of the goods can be arranged for immediately. Pallets or transport units with refrigerated goods must be visibly and conspicuously labeled.

7 Personnel

Well-trained personnel are an important quality factor in the pharmaceutical business. This point also applies specifically to subcontractor or shipment company personnel.

Each employee must be informed that he/she is personally responsible to know and keep the SOPs and regulations, and to document and report to supervisors any causes, deviations, defects or other observed shortcomings (e.g., put remarks on transport list/trip list in a blank field, report to transport manager).

The pharmaceutical trade and the companies it commissions must use only trained personnel to make deliveries. The only exception to this is in case of emergency shipments for defined medicinal products.

During the trip, each driver must be reachable by telephone or his supervisors must be able to inform him immediately of any problems or deviations.

8 Hygiene

Vehicles must be kept clean and tidy. There is a cleaning plan with intervals that must be kept. Reusable shipment containers must be regularly cleaned.

This must be documented by means of a vehicle *cleaning list*. Please ensure that suitable cleaning agents are used. Natural wear and cosmetic defects are however acceptable.

9 Transport training sessions

In the following, three areas are specified for providing uniform training sessions. The training sessions should be designed according to in-house conditions. They are to be carried out once annually or upon the start of an employment relationship. The information about trainings should be stored for a period of five years. The concerned persons shall be provided with written documents from the training sessions. Carried out training session must be confirmed by the concerned employee ('I have read, I did understand, I will follow the instructions')

The three areas include:

- *General training*
- *Loading*
- *Temperature*

General training sessions:

Product information:

This area includes general training sessions on hazards and precautionary measures when dealing with medicinal products, and special shipment conditions for specific products.

How to proceed when shipping medicinal products:

This area deals with the general instructions about how to proceed when shipping drugs. This includes, for example, handling medicinal products in such a way that damage and adverse effects are avoided, precautionary measures for unforeseen occurrences with medicinal products, etc.

Vehicle security:

Measures to protect products from unauthorized access during loading and unloading, and during transport.

Hygiene:

This point regulates cleaning of the vehicle, the loading area, cleaning intervals and the methods and procedures used.

Loading:

Loading:

Training for loading in areas protected from the weather, which are not accessible to the public.

Load security:

Load security is an important factor when avoiding damage to products. Also important is the safety of the hauler and other participants. Hazardous goods in particular must be properly secured.

Temperature:

Temperature range:

A prescribed temperature range must be kept in the loading area. The shipper is responsible to keep within this range.

Refrigerated goods:

Refrigerated goods must be properly packed. By keeping the prescribed loading area temperature, the temperature of refrigerated goods can also be better kept.

How to proceed in case of disruptions to the climate control:

In case of a disruption to the climate control, the shipper is trained how to proceed in situations where the required temperature range can no longer be guaranteed.

How to proceed in case of traffic congestion or accident:

Includes precautionary measures, safeguards, further transport, etc.

10 Returned shipments

Sections 1-9 correspondingly apply to any returns.