CERTIPHARM REQUIREMENTS

FOR THE

TRANSPORT OF HEALTH PRODUCTS

Head office - Secretariat
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1 – SCOPE OF APPLICATION

This specific standard reference document sets out the quality management system requirements for when an organisation:

a) has to demonstrate its ability to transport health products in accordance with customer needs and with applicable legislation and regulations, and
b) aims to increase transport performance by implementing the system effectively, including the processes, in order to improve the system and to ensure compliance with the customers' specification sheets and applicable legislation and regulations.

All the specific standard reference document requirements are generic and are intended to apply to all organisations for the transport of health products, whatever their nature or size.

From among the health products defined by the ANSM (National Security Agency for Medicines and Health Products), CERTIPHARM assesses the measures taken to handle the transport of the following consignments of packaged health products:

- medicinal products for human use including vaccines and medicinal products derived from blood,
- medicinal products for veterinary use including vaccines,
- medical devices (as defined in the EU directive 93/42),
- cosmetic products.

In addition to health products, the standard reference document also applies to active pharmaceutical ingredients (API) and to manufacturing agents.

Exclusion: excluded from the scope of the standard reference document are:
- labile blood products
- ancillary therapeutic products
- biological samples
- biological waste (HCW).

This document applies to entities called upon to handle consignments of health products meeting the above definition, however such entities are organised or operate:
- single or multi-site, working directly or with a network,
- all types of transport: land, air and sea.

Organisations that outsource transport operations in whole or in part, such as a forwarding agent (road, sea, air), may apply for CERTIPHARM certification.

2 – NORMATIVE AND REGULATORY REFERENCES

- The French Public Health Code
- Decision of the ANSM 20/02/2014 on Good Distribution Practice
- EU Guidelines of 7 March 2013 68/01 on “Good Distribution Practice of Medicinal Products for Human Use”
- Recommendations on the transport of health products under controlled temperature (5°C ± 3°C) – French National Council of Pharmacists - Central Council B - October 2012
- Directive 93/42
- Letter from the French Council of Pharmacists of 20/03/2002
- ANSM Documents on the conservation of medicinal products in case of extreme cold or in the case of heat wave conditions (ANSM - 19/05/2012).

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3 - TERMS AND DEFINITIONS

Agent
A natural person or legal entity, not necessarily a carrier, which, in consideration for remuneration, is responsible for transport services, in its own name, under its own liability and on behalf of its customer, being free to choose the ways and means of such transport. The agent shall act as guarantor for the successful completion of the transport.
Synonym: transport auxiliary

Batch number
Distinctive combination of numbers or letters or numbers and letters that specifically identifies a batch.

Calibration
Operations that, under specified conditions, establish a relation between the values indicated by a measuring instrument or a measuring system or values represented by a material measure and the corresponding known values of a measured quantity.

Consignee
Person (natural or legal) to which the package(s) must be delivered.

Deviations - (CERTIPHARM Definitions)
Assessment of the quality system for classifying deviations from the applicable standard reference document as critical, major or minor:

Critical: Failure to satisfy a requirement in the standard reference document relating to the organisation, application or formalisation of the quality system resulting in a risk for the company's customers or the final users of the product/service delivered by such company.
Note: this type of deviation requires immediate corrective action.

Major: Failure to satisfy a requirement in the standard reference document relating to the organisation, application or formalisation of the quality system not resulting in a risk for the company's customers or the final users of the product/service of such company.
Note: this type of deviation requires medium-term corrective action (date to be specified).

Minor: Failure to satisfy a requirement in the standard reference document without resulting in any particular risk.
Note: this type of deviation requires the initiation of an improvement in the quality system (to be verified at the subsequent audit).

Medicinal product
Substance or combination of substances presented as having properties to treat or prevent disease in humans or animals, as well as any substance or combination of substances that may be administered to them, with a view to making a medical diagnosis or restoring, correcting or modifying their physiological functions by exerting a pharmacological, immunological or metabolic action.

Measurement
Measurement is the process of giving a value to an observation.

Metrology
Measurement science in the broadest sense.
Metrological testing is proving, by way of measurements (calibration), that specified requirements have been met. The findings of an audit results in a decision of compliance (followed by a return to service), or non-compliance (followed by adjustment, repair, a downgrade or reform of the device). Adjustment means to bring the measuring accuracy of the device back to predefined tolerance levels.

Procedure
Description of the operations, precautions or measures to be taken in an area, directly or indirectly relating to the manufacture of the medicinal products.

Processes
Set of interrelated or interacting activities that transform inputs into outputs.

Qualification
Operation designed to show that a piece of equipment/process works correctly and genuinely provides the expected results. The concept of validation is sometimes widened to incorporate the concept of qualification.

Traceability
Ability to trace back the history, implementation or location of what is being examined.

Transport subcontractor
Independent operator running a service on behalf of an agent who is the ordering customer.

Validation (CERTIPHARM definition)
Establishment of proof, in accordance with the principles of good distribution practice, that the implementation or use of any process, procedure, equipment, activity or system leads to the genuine attainment of the expected results.

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2

4 - MANAGEMENT SYSTEM

4.1 - Definition of the scope of application of the quality management system

The organisation must define:

- The transport management (network, load breaks including weekends and bank holidays, modes of transport, transit point, time periods, responsibilities),
- The use of subcontracting services (terms and conditions, extent),
- Membership of any group, description of the connections between the group and the audited organisation,
- The extent (%) of the activity devoted to health products and the nature of any products transported other than health products,
- The characteristics of the health products (e.g. medicinal products, medical devices, laboratory reagents) and any specific constraints,
- The average amount of daily movements (number of positions).

The organisation must define the limits and applicability of the quality management system so that it can establish its scope of application.

The organisation must apply all the requirements of this specific standard reference document in the defined scope of application of its quality management system. The scope of application of the organisation's quality management system must be available and be kept updated in document form.

4.2 - Quality management system

To obtain the desired results, including improvement in its health product transport performance, the organisation must define, document, implement, update and continuously improve a quality management system, including the necessary procedures, in accordance with the requirements of this specific standard reference document.

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5 - MANAGEMENT RESPONSIBILITIES

The management must demonstrate its commitment to the quality management system by:

a) assuming responsibility for the effectiveness of the quality management system;
b) ensuring that the policy and quality objectives for the quality management system are defined and documented;
c) ensuring that adequate resources are available to implement and improve the quality management system;
d) conveying the importance of having an effective quality management system and of complying with the requirements of such system;
e) ensuring that the quality management system achieves expected results.

Staff allocation must be ascertained in order to determine the level of skill and responsibility required for the operations or services provided.

A nominative organisation chart must be kept up-to-date. A formal definition of the required responsibilities, supervision and skills must be drawn up to ensure transport of the health product is well-managed. A person shall be appointed to update and improve the transport management system for the health products. This person shall report to the management on the running of the system. A formal definition of duties must be drawn up.

A formal definition of replacements for key positions must be drawn up.

The distribution of the workforce (permanent and temporary staff) must be ascertained. An organisation chart must be provided per operating site.

6 – PLANNING

6.1 - Risk analysis and response

The organisation must take into consideration the requirements set out in 4 above and define the risks that need to be taken into account in order to:

a) give assurance that the quality management system manages the transport of health products and can achieve the expected result(s);
b) identify the risk of exceeding defined temperature limits;
c) prevent or reduce undesirable effects (e.g. theft, excess temperature, non-compliance with deadlines, contamination, damage) and
d) improve.

The organisation must plan the measures it will implement to address the risks identified.

6.2 – Planning for change

A procedure must be set up to define the cases in which change management is to be applied. It shall specify for each case: the responsibilities, impact assessment, the implementation methods, the effectiveness of the result, the approval and dissemination of the information to the ordering customer if necessary.

7 – SUPPORT

7.1 - Facilities

The organisation must define, provide and maintain the facilities necessary for the implementation of its activities and for ensuring the compliance of its transport services.

7.1.1 - Material and equipment

A list must be made of any materials and equipment (e.g. cooling or heating units, sensors or recorders, vehicles, cleaning equipment, fasteners, automatic monitoring equipment) that have an effect on the quality of the product or the transport service. Neither the condition nor the use of such materials or equipment should generate any risk of product deterioration.

7.1.2 – Cleaning

When equipment or materials are used that are not exclusively reserved for handling health products, such equipment and materials must be clean, dry and cleaned at regular intervals to ensure that transport and preservation are compatible with the health products. A written procedure and records must be established for such cleaning operations.

7.1.3 - Maintenance

A maintenance plan complying with the regulations in force should be available. A record shall be made of the maintenance operations carried out.

7.1.4 – Premises

The premises must be designed and adapted to ensure that the health products are preserved under proper conditions.
For each operating site, the organisation must establish a topographical plan of the premises showing:

- the provision and number of arrival and departure docks,
- the direction of the main handling flows,
- the existence of isolation areas for temporary storage (e.g. disputes, returns),
- specific premises: cold room and secured rooms.

They must guarantee the products against theft, breakage, deterioration and damage.

Temperature-controlled premises:

- regulation enabling the temperature to be maintained in places where this is required due to defined tolerance bands,
- continuous or sequenced temperature recording ensuring the temperature is maintained during storage of the health products.

Premises not equipped with temperature control:

- Temperatures must be monitored regularly and recorded.

A specific isolation area for goods that have been damaged, rejected or are subject to dispute should be defined and be accessible solely to authorised persons.

The premises must be kept in a clean condition. A detailed cleaning plan must be drawn up and a record be made of its implementation. Checks on its effectiveness must be documented.

An effective pest control plan must be organised and recorded.

Staff must comply with minimum hygiene regulations on the site: There are bans on eating, drinking and smoking in areas used for the storage or transport of medicinal products; these instructions are to be displayed and enforced.
Instructions on eating, drinking and smoking restrictions in areas used for the storage or transport of medicinal products must be displayed, respected and overseen.

7.1.5 - Management of measuring instruments

Measuring instruments having an effect on the quality of the service: temperature sensors, temperature software, hygrometers etc., must be checked and/or calibrated at regular intervals according to a documented procedure.
An interval must not exceed one year.

7.1.6 - Computer system

The computer systems used must be defined and checked.
The description will cover the main features of the system, interactions with other systems and security and safeguard measures to protect against any modification, deletion and accidental or voluntary alteration to the data or programmes.
The computer systems must be checked before they are put into service or when any major changes are carried out (see 6.2).

Special case of websites: the website must contain information that complies with the transport services provided.

7.2 - Skills

The organisation must:

a) define the skills needed by staff who are responsible for work impacting the performance and effectiveness of the quality management system;
b) ensure that such staff obtain these skills from a foundational or professional training course, or from relevant experience;
c) if necessary, take action to acquire the necessary skills and assess the effectiveness of such action; and
d) keep relevant documented information of such skills, as provided.

A training plan must be in place to ensure staff have the appropriate accreditations and maintain defined skills: all persons, including temporary staff, whose work relates to the management of health product transport, must be given training on:
• the importance of complying with the quality management system, the procedures and the consequences on human health if they fail to do so,
• best practice, including that on hygiene.

Refresher courses shall be defined and conducted at fixed intervals (maximum 3 years).
The effectiveness of the training courses shall be assessed and then followed up with action if required.

Measures must be put in place to ensure that recourse to temporary staff does not affect the quality of service.

The company must ensure that its staff and its subcontractors are trained and competent in relation to the specific requirements of the transport of health products.

When staff members are recruited or return after long periods of absence (e.g. 6 months), the welcome/integration phases and the transfer of necessary know-how must be defined and recorded.

7.3 - Information Management

The organisation's quality management system must include:

a) the defined rules (including the procedures) required by the specific standard reference document;
b) the records that the organisation deems necessary for managing the transport of health products.

A description of information management responsibilities must be drawn up and documented.
Good information management practices must be implemented (verification, dissemination, modifications, corrections, traceability, archiving), including for documents and records held on computerised media.

Records demonstrating compliance with this Certipharm specific standard reference document must be available and retained for a period of time conform to regulatory requirements and a minimum of three years.

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8 – PERFORMANCE OF OPERATIONAL ACTIVITIES

8.1 – Relationship with the ordering customer and health product transport requirements

A specification sheet shall be drawn up between the ordering customer and the carrier ensuring the latter's capacity to meet the customer's requirements and confirming them.

If the ordering customer is a pharmaceutical company, the specification sheet shall be signed or co-signed by the company's Official Pharmacist.

As a minimum, it must include:

- the "normal" conditions of temperature and transport time for the consignments assigned as well as the customer's acceptable temperature bands and time limits (e.g. suppositories, suspensions);
- the procedures to follow in case these limits are violated. The specific labeling provisions for health products. If the ordering customer refuses to identify its consignments in a specific and explicit manner (e.g. a sticker stating "health products", "medicinal products", a drawing, logo, temperature restriction), the customer will have no guarantee with respect of the terms and conditions of transport as described in the standard reference document;
- the nature of the packaging. When the customer packs the product to preserve it and in certain cases to maintain its temperature (insulating packaging, dry ice etc.), the temperature management of the health product depends in part on its packaging and in part on the terms and conditions met by the carrier. The labels added by the carrier should not obscure the original information affixed by the ordering customer;
- the action to take (especially emergency measures for toxic products, narcotic drugs, psychotropic drugs if known to the carrier) and the emergency contact persons if issues arise (theft, breakage, damage, extreme temperatures etc.);
- the obligations to be fulfilled upon delivery to a health professional: compulsory by hand delivery to the addressee;
- documents attesting to delivery according to the contract;
- the limits and nature of any authorised subcontracting, the requirement of special conditions if any.

8.2 – Management of transport subcontracting

The carrier shall identify its transport subcontractors and keep an up-to-date list specifying their respective activities until delivery is made. This may cover any type of transport operation including handling operations.

It is the carrier's responsibility to ensure that all its transport subcontractors are aware of and comply with the requirements of this standard reference document.

A specification sheet setting out the applicable requirements of this standard reference document shall be put in place and validated by the transport subcontractor.

A transport subcontractor audit programme shall be drawn up annually to ensure compliance with the specification sheet. The programme shall take into consideration the size of the transport subcontractors and their performance.

There must be a documented referencing, review and reassessment procedure of the subcontractors involved in the transport chain.
This procedure must contain referencing and review criteria relating to the requirements of the Certipharm standard reference document.
Reassessment shall be carried out at least once a year and checks shall be made of the effectiveness of the improvements the transport subcontractors have been asked make.

The transport subcontractor management activities shall be recorded.

8.3 – Management of transport services

8.3.1 – Provision of transport at ambient temperature

The operating procedures must describe: the quality and quantity controls of the transport service, the loading and unloading operations, the compliance checks and cleanliness of the equipment and the freight compatibilities. The concept of "ambient temperature" in the case of health products should not be interpreted as "any temperature": "tolerance bands" must therefore be stated with the possibility of exceeding them for short periods, such excesses of time and temperature falling within the agreements (contracts) made with the ordering customer.

Temperature measurement

For transport and on-site transits, the "acceptable ambient" temperature for consignments is fixed at between +5 and + 30°C, according to stability studies on medicinal products and averaged regional readings. It shall therefore be monitored regularly. Temperatures will be noted and recorded in cases where these values violate the limits.
If the limits accepted by the ordering customer in the contract are violated (on a regular or exceptional basis), this information - variances in temperature or time - must be provided to the ordering customer and to the consignee, in accordance with the defined method and time limits.
A risk assessment of temperature violation (+5, +30) based on measurement campaigns must be carried out on all transport operations (e.g. removal/collection and distribution rounds, transfer from one site to another) and the identified risks and management actions be validated by the ordering customer and the official pharmacist shipper. This assessment must be reviewed at least every 3 years. It may be annexed to the specification sheet (see ch.8.1 on the specification sheet).

Labelling

The ordering customer's labelling must remain unchanged.

Conditions for the takeover and delivery of medicinal products; prevention of contamination and deterioration
Preservation: the packages must be handled with care - to prevent falls, shocks, crushing, infiltration, leakage, breakage or theft - while respecting all instructions on the boxes with regard to fragility, direction (up/down for example) or the temperature if necessary. At every transport stage, they must be placed in clean areas and be protected from bad weather and pests. They should never be in direct contact with the ground.

The carrier will give instruction as to the compatibility of the medicinal products with other types of freight to avoid the risk of spoilage or contamination. In particular, health products must be separated or isolated from unpackaged food products, seafood or unprocessed meat products, live animals or hazardous products according to their regulations, soiled products, tyres, etc.

Depending on the nature of the load, the carrier may provide additional protection (e.g. pallet covering) to avoid any risk of contamination.

In the event a consignment leaks during transport or whilst in a dock holding area, the carrier must plan for isolation, safety and handling measures in order to avoid contamination of other consignments and potential accidents. A risk assessment carried out in relation to the transport terms and conditions and the nature of the freight being carried will determine which measures should be taken. The leaking

consignment and nearby contaminated consignments may be isolated using labelled leakproof bags that may vary from one carrier to another. In the same way, the technical solution must be adapted to these conditions (volume, vehicles etc.), to the nature of the freight and to the related environmental risks.

Upon delivery to health professionals, the consignments of medicinal products must never be left at a door, even in the shade, or given to any person other than the designated consignee.

Prevention of mix-ups and confusion
An adaptive physical or administrative management approach must be used to prevent mix-ups or confusion between products or consignees.

Special services
For products requiring special conditions (narcotic drugs, psychotropic drugs, highly active products, radioactive products, temperature-sensitive products), the special provisions set out in the specifications sheet must be implemented.

Traceability
Operations relating to the health products must be effectively and permanently traceable (reception, transit, checks, loading, transport, delivery to designated persons).
An appropriate traceability system must be in place for the health product consignments. The traceability system should be tested at least at every significant change affecting such traceability. The effectiveness must be documented.
This traceability must include as a minimum:
- the dates and times of any load breaks,
- temperatures if certain temperatures are required,
- evidence of takeover, transfers of liability to a third party (subcontractor) and delivery of the consignments.

8.3.2 – Specific requirements for temperature-controlled transport

Controlled temperature

This clause covers all refrigerated enclosures used to maintain the temperature chain: vehicles, containers, transit premises - up until the final consignee.

The ordering customer will define the temperature range for temperature-controlled transport. This will usually be between + 2°C and +8°C or between +15°C and + 25°C with no violation of these limits and ensuring that ambient climatic conditions (summer, winter) have no detrimental effect.
There is no exclusion for negative cold transport (frozen products).

Temperatures will be recorded continuously - by reliable temperature sensors arranged in a representative manner within the enclosure. The recordings will be made at least every 15 minutes, which can be adjusted (up to 2 minutes) depending on the products' sensitivity to low temperatures.

Securement
Cold units must be equipped with an automatic circuit breaker to mitigate against any damage caused by leakage and therefore to prevent freezing.
An alarm system to detect immediately any drift of temperature must also be in operation.
An incident management protocol - approved by the ordering customer - must be applied (immediate corrective action, examined preventive action, information from the ordering customer).
Undelivered products (e.g. returns) must be maintained under the same temperature conditions.

Qualification
The premises and equipment will be qualified (mapping at the time of the first delivery and then afterwards at regular intervals not exceeding three years). The qualification reports will be available.
Moreover, in the event of a technical intervention, the impact on the refrigeration equipment must be assessed and be validated in writing.

Temperature traceability requirements
The carrier must ensure that temperatures can be traced throughout the takeover period of the products (from removal until delivery to the consignee, including in transit premises, if applicable).

As a minimum, records shall be kept for the period specified in the specifications sheet and for at least three years.

8.4 – Management of non-compliance

Non-compliance
Events of non-compliance must be examined immediately.
The measures for handling events of non-compliance: analysis, implementation and follow-up of corrective action, must be defined and documented.
A procedure will describe in detail the handling of damaged or lost consignments as well as set out the instructions and information to be sent to the ordering customer in the event of theft. Internal staff concerned must be made aware of any specific requirements provided by the ordering customer.
The procedure for managing non-compliant products must include as a minimum:
- rules for blocking and releasing products,
- rules for identification (labeling, for example) and isolation,

- the records to be drawn up and retained,
- the responsibilities and authorities.

Customer complaints

Complaints must be managed on a systematic basis. The complaints handling procedure shall cover complaints from shippers and consignees as well as any anomalies detected before presentation to the consignee (in the case of a series of carriers).

The severity of the complaints must be assessed in order to be handled appropriately. A documented procedure will set out the rules, responsibilities, authorities and records for handling complaints.

Information resulting from the processing of complaints must be analysed and used for continuous improvement purposes in order to limit the risks identified.

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9 – PERFORMANCE ASSESSMENT

9.1 – Quality indicators

The organisation must define:

a) that which needs to be monitored and measured;
b) the monitoring, measuring, analysing and assessing methods necessary to ensure that the results are valid;
c) when the monitoring and measuring need to be carried out; and
d) when the monitoring and measuring results need to be analysed and assessed in order to action improvement.

The organisation shall draw up quality indicators regrouping the measures for assessing performance and also the effectiveness of the quality management system. It must keep records of the results from the quality indicators.

9.2 - Internal audit

The organisation shall draw up and keep up-to-date written procedures for the planning and conduct of internal audits. These procedures will help to ascertain whether the activities relating to the transport of health products and the corresponding results comply with the requirements of the Certipharm standard reference document and will also help to determine the effectiveness of the health product transport management system.
Internal audits will be scheduled according to the nature and size of the activity being audited. Nevertheless, these cannot be carried out more frequently than the duration of a certification cycle, i.e. three years. Such audits must extend to cover all the activities mentioned in the Certipharm standard reference document.

The internal audits will be conducted by persons independent of those with direct responsibility for the activity audited, and be trained in this type of activity.
The results of the audits will be recorded and brought to the attention of those responsible for the domain under audit.

Those responsible for this domain undertake to carry out corrective measures as soon as possible to remedy the deficiencies found during the audit.
The shortcomings observed will be recorded and documented, whether they originate internally or externally.
Consequent corrective measures will be taken, which must be recorded. The corrective measures decided upon will be followed up until their effectiveness has been ascertained.

9.3 - Annual audit

The company Management shall carry out a regular audit (at least annually), to evaluate the operation and performance of its quality management system.

This audit will include an analysis of the following items (non-exhaustive list):

- The results of inspections
- The results of quality indicators
- The internal and external audit reports (and associated action plans)
- The events of non-compliance
- The complaints
- The transport subcontractor evaluations
- The achievement of objectives defined in the quality policy
- The context developments that could have an effect on the system (e.g. regulations, norms).

This audit shall be documented, along with the observations and decisions made for each subject concerned. The improvement measures decided upon shall be followed up in the context of the continuous improvement process.

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10 - IMPROVEMENT MEASURES

When an event of non-compliance occurs, including one relating to a complaint, an internal or external audit or a connected activity, the organisation must:

a) respond to the non-compliance, and if necessary:
   - take action to manage and correct it; and
   - deal with the consequences;

b) assess whether it is necessary to take action to eliminate the cause(s) of the non-compliance, such that it will not be repeated or arise elsewhere, by:
   - carrying out a review and analysing the non-compliance;
   - investigating and analysing the causes of the non-compliance; and
   - investigating whether similar non-compliance exists or could arise at a later date;

c) implement any action required;

d) examine the effectiveness of any corrective action taken;

e) update the risks and opportunities defined during the planning stage, if necessary; and

f) modify the quality management system, if necessary.

The corrective action must be appropriate to the consequences of the non-compliance encountered.

The improvement process must be initiated and implemented if a preventive improvement need is identified, in particular during the annual audit.

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