

Charter governing the Dispatch, Transportation and Reception of Medicinal Products and Medical Devices

Contributors/Authors

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CHRONOPOST, EUROTRANSPHARMA, GANDON, GEODIS LOGISTICS, HEPPNER.

Introduction

To succeed in the challenging task of making medicinal products and medical devices available as quickly as possible throughout France, efficient logistics interaction between Shippers, Carriers and Distributors is key.

Transportation is an essential link in this medicinal product and medical device distribution chain.

Changes in working conditions and the ongoing development of technologies are such that the relationship between real-life practice and legislation is not always appropriate or relevant.

On the one hand, transportation legislation regulates this vast industry without the use of precise specifications, while on the other hand, the French Public Health Code defines the pharmaceutical responsibility for transportation-related operations (see also: 'Recommended good practices applied to the transportation of healthcare products' issued by the French National Chamber of Pharmacists) and finally the 'Guide to Wholesale Distribution Good Practices sets out the conditions required to maintain quality levels during the transportation of pharmaceutical products (this document provided the guidelines underpinning the preparation of this charter).

Given the multiplicity of regulations, a charter agreed by the different partners is necessary; it does not set out to provide a replacement for current legislation, but rather to adapt and simplify the relationships between partners in ways that ensure a level of quality that benefits everyone.

Purpose

This charter is integral to the wider process of standardizing inter-professional interaction with the purpose of optimizing flows of information and products. It specifies the operating rules governing deliveries from shippers to distributors.

It provides the basis for the relationship between the Shipper which DISPATCHES the products, the Carrier which has responsibility for their TRANSPORTATION, and the Distributor which handles their RECEPTION, as well as the basis for the specifications agreed between the shipper and the carrier. The rules set out in the specifications may not contradict the standards agreed in this charter.

Its acceptance by shippers, distributors and each carrier engaged by the shipper/loader for deliveries made either by the shipper or via a subcontractor, partly addresses the issue of delivery supervision.

It must be accompanied by systematic introduction of the Full Dispatch Advice (DESADV) message from shippers to distributors and the Reception Advice (RECADV) message from distributors to shippers.

This charter does not exclude possible separate individual agreements between partners.

Reference used: Charter governing the Dispatch, Transportation and Reception of Medicinal Products and Medical Devices (Version 1).

Charter

Charter between Shippers/Loaders and Carriers

For a delivery to be made as efficiently as possible, the order preparation and dispatch process must comply with the following:

- Handling Units (H.U.) must be labeled in such a way as to prevent any type of problem.

Labels used must not be accidentally detachable and the recipient must be clearly identified. Where the H.U. is a pallet, it must carry the following to provide all partners with the practical information they need: a 'Do Not Break Stretch Wrap' label on each side, an easily accessible pouch containing the delivery note and a logo-printed stretch wrap or tamper evident security tape identifying the shipper.

- A Handling Unit may not be created out of a grouping of orders from several contractors, unless otherwise agreed.

For practical and safety reasons, it is recommended that pallet (handling unit) size should not exceed 1.70 meters (or 1.60 meters high for air freight).

- The physical dispatch must match the number of Handling Units shown on the shipping order.

This check can be made at the point of loading or following the delivery report. If the Carrier confirms dispatch without flagging up any nonconformity, then any difference in the number of Handling Units received will trigger a carrier dispute.

Charter between Shippers/Loaders, Carriers and Distributors/Recipients

The recipient must, on request, be provided with the identities of the carriers that have taken charge of the products and those that will physically deliver them.

The delivery dates

Arrangements regarding delivery dates and schedules are made individually by agreement between Shippers and Recipients or between Carriers and Recipients in full compliance with all applicable regulations. In the absence of any such individual agreement, deliveries must be made during the opening hours of those departments authorized to receive goods on the premises of the recipient, provided that the carriers have been notified of these opening hours.

The delivery

The consignment note provided by the driver must be a (full or partial) true copy of the shipping order. It is provided in printed form or in electronic form (on a smartphone, tablet or computer), and must show:

- The name of the shipper
- The name of the recipient
- The name of the carrier
- The name of the person or entity placing the order
- The date of collection
- The anticipated delivery date
- The number of Handling Units to be delivered to the recipient
- The weight
- Controlled temperature transportation conditions must be indicated, where appropriate: 2°C-8°C or 15°C-25°C.

Electronic consignment notes may be used for all deliveries. Where the consignment note contains detailed reservations, the Carrier must provide it in printed form. **Only** those reservations entered on the printed consignment note have legal standing.

Recipients ensure that:

- the Handling Units are intended for them
- the Handling Units carry tamper evident security tape and an identification label
- the number matches that shown on the consignment note
- the Handling Units appear to be in good condition

If an H.U. is damaged, a detailed reservation will be issued in respect of this unit

For insulated H.U. transportation, the H.U. (or H.U.s) containing products subject to 'logistics-related temperature constraints' must carry a label indicating the delivery cutoff date and time (completed by the supplier at the time of packaging or shipment).

Any delivery beyond the cutoff time will be the subject of a detailed reservation issued to the carrier. The customer will contact the supplier to decide whether the product can be offered for sale or whether a carrier dispute should be raised.

If it is not possible at the time of receipt to demonstrate that the consignment has been kept at the required temperature, the recipient enters a written reservation on the consignment note, isolates the products at the required temperature and contacts the pharmaceutical company to decide whether the product can be offered for sale.

On completion of the delivery inspection, the consignment note is returned to the driver on the same day carrying the following information:

- The name and signature of the person receiving the delivery
- The recipient's company stamp
- The delivery date and time (if required)
- Detailed reservations (where necessary)

The formulation of detailed reservations

These reservations are acceptable as evidence only when in writing. The Carrier must provide the recipient with two copies of the consignment note so that any reservations can be detailed in writing. The consignment note is signed by the Recipient and by the Carrier where there is any counter-reservation (the driver and the recipient cannot agree on the reservation expressed). These reservations can be raised only where non-compliance with the following points is claimed:

- Recipient error,
- Non-compliance with the information contained in the consignment note,
- Visible damage.

The list of formulas to be used is clearly established, universally accepted and can be summarized as a combination of the following reasons and sub-reasons:

- H.U. missing: relative to the Dispatch Advice/Delivery Note
- H.U. too many
- H.U. damaged, rejected: ripped open and/or crushed
- H.U. damaged, rejected: wet
- H.U. damaged, rejected: open
- H.U. damaged, rejected: traces of seepage
- H.U. damaged, rejected: temperature incorrect
- H.U. damaged, rejected: other (to be specified)
- H.U. damaged, retained for sorting: ripped open and/or crushed
- H.U. damaged, retained for sorting: wet
- H.U. damaged, retained for sorting: open
- H.U. damaged, retained for sorting: traces of seepage and/or stains
- H.U. damaged, retained for sorting: other (to be specified)
- H.U. isolated for analysis: temperature incorrect
- Recipient error attributable to carrier

These detailed reservations are confirmed to the carrier by registered letter within three days (excluding public holidays) of receipt of the goods concerned (Art L133-3 of the French Commercial Code). A copy of the letter is sent by ordinary mail or any other means to the department responsible for handling the dispute.

Detailed reservations notified to the carrier in accordance with the provisions set out in this charter may form the basis of a subsequent dispute. This dispute must be settled within a maximum period of two months.

We must however take into account the specific features of the products transported to optimize health product availability and ensure compliance with the French Public Health Code.

- Where a damaged carton could potentially enable the release of its contents if returned to the carrier, it will be retained by the recipient.

In this scenario, the wording of the detailed reservation will be: H.U. damaged and retained for destruction.

After a minimum period of 15 days, and unless otherwise instructed by the shipper, the damaged H.U. will be destroyed and a certificate of destruction sent to the pharmaceutical company.

- By specific contractual agreement with the shipper, a slightly damaged H.U. may be retained by the recipient so that its contents can be sorted into salable and unsalable units. In this case, the wording of the reservation will be the same as in the previous scenario, but the confirmation by mail will indicate only the number of unsalable units.

Glossary

Order: the order issued to the shipper (direct or subcontracted) by the Distributor and detailing one or more product reference indexed by a unique 'Distributor Reference for the Order' identifier.

Handling Unit (H.U.): An individualized entity consisting of shipping packages (security tape stretch-wrapped pallets, pallets grouped for handling, individual packages, etc.) and passed by the shipper to the carrier for delivery in the same condition to the recipient. Under no circumstances may the carrier split or group H.U.s in order to create another H.U.

The Handling Unit definition is used in the transportation regulations, and is commonly referred to as a Shipping Unit in electronic communications (e.g. DESADV).

Package: An individually handleable H.U. The package is the smallest shipment packaging unit.

Pallet:

Scenario 1: Loading platform for handling goods: in this case, the pallet is merely a supporting structure, and only the H.U.s (individual packages) it carries are relevant. These are unbundled and checked on arrival by the recipient.

Scenario 2: Handling Unit: in this case, the pallet takes the form of a stretch-wrapped entity, sealed with a tamper evident security tape identifying the shipper/loader.

Shipment: one or more handling units.

Consignment note: also known as a receipt or CMR in French (Convention de Transport des Marchandises par la Route), the consignment note is a contractual document prepared by the Carrier on the basis of information provided by the Shipper, and accompanies the transported goods at every stage of transportation. This document contains the following information: the contact details of the shipper, recipient and carrier, the number and weight of handling units, and any additional instructions.

It provides proof of delivery of the goods and is the official document to be used for the notification of detailed reservations.

Delivery note: the delivery note is prepared by the shipper and provided to the recipient to indicate the quantity and nature of the goods received.

Security tape: also known as tamper evident tape, it takes the form of an adhesive packaging tape carrying the name of the shipper or stretch-wrap film carrying a logo applied by the Shipper. Its purpose is to ensure the integrity of the H.U.

Shipper/Loader: the company (pharmaceutical company or its consignee) that organizes the transportation of goods on behalf of a principal or on its own account, but does not provide the transportation service.

Principal: company (laboratory or its consignee) contracted to provide transportation.

Carrier: the carrier is responsible for the goods from collection to delivery, and for ensuring full compliance with all clauses of the transportation contract.

Recipient: person or place receiving the goods, as identified in the consignment note.

Appendices

Extract from Chapter 9.2 TRANSPORTATION of Good Distribution Practice of medicinal products for human use

The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described by the manufacturers or on the outer packaging.

If a deviation such as temperature excursion or product damage has occurred during transportation, this should be reported to the wholesaler distributor and recipient of the affected medicinal products.

A procedure should also be in place for investigating and handling temperature excursions.

It is the responsibility of the wholesale distributor to ensure that vehicles and equipment used to distribute, store or handle medicinal products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity.

There should be written procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

Risk assessment of delivery routes should be used to determine where temperature controls are required.

Equipment used for temperature monitoring during transport in vehicles and/or containers should be maintained and calibrated at regular intervals at least once a year. Dedicated vehicles and equipment should be used, where possible, when handling medicinal products. Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the medicinal product will not be compromised.

Deliveries should be made to the address stated on the delivery note and into the care or the premises of the consignee. Medicinal products should not be left on alternative premises.

For emergency deliveries outside normal business hours, persons should be designated and written procedures should be available.

Where transportation is performed by a third party, the contract in place should encompass the requirements of Chapter 7. Transportation providers should be made aware by the wholesale distributor of the relevant transportation conditions applicable to the consignment.

Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facilities.

Reminder: the carrier may under no circumstances repack a package damaged in transit. This avoids the potential issue of an apparently intact package containing damaged products.

Decree 2017-461 of March 31, 2017 relating to Appendix II of Section 3 of the French transportation code regulations regarding the standard contract applicable the transport of goods on public roads where no specific model contract exists

11.2.1.3. Under all circumstances, where a carrier arrives early, the periods referred to in Articles 11.2.1.1.1. and 11.2.1.2. shall commence only from the agreed appointment time or the start time of the agreed time slot.

11.2.2. Suspension of downtimes:

In the event of an agreed appointment time and/or time slot being missed, those periods of availability not elapsed at the time when the goods shipping department or goods reception department closes shall be suspended until the opening time of the department concerned on the first subsequent working day.

In the event that an agreed appointment time and/or time slot is not missed, or there is no agreed appointment time or time slot, the suspension referred to above does not apply.

11.3. Overrun of downtimes:

In the event that the periods thus fixed are overrun for reasons not attributable to the carrier, the latter shall receive from the party responsible an additional payment to cover the downtime costs of the vehicle and/or crew, this amount to be invoiced separately in accordance with the provisions of Article 18 below. If loading operations have not begun by the end of the periods deducted in accordance with Articles 11.1 and 11.2, the carrier shall be entitled to refuse acceptance of the goods with no compensation payable.

Extract from *Le Lamy Transport*, volume 1, relating to loading and unloading times

“For the shipping or delivery of an order:

- Less than 100 kg and fewer than 20 H.U.s: 15 min.
- More than 100Kg and more than 20 H.U.s: 30 min.
- Between 3 and 10 metric tons where the time slot is respected: 1 hr., 30 min.
- More than 10 metric tons where the time slot is respected: 2 hr.”

CARRIER DISPUTE ON RECEPTION OF GOODS

COMPANY / BRANCH	Ile de France	LETTER OF RESERVATION ADDRESSED TO THE DELIVERING CARRIER	
Contact name	Mme Durand, Marie		
Phone	01 49 01 02 03		Registered letter / copy to the SHIPPER
Fax	01 49 01 02 03		Groupe Transport
e-mail	mdurand@grossiste-repartiteur.fr		104 Avenue Général Leclerc
Case number	01137252		ZA des Hayettes
Date	30/05/2018		95000 PONTOISE
Shipper	LABORATOIRE FRANCE		
Customer code	3486		

Order date and no.	24/05/2018	205148	Date of receipt	29/05/2018	Weight advised	175
Date and DA/DN no.	25/05/2018	463947003	Receipt no.	463947003	Number of packages advised	1
					Number of pallets advised (if contracted)	

REASON FOR THE DISPUTE	ASSOCIATED SUB-REASON	ASSOCIATED CLARIFICATION
101 - MISSING	01 - Other (specify)	2 - Do not send a supplementary shipment
102 - TOO MANY	03 - Ripped open. Crushed	Issue credit note / We will reorder
103 - DAMAGED, REJECTED	06 - Wet	4 - Retained / To be invoiced
104 - DAMAGED, RETAINED FOR SORTING	07 - Open	5 - To be returned / Issue credit note
105 - ISOLATED FOR ANALYSIS	08 - Traces of seepage. Stains	6- Returned / Returned to transportation company
110 - RECIPIENT ERROR ATTRIBUTABLE TO TRANSPORTATION COMPANY	09 - Relative to Dispatch Advice/ Delivery Note	
	17 - Temperature incorrect	

ITEM DETAILS

ITEM CODE	ITEM NAME	DISPUTE REASON CODE	ASSOCIATED SUB-REASON CODE	ASSOCIATED CLARIFICATION CODE	NO. OF PACKAGES DISPUTED	QUANTITY DISPUTED	QUANTITY SHOWN ON DEL NOTE/DISPATCH ADVICE	QUANTITY RECEIVED
3400930421562	DOLIRUTIL 400MG CPR BTE 30 Damaged, retained for sorting-Ripped open, crushed-Do not send a supplementary shipment, Issue credit note, We will reorder. Batch no. 242294	104	03	02	1	30	120	120

ATTACHMENT(S): TRANSPORTATION RECEIPT DN

RESPONSE OF SHIPPER (to be passed on to the distributor and/or attach this document to the Credit note / Adjustment invoice)

Date: Dispute supervised by:..... Tel.: Fax:

- CREDIT NOTE / INVOICE: Enter the document references.....
- OTHER Explanations:.....

<input type="checkbox"/> FOLLOW-UP	<input type="checkbox"/> DISPUTE RESOLVED	Stamp, date and signature of distributor Grossiste Répartiteur RECEPTIONNE LE 29 MAI 2018 <i>Non Primus signature</i>
Date:.....	Date of resolution:.....	
Remarks:.....		

<p>Carrier Transporteur Groupe France S.A.S. €500.000 ZA des Hayettes 104 avenue Général Leclerc 95000 PONTOISE VAT no. FR01545723456</p>	<div style="border: 1px solid black; padding: 5px; font-weight: bold; font-size: 1.2em;">HEALTH</div>	<div style="border: 1px solid black; padding: 2px;"> <p>CONSIGNMENT NOTE No. 45678912</p> </div>	<div style="border: 1px solid black; padding: 2px;"> <p>ROUND 060</p> </div>	<div style="border: 1px solid black; padding: 2px;"> <p>NO. HU 1</p> </div>										
<div style="border: 1px solid black; padding: 2px;"> <p>345678 LABORATOIRE FRANCE</p> <p>SHIPPER 82 AVENUE Jean-Jaurès 94600 CHOISY-LE-ROI FRANCE</p> </div>	<div style="border: 1px solid black; padding: 2px;"> <p>Wholesale distributor Ile de France</p> <p>RECIPIENT 123 AV CHARLES DE GAULLE 93000 BOBIGNY</p> </div>	<div style="border: 1px solid black; padding: 2px;"> <p>WEIGHT (kg) 175.0</p> </div>												
<div style="border: 1px solid black; padding: 2px;"> <p>Shipped 05/28/2018 DESCRIPTION OF GOODS</p> <p>ITEM CODES 463947 195585</p> </div>		<div style="border: 1px solid black; padding: 2px;"> <p>Shipped 05/28/2018 DESCRIPTION OF GOODS</p> <p>65 packages in 1 Pallet</p> </div>			RECIPIENT COPY									
<div style="border: 1px solid black; padding: 2px;"> <p>DELIVERED BY CARRIER</p> <p>TRANSPORTEUR GROUPE FRANCE ZA des Hayettes 104 avenue Général Leclerc 95000 PONTOISE Tel. 0124567890</p> <p style="text-align: right;"><i>Non Pénson signature</i></p> </div>		<table border="1" style="width: 100%; border-collapse: collapse; font-size: 0.8em;"> <tr> <td style="width: 15%;">HAZARDOUS MATERIALS</td> <td style="width: 15%;">CONTRACT TYPE</td> <td style="width: 15%;">CARRIAGE EXC. TAX</td> <td style="width: 15%;">VAT</td> <td style="width: 15%;">COST INC. TAX</td> </tr> <tr> <td style="text-align: center;">NO</td> <td style="text-align: center;">CARRIAGE PAID</td> <td></td> <td></td> <td></td> </tr> </table> <p style="text-align: center; font-style: italic;">recu 2 colis cassés conservés pour tri</p> <div style="text-align: right;"> <p>Wholesale Distributor DATE RECEIVED MAY 29, 2018</p> <p><i>Non Pénson signature</i></p> </div>			HAZARDOUS MATERIALS	CONTRACT TYPE	CARRIAGE EXC. TAX	VAT	COST INC. TAX	NO	CARRIAGE PAID			
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SUMMARY

In the context of inter-professional interaction between manufacturers, authorized agents and distributors, the control of physical flows plays a key role in ensuring the availability of medicinal and health products as quickly as possible throughout France.

It involves pharmaceutical companies (Shippers and Distributors) and transportation companies, which are governed by separate legislation.

To facilitate their relationships, these partners have drawn up a Charter in two parts: one part setting out the rules for interaction between Shippers and Carriers, and the other standardizing the relationship between Shippers, Carriers and Distributors.

This charter forms the basis of specifications agreed between the shipper and the carrier, responds partially to the issue of delivery supervision, and does not rule out possible separate individual agreements.

KEY WORDS

Charter – Dispatch – Transportation – Reception – Delivery – Logistics – Flows – Medicinal Products – Medical Devices – Shipper – Loader – Supplier – Carrier – Distributor – Recipient – Handling Units – Shipping – Package – Order – Pallet – Carton – Dispute – Consignment Note – Delivery Note – Security tape – Wholesaler



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