Delivery instructions

Date: 08/2016

General Section

Explanation

The delivery instructions listed here are valid for all orders from Teva Deutschland. Teva Deutschland includes:

- AbZ-Pharma GmbH
- Merckle GmbH
- Merckle Biotec GmbH
- Teva Biotech GmbH
- Pliva Real Estate GmbH
- ratiopharm GmbH
- ratiopharm Immobilienverwaltung GmbH & Co. KG
- Teva GmbH
- Teva Health GmbH
- Teva Pharma GmbHTranspharm Logistik GmbH

These companies are hereinafter referred to as “Teva”.

Apart from these general delivery instructions, additional specifications may need to be noted, depending on the material/goods group or type of service, e.g.:

- Delivery instructions for finished goods/finished cytostatics/give-aways and service articles
- Delivery instructions for raw materials
- Delivery instructions for packaging materials/packaging

Deviations from any delivery instructions can only be made by written agreement. An oral agreement is not valid.

These delivery instructions do not constitute a release from the current obligatory legal regulations.

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1. Confirmation of order and invoice

1.1 Confirmation of order

Only a copy of the order from Teva should be used to confirm the order.
If the supplier has important reasons for using its own form to confirm the order, the following general data must be provided in addition to the Teva confirmation:

- Teva purchase order number
- Teva material number as well as the product name/order reference used by Teva
- Name and address of the manufacturer
  The name must match the details on the order, otherwise the supplier must immediately inform Teva of the deviation
- Deviations from the orders must be indicated clearly

Deviations from the Teva order must be agreed in writing.
The supplier must send the signed order confirmation by email or fax within 10 business days of order placement to the contact person for the order.
The order confirmation must not be sent to Teva more than once.

1.2 Invoices

A single copy of the invoice must be sent by the supplier to the invoicing address given on the order.

The following information must be included on the invoice:

- The full name and postal address of the service provider and the postal address of the service recipient specified on the invoice
- The tax number of the service provider issued by the Tax Office or the VAT identification number issued by the Federal Central Tax Office
- The VAT identification number of the service recipient specified on the Teva order
- The date of issue
- A unique, consecutive number with one or more rows of numbers allocated by the invoicer to identify the invoice (invoice number)
- The quantity and type (standard trade name) of the items delivered or the scope and type of the other service
- The time of the delivery or other service
- The fee for the delivery or other service itemised by tax rate and individual tax exemption, as well as each previously agreed reduction of the fee, insofar as these have not already been incorporated into the fee

- The tax rate to be used for the fee and the amount of tax to be paid, or in the case of a tax exemption, a note that a tax exemption has been applied to the delivery or other service
- Teva material number
- Teva product name
- Purchase order number

The Teva purchase order number or the cost centre of the Teva employee who has placed the order is also required. Teva cannot pay the delivery invoice if this is not provided.

Teva offers its suppliers the option to submit invoices to Teva by email in PDF format. Certain requirements must be met in this case. For more information on the process, please contact:

- Accounts_Payable_Ulm@ratiopharm.de

2. Packaging requirement

The supplier must pack and identify the items to be delivered in the required and appropriate manner so that they cannot be damaged under normal transport conditions and will not damage other goods.
Furthermore, the regulations in Section 4.2 ***Hazardous goods*** must be observed.

2.1 Pallet specifications

Generally, only deliveries on new or mint condition (hygienically clean) Euro-Pool pallets (800mm x 1200mm) with IPPC markings will be accepted (see ***Annex 3***). Damaged pallets must immediately be exchanged to avoid injury, e.g. from protruding nails or splinters. The pallets used must be “heat-treated”. Pallets branded with “PKP” will not be accepted.
Containers must not extend past the edge of the pallet. The containers must be secured on the pallet. Where load securing allows, the entry channels must be kept free.

3. Loading and transport

Notwithstanding the agreed delivery conditions (Incoterm), Teva reserves the right to collect the items to be delivered using, or on behalf of, Teva Transport Management. The supplier is obliged to conform to the following specifications, insofar as they are accepting or are contracted to provide the loading and transport services in whole or in part, either on the basis of the order or as expressly agreed in writing with Teva Transport Management according to the order.
The supplier is obliged to provide appropriate and standard compensation of freight costs if Teva assumes the suppliers' contractually guaranteed transport service in whole or in part.

3.1 Loading

Insofar as the conditions or common usage do not provide otherwise, the sender must load, stow and secure the goods safely for transport (loading) as well as unload. The freight carrier is responsible for safe loading.

This does not affect the identification of hidden defects and is subject to the contractual arrangements where a supply contract is in place. The legal regulations are otherwise in force.

3.2 Transport vehicle

All pharmaceutical transport is to be carried out exclusively using GDP (Good Distribution Practice)-compliant vehicles. The regulations can be found in the current version of the GDP Guidelines.

3.3 Data logger

Each pharmaceutical transport is to include data loggers.
The types of data loggers used should be TempTale (single use) or Marathon (single use).
In individual cases, the supplier can order the required data logger by email at least 10 days before dispatch at:

- temperature-datalogger@ratiopharm.de

In general:

- The data loggers must be activated before dispatch and labelled with the date and batch designation
- Two data loggers per delivery or load must be placed in two different positions of the delivery/load
- For sea and air freight, two data loggers are to be included for every 24 pallets
- The data loggers must be included in a separate carton on the incomplete pallet
- The carton must be clearly labelled and bear the following text:
  “Data logger inside” (corresponding labels are provided with the data loggers if required)
- The delivery papers must note the pallet on which the loggers are located

3.4 Collection using Teva's own vehicles

All dispatches are to be reportedpunctually to the following email address, no later than three business days before the scheduled delivery:

- dispo.fuhrpark@ratiopharm.de

For notification, use the “Notification of collection” in the Annex (see ***Annex 1***). The following information is required in each case:

- Teva purchase order number
- Purchase order number/supplier's order confirmation number
- Teva product name/order reference
- Type of carrier/container

- Number of containers
- Dimensions (LxWxH)
- Gross and net weights
- Collection address
- Contact person
- Supplier's collection times
- Preparation date of goods
- Indication of hazardous goods
- Confirmation of proper load securing
- Miscellaneous

Teva Transport management will provide the supplier with timely feedback regarding the exact collection time.

3.5 Collection by service providers contracted by Teva

All dispatches are to be reported to the following email address three days before the preparation time (however, no later than three business days before the agreed delivery time):

- DL-DE-CTMOperations@ratiopharm.de

To report the dispatch, use the template “Template Transport Order CTM” (see ***Annex 2***).

The following template fields must be filled in:

- Contact person with name, phone, email (“Ordered by” and “Phone / E-mail” fields)
- Collection address and contact person (“Pickup address” field)
- Delivery address and contact person (“Delivery address” field)
- Preparation time and loading times (“Loading date / time” field)
- Number of pallets (“No. of pieces” and “Packaging type” fields)
- Exact product description (“Description of goods” field)
- Pallet dimensions (“Dimensions of pieces” field)
- Special instructions, e.g. hazardous goods, narcotics, cytostatics (“Special handling instructions” field)
- Temperature specifications (“Temperature regime” field)
- Value of goods (“Shipment value” field)
- Delivery conditions according to order (“Incoterm” field)
- Purchase order number (“Shipping remarks” field)

3.6 Transport exclusively by the supplier

If the supplier itself will provide the transport to the agreed location or contract a third party to provide the transport, please note the following:

Goods receipt times TevaDeutschland (Ulm, Neu-Ulm, Blaubeuren)

The following goods receipt times apply:

Monday to Thursday: 7:00 am - 3:00 pm

Friday 7:00 am - 11:00 am

A time window must be booked for the delivery at Teva, register at:

- www2.cargoclix.com/merckle-ratiopharm

For technical queries, please contact the supplier Cargoclix using the following details:

- timeslot@cargoclix.com
- Tel. +49 (0) 7233 - 97480

4. Legal provisions

4.1 Narcotics

Narcotics of Classes II/III must be delivered exclusively to the location and person specified in the contract together with the relevant documentation pursuant to the Ordinances, following prior written notification.
On delivery, the delivery documentation must be surrendered spontaneously to the employees in Goods Inward.
The copy for the supplier will be sent by post within three business days of the completed delivery.

For narcotics, the void patterns from the beginning and end of the packaging must be sent promptly to the following address:

Merckle GmbH
QO Endproduktkontrolle
Graf-Arco-Strasse 3
89079 Ulm

Alternatively, scans of the packaging material used including the batch and expiry date can be sent by email to:

- batchdocumentation@tevaeu.com

4.2 Hazardous goods

General information

A) Legal specifications
Insofar as the ordered product concerns a dangerous good in the sense of the GGBefG (Gefahrgutbeförderungsgesetz, Hazardous Goods Act), you are obliged to observe and conform with all national and international legal regulations as amended from time to time (e.g. regulation-compliant packaging, identification and labelling of containers, preparation of transport documentation, etc.).

B) Hazard classification
The correct hazard classification for all modes of transport is part of the scope of delivery and must conform minimally to Item 14 of the EU Safety Data Sheet.

Specific information

For the legal terms “dispatcher”, “dispatcher's contractor” or “loader” unclearly defined in the GGVSEB (Gefahrgutverordnung Straße, Eisenbahn und Binnenschifffahrt, Conveyance of Hazardous Goods by Road, Rail and Inland Navigation), the following general agreements apply to guarantee safe transport (note: deviations must be agreed in writing):

i.) Dispatcher

Teva is only the dispatcher if hazardous goods are collected using its own vehicles (§ 2(1), 1st clause GGVSEB).

In this case, our drivers will carry a transport paper prepared by us for collection pursuant to 5.4.1 European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)). Only this transport paper is valid for the transport procedure.

For raw material orders, our classification of the material (reviewed by specialists) will be provided in the order. If your classification differs, please indicate this immediately upon receipt of the order. A dispatch may only proceed when the classification and the associated packaging, identification and labelling conform to international specifications.

For self-collection by our fleet, you are obliged to notify our Planning department of the following details in writing in advance pursuant to paragraph 5.4.1.1.1 letters a to f and k ADR:

a) The UN number

b) The official designation of the transport (together with the technical designation, insofar as special regulation 274 is assigned in Chapter 3.2 Table A column 6)

c) The numbers of the hazard label template to be used as given in Chapter 3.2 Table A column 5 ADR or pursuant to a special regulation in accordance with column 6

d) The packaging group

e) The number and description of the dispatch pallets

f) The total quantity of each hazardous good with different UN numbers, different official names for the transport or different packaging groups (as volume or gross or net mass)

g) Where assigned, the tunnel restriction code given in Chapter 3.2 Table A column 15 ADR

h) If this concerns road traffic goods subject to § 35 GGVSEB, indicate the observations in § 35

Teva is **not** considered the dispatcher if hazardous goods are **not** collected with its own vehicles (§ 2(1), 2nd clause GGVSEB)
If the transport is made on the basis of a transport contract, the dispatcher is considered to be the dispatcher specified in this contract. Your duties as dispatcher are detailed in § 18 GGVSEB.

ii) Dispatcher's contractor according to § 17 GGVSEB.

a) If Teva, in its capacity as recipient pursuant to § 20 GGVSEB, is also considered under certain circumstances to be the contractor of the dispatcher, the obligations from § 17 GGVSEB are transferred to you, as only you as the supplier/manufacturer are able to fulfil these obligations in the logistical process.
b) The same regulation applies to § 410 HGB (Handelsgesetzbuch, German Commercial Code) with regard to the term “dispatcher” used there (“Hazardous goods: if hazardous goods must be transported, the dispatcher must inform the freight carrier promptly in writing of the exact nature of the hazard and, where required, of the safety precautions to be taken.”).

iii) Loader pursuant to § 2(3) and § 21 GGVSEB

Teva is only considered the loader in the sense of § 2(3) sentence 2 GGVSEB if we actually have the influence to fulfil the loader's obligations during the logistical process. If we incur damages as a result of non-compliance with this regulation, they will be transferred to you.

Reason:
In contrast to the international ADR, German legislation defines three standard addressees (simultaneously):
a) Companies that load enclosure materials (§ 2(3) sentence 1 GGVSEB)
b) Also the company that, as the immediate owner of the hazardous goods, hands these over to the carrier for transport or transports them itself (§ 2(3) sentence 2 GGVSEB)
c) The driver (§ 29 GGVSEB)

Problem: there are cases where the loader's obligations (primarily the obligation to ensure secure loading) cannot be observed by all parties concerned at the same time (e.g. shuttle transport, import traffic via sea ports where containers are fixed with security seals which must not be opened by the driver, etc.)

4.3 Safety Data Sheet

Where the delivered material is a hazardous good, the supplier is obliged to submit the current safety data sheet for the corresponding product pursuant to Regulation (EC) No. 1907/2006/EC, Annex 2 (in the current valid version) with the order confirmation.

In the event of changes, the supplier is obliged to provide Teva with each current version spontaneously and promptly.
The supplier must ensure that the registration number in the safety data sheet assigned pursuant to Article 20(1) in the ordinance above is provided.

If the delivered product is not a hazardous good in the sense of the Gefahrstoffverordnung (German Hazardous Goods Ordinance), the supplier must confirm this in writing.
Please send the safety data sheets by email, with the purchase order number or Teva material number, to:

- msds@ratiopharm.de

Regulation (EC) No 1907/2006 - REACHRegistration obligation:
Materials which are not exclusively used in medicinal products (e.g. used in medical devices and cosmetics) must be registered (for manufacturing/import of quantities > 1,000/year per manufacturer/importer). Non-registered materials must no longer be used (“no data, no market”).
In this case, the supplier must report whether it has registered the raw material.

Marketing authorisation obligation:
Materials with defined critical properties (“SVHC materials” = substances of very high concern) may only be used if you as the manufacturer have received marketing authorisation from the ECHA for our planned use (e.g. use in cosmetics or medical devices).
The supplier must report whether the material is listed in Annex XIV of the REACH regulation and whether the corresponding marketing authorisation is available for the planned use. The relevant marketing authorisation documents must be provided.

Identified use:
For materials which are manufactured or imported in quantities greater than 10,000/year and which are used in medical devices or cosmetics, REACH requires details of the identified use and the elaboration of exposure scenarios.

In this case, the supplier must provide a safety data sheet including the identified use and exposure scenarios pursuant to REACH.

Products:

Products (e.g. spray pumps, measuring cups, dosing spoons, packaging) are also covered by REACH, insofar as SVHC materials (see above) are present in the product in quantities greater than 0.1 percent of the mass. The ECHA must be notified of cumulative annual quantities (produced or imported) greater than or equal to 1,000. If materials are intended to be released from products (e.g. in air fresheners), the expanded specifications as described above apply. The supplier must report whether the SVHC materials are present in the products in quantities greater than 0.1 percent of the mass. The exact mass portions in the product must be stated.

All correspondence regarding REACH must be sent to the follow email address:

- reach@ratiopharm.de

Annexes

Annex 1 Notification of collection	 Abholavis.doc
Annex 2 Template Transport Order CTM	 Template Transport Order CTM.xlsx

Annex 3 Pallets	When using pallets, note the following: - Nail positions correct - Correct identification - IPPC standard - Condition: new or mint (hygienically clean) - Dimensions: 800mm x 1200mm