

SUPPLIER GUIDELINE

V.2021

Introduction

This document is the Médecins Sans Frontières European Supply Centers (“MSF ESCs” or individually “MSF ESC”) Supplier Guidelines. It is intended to provide detailed instructions to suppliers of Goods to the “MSF ESCs” listed below:

- (1) **MSF Logistique**, 3 rue du Domaine de la Fontaine 33 700, Mérignac France (“**MSF Logistique**”)
- (2) **MSF Supply**, Chaussée de Vilvorde 140, 1120 Neder-Ober-Heembeek, Belgium (“**MSF Supply**”) and
- (3) **Artsen zonder Grenzen**, Plantage Middenlaan 14 1018 DD Amsterdam, Netherlands (“Artsen zonder Grenzen (“**MSF Nederland**”)

These Guidelines should be read together with the MSF ESCs’ General Purchase Conditions (“GPC”). Where applicable, capitalised terms and expressions used in these Guidelines shall have the meaning ascribed to them in the GPC.

1. Purchase Orders

Purchase Orders shall contain the following minimum information:

- MSF ESC Purchase Order reference;
- Total price;
- Applicable Incoterm;
- Delivery address; and
- In respect of each Good, the MSF ESC item description and code, quantity, Delivery Date and price per unit.

2. Pre-Delivery Documents

Except for the Goods covered by the EU Directive 2001/83/CE, EU Directive 93/42/CEE, EU Regulation 2017/745, EU Regulation 98/79/ EC or EU Regulation 2017/746 (hereinafter referred to as the “Medical Devices”), the Supplier shall deliver the following documents to the MSF ESCs prior to delivery of the Goods:

- Packing List,
- Analysis Certificate,
- Invoice,
- Transport documents (Air Way Bill, Bill of Lading or CMR),
- ASN template (for MSF Nederland only)

The following documents must be provided by the Supplier prior to delivery of Medical Devices:

- Packing List
- Invoice
- Transport documents (Air Way Bill, Bill of Lading or CMR),
- Certificate of Analysis,
- Certificate of Sterility or certification of Sterilization for sterile products,

- Certificate of Compliance, Certificate of Conformance or equivalent,
- any other relevant batch related release document requested by MSF ESCs.

3. Packing List

The Packing List shall include the following minimum information:

- MSF ESC Purchase Order reference;
- Delivery address;
- Description and quantity of each Good delivered per package with reference to the package number;
- Batch numbers, Serialized Falsified Medicines Directive code or Serial numbers for each Good delivered, as well as expiry dates and related quantities;
- Weight & volume (in dm³ if possible) of each package;
- Number of packages for each pallet;
- Total weight, total volume (in dm³, if possible), total number of packages, total number of pallets; and
- Name of supplier, name of manufacturer, country of origin for each Good delivered.

4. Delivery Documents

The following documents must be provided by the Supplier with each delivery of Goods:

- Packing List (either as a separate document with the delivery or in a document bag on the external packaging) and one Packing List for each delivered order;
- Certificate of origin (form A or EUR1);
- Transport document (original) – Airway Bill, Bill of Lading or CMR;
- Shipper's Declaration (where applicable);
- Customs documents and any other documents required for export or customs control (subject to mutual consultation);
- Certificate of Analysis for each delivered batch (in English); and
- Any other documents requested by MSF ESCs (including but not limited to, a valid Certificate of Pharmaceutical Product (CPP) as per WHO Certification Scheme on the Quality of Pharmaceutical Products, evidence of compliance with current Good Manufacturing Practice (cGMP) linked to the Goods production site, the Market Authorization (MA), Health certificate for NFOS, quality documents).

5. Packaging and Labelling Requirements

The Supplier shall ensure that:

- Goods are delivered in individual packages on standard Euro EPAL pallets (80cm x 120cm x 16.6cm), or similar standard pallets available in the Supplier's jurisdiction, and wrapped in transparent film;
- all pallets are in a good state of repair and treated for insects in accordance with ISPM 15 (as evidenced by the appropriate mark);
- each Purchase Order is contained in a separate package;
- Goods are packaged adequately to provide protection against outside influences, particularly against weather conditions prevailing during exportation and transportation including moisture, cold, heat, light and air; in particular, any carton shall be minimum double ply and, for Medical Goods, preferably use white or metallic colours and avoid brown cartons; any fragile articles must be adequately packaged to comply with air and road transport requirements and applicable laws and regulations (including all IATA and IMO regulations);
- individual packages packed on the pallets are sufficiently solid and sufficiently filled (with no empty spaces) to avoid crushing on stacking;
- individual packages are adequately sealed using as much tape as necessary;

- where possible, the maximum weight per package is 35kg; in the event that the total weight of the package exceeds twenty-five (25) kilogrammes, sidewinders (heavy duty handles) will be provided; Heavy Package Handling Label has to be placed on packages exceed twenty-five (25) kilogrammes;
- the minimum volume per package is ten (10) litres;
- whenever a package contains mixed articles (i.e. mixed items, batch numbers or serial numbers) a specific warning label is included;
- all Goods composed of multiple parts are delivered in one (1) single package;
- identical Goods are packaged in identical packaging (i.e. carton dimensions and quantity) unless otherwise approved by MSF ESC in writing; and
- each individual package contained on a pallet is visible from the exterior and contains the following minimum information, which shall also be visible from the exterior when packed on the pallet:
 - MSF Purchase Order reference
 - package number (each package shall be numbered separately);
 - supplier item reference (EAN product code in barcode where possible);
 - description of the Goods;
 - weight;
 - quantity;
 - name of manufacturer;
 - composition;
 - batch number or serial numbers (with barcodes if possible); and
 - expiry date.

The Supplier acknowledges and agrees that the pallets will not be returned.

6. Packaging and Labelling of Dangerous Goods

The Supplier shall ensure that:

- dangerous Goods are properly classified, documented, certified, described, packaged, marked and labelled, on the primary, the secondary and the final packages, in accordance with all applicable laws, regulations, standards or accepted industry practices (including the International Maritime Dangerous Goods (“IMDG”) Code, International Maritime Organization (“IMO”) Dangerous Goods Regulations and the International Air Transport Association (“IATA”) Dangerous Goods Regulations);
- packing instructions for “Passenger and Cargo Aircraft” are followed
- Loose lithium ion batteries (UN3480) must have a maximum remaining rest charge of 30% and must be delivered with a signed Statement of Charge. Test report 38.3 should also be provided.

Dangerous Goods in “Limited Quantity” (“Y” packing instructions) will not be accepted.

“Cargo Aircraft Only” packages will be accepted only with the prior written consent of MSF ESC.

If the Supplier is unable to package the dangerous Goods separately in accordance with the above, the Goods shall be delivered to MSF ESC for packaging.

The latest edition of the Material Safety Data Sheet (“MSDS”) must be provided for all dangerous goods classes, excepted for carbon dioxide and solid (dry ice). The MSDS shall be in English.

7. Thermosensitive Goods

The Supplier shall ensure that Thermosensitive Goods are:

- packaged and delivered separately in accordance with the requirements set forth in their labelling or patient information leaflet and with any other temperature control requirements agreed with MSF ESCs;

- clearly labelled as such on at least three sides of the outer packaging;
- always sent according to the manufacturer's instructions:
 - for "Validated thermosensitive" Goods: delivered together with a statement signed by the Supplier's Responsible Pharmacist attesting to the maintenance of adequate temperature control conditions throughout the period of transportation for such Goods; or
 - for "Traced thermosensitive" Goods: equipped with an adequate temperature monitoring device in each package.

For the purposes of this Supplier Guideline, "Thermosensitive Goods" mean any products which i) require a temperature control according to the requirements set forth in their labelling or patient information leaflet and/or ii) when not stored or transported within predefined environmental conditions and/or within predefined time limits, may be degraded to the extent that they no longer performs as originally intended.

8. Supplier Invoice

The Supplier shall ensure that each Purchase Order and each Delivery of Goods shall be the subject of a separate invoice, and that each invoice includes the following details:

- Purchase Order reference (MSF ESC and Supplier);
- delivery address;
- name of manufacturer / Country of origin;
- MSF ESC item code;
- supplier item code;
- description of Goods;
- total quantity of Goods delivered;
- unit of measurement;
- price per unit of Goods;
- total price of Goods delivered; and
- additional costs not already included in the Incoterm on the order (Incoterms 2020) deliveries.

All questions relating to payments should be submitted by email to the MSF ESC accounts payable department at:

- MSF Supply: accounting.msfsupply@brussels.msf.org
- MSF Logistique : DL-BDX-Paymentrequest@bordeaux.msf.org
- MSF Nederland: finance.office@amsterdam.msf.org

The Supplier shall send the invoice to the MSF ESCs as follows:

For MSF Supply:

- an electronic version must be sent to: accounting.MSFSUPPLY@brussels.msf.org.
- the original version must be sent to: MSF Supply, Attn. Finance Dept, Chée de Vilvorde / Vilvoordsestwg 140, B-1120 Neder-over-Heembeek Belgium

For MSF Logistique:

- an electronic version must be sent to: MSFLOG.invoice@bordeaux.msf.org.
- electronical version must be in pdf format only. Please don't send ZIP files with several invoices

- the original version must be sent to: MSF Logistique, Attn. Finance Dept, 3 rue du Domaine de la Fontaine 33 700, Mérignac France

For MSF Nederland :

- an electronic version must be sent to: invoices.finance@amsterdam.msf.org
- electronic version must be in pdf format only. Please don't send ZIP files with several invoices

9. Requirements for Medical Goods and Therapeutic Food

The Supplier warrants that the Medical Goods and Therapeutic Foods supplied to MSF ESCs comply with the followings:

- Good Manufacturing Practices, Good Distribution Practices and Technical Report Series 823 and 902 issued by the World Health Organisation;
- the Model Quality Assurance System for procurement agencies issued by the World Health Organisation;
- any applicable national and international laws, regulations, guidelines and standards with respect to the production, distribution and marketing of Therapeutic Food and Medical Devices; and
- any other relevant standards notified by MSF ESC to the Supplier in writing prior to entry into the Agreement.

The Supplier warrants that the Medical Goods supplied to MSF ESCs i) conform to the requirements and specifications set forth in the relevant Stringent Regulatory Authorities (SRA) regulatory filing and ii) are safe for human consumption and/or use.

Except for Medical Devices, the Supplier shall ensure that the secondary packaging (exterior labelling) of all Medical Goods contains the following minimum information (if applicable):

- INN of the active ingredients;
- dosage form;
- quantity of active ingredients;
- product reference;
- batch number;
- expiry date;
- manufacturing date, when possible;
- specific storage conditions;
- name and address of the entity responsible for placing the Medical Good on the relevant market in which it is destined for sale, being the product licence holder and/or distributor;
- name and address of the representative in UE, and/or manufacturer, and/or the entity responsible of EC;
- number of units per pack;
- number of product registration, when possible; and
- route of administration.

Except for Medical Devices, the Supplier shall ensure that the primary packaging (blisters, bottles, tubes, ampoules, vials) of all Medical Goods contains the following minimum information (if applicable):

- INN of the active ingredients;
- quantity of active ingredients;
- batch number;
- expiry date;
- manufacturing date, if possible;
- name of the product licence holder and/ or distributor;
- name of the representative in UE, and/or manufacturer, and/or the entity responsible of EC; and



- route of administration.

The Supplier shall ensure that the following information is mentioned on the secondary packaging and/or the primary packaging of each unit of Medical Devices supplied to MSF ESCs and/or on the packaging of multiple Medical Devices:

- Product brand or trade name
- Product reference or catalogue number
- Batch number
- Expiry date if applicable
- Storage conditions
- Name and address of the legal manufacturer
- Name and address of authorized representative such as importer or distributor for imported MD or IVD
- Name and address of the EC representative if applicable
- Indication of the net quantity of contents, expressed in terms of weight or volume
- Unique Device Identification (UDI)

Unless otherwise agreed by MSF ESC in writing, the Supplier shall ensure that all information provided for the Goods is in English (first preference) or French.

