



# **Technical Requirements for Medicines and Health products In ITBs/RFQs**

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## ACRONYMS

API	Active Pharmaceutical Ingredient(s)
BL	Bill of Lading
CPP	Certificate of pharmaceutical product
COA	Certificate of analysis
EML	WHO Model of Essential Medicines List
ERP	External Review Panel
FDC	fixed-dose combination
FPP	Finished Pharmaceutical Product
GMP	WHO Good Manufacturing Practices
INN	International Non-proprietary Names
ITB	Invitation to Bid
KPI	Key Performance Indicator
LTA	Long Term Agreement
NRA	National (Medicines) Regulatory Authority
OOS	Out Of Specifications
PILS	Patient Information Leaflets
PO	Purchase Order
PQS	Performance, Quality and Safety
QCL	Quality Control Laboratories
RFQ	Request For Quotation
TSL	Total Shelf Life

## 1. BACKGROUND

WHO seeks to provide timely access to affordable, quality pharmaceutical products in accordance with the WHO Quality Assurance Policy (2018). This includes medicines, biologicals, and medical devices procured to support WHO programmes worldwide.

WHO pharmaceutical products are aligned with normative standards and guidelines and are designed to facilitate rational use across different health care services. Product selection is informed by the WHO Model List of Essential Medicines (EML), disease-specific treatment guidelines, and disease commodity packages.

This document provides guidance on the technical specifications and requirements for products procured by WHO.

## 2. PRODUCT INFORMATION

### Technical specifications

The product(s) supplied shall be compliant with the WHO technical specifications provided in the Annex1a Excel Form Technical Offer.

Whenever the offered item(s) are not in compliance with WHO specifications and alternatives are offered, it is the supplier's responsibility to provide a full description and documentation the items proposed. This item(s) shall be clearly marked as not being in compliance with specifications stated in the Annex1a Excel Form Technical Offer. A field for comments is included to explain variations from the WHO specifications.

Each Finished Pharmaceutical Product (FPP) must be fully identified with the following additional explanations:

1. Products shall be identified by their International Non-proprietary Names (INN). Generic name(s), others shall be stated if different from INN;
2. The Active Pharmaceutical Ingredient(s) (API) shall be stated as base, salt, ester or pro-drug compound as applicable;
3. Vendor shall include relevant pharmaceutical dosage form and dosage form attributes e.g if tablets are functionally scored, dispersible, enteric coated, bi-layered, film coated, sugar coated;
4. Specification of the strength per dosage unit or the amount of active ingredient per dosage unit. Where this is given in terms of the salt, ester or prodrug, the equivalent amount of active moiety must be specified;
5. Specification of the route of administration e.g IM, IV, SC, Per Os, Rectal;
6. Specification of inactive ingredients and/or excipients of medical/ pharmaceutical relevance, amount in the dosage form or per dosage unit, e.g contains Alcohol 10%;
7. Indication whether the product is fixed-dose combination (FDC), e.g co-pack/co-blister, co-formulated.

If requested the most current version of the Interagency Finished Pharmaceutical Product Questionnaire should be submitted<sup>1</sup>.

## Packaging

Packaging of the medicinal products shall comply with WHO Technical Report Series (TRS) No. 902, Annex 9 – Guidelines on Packaging for Pharmaceutical Products, and relevant WHO GMP guidance<sup>2</sup>:

- Primary packaging refers to packaging components in direct contact with the medicinal product (e.g. blisters, bottles, vials, ampoules, closures).
  - sterile or non-sterile as appropriate. E.g. for sterile items, transparent film to allow clear identification of the content – sachet, plastic box, peel-off sachet;
  - For pharmaceutical products in tablets/capsule. blister pack is are mandatory unless specify otherwise ;
  - Glass containers will not be accepted above a maximum of 250 ml. if requested, glass bottles must be separated by criss-cross box dividers or box partitions or be packed individually in cartons.
  - For glass ampoules, single ended, break-off necks are required;
  - Primary packaging must bear appropriate labels providing content and usage information.
- Secondary packaging refers to packaging components not in direct contact with the product, intended to protect, identify, and group primary packages (e.g. cartons, outer boxes):
  - Provide adequate protection to the primary packaging during storage and distribution
  - Allow for clear product identification, traceability, and labelling
  - Be robust enough to withstand transportation and climatic conditions relevant to the destination country
- Dose measurement and dose delivery devices:
  - A dose measurement and dose delivery device is required to be included with the container-closure system for administration of oral liquids or solids (e.g. solutions, emulsions, suspensions and powders or granules), whenever the package provides for multiple doses;
  - The dosage scales/volumes embossed on dose measurement devices must be in METRIC units. The use of teaspoonful and other such measurements is not acceptable;
  - For oral liquids or powders for oral liquid, supplier might be required to submit study results that confirm the suitability of the container-closure system contact materials and this should also include extraction studies and interaction studies (migration/sorption);
  - For a device accompanying a multi-dose container, the results of a study might be requested demonstrating the reproducibility of the device (e.g. consistent delivery of the intended volume);
  - An applicator is required to be included for each vaginal pessaries.

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<sup>1</sup> <https://www.who.int/publications/m/item/updated-interagency-finish-pharmaceutical-product-questionnaire>

<sup>2</sup> <https://www.who.int/publications/m/item/annex-9-trs-902>

## 2.3 MANUFACTURING SITES

For each products, the supplier shall indicate the name and current valid address of the manufacturing site(s) and provide correspondent GMP valid certificate in English. In addition, the supplier shall provide a valid manufacturing license provided by the National Regulatory Authority (NRA). Manufacturing site should appear on the secondary packaging including respective workshop /unit /block.

Once contracted, the supplier shall inform WHO of any change in the status of GMP certificates identified in the list of manufacturing sites included in the respective bid.

In case of any manufacturing facility relocation or substitution of manufacturing facilities, the supplier shall notify WHO of the change and request approval to supply the contracted products from the new location. The aforementioned changes must be approved by WHO after an evaluation of the GMP certificate of the new location performed by the Quality Assurance Group. The WHO approval of the aforementioned changes will be provided in writing and if necessary reflected in the contract.

Failure to obtain approval of such changes of status may result in the termination of the Long Term Agreement (LTA) and any pending orders.

### 2.1. SHELF LIFE

For an ITB, the product with the longest Total Shelf Life (TSL) will be preferred when comparing similar products. If a product requires a diluent, the diluent shall have at least the same shelf life as the corresponding product.

The assigned shelf life and recommended storage temperature conditions shall be indicated on the finished pharmaceutical product (FPP) labels and included in the package inserts and patient information leaflets. For oral powders for suspension or solution, powders for injection, injections that may be further diluted, or multi-dose containers, the supplier shall indicate the storage conditions and shelf life after reconstitution, dilution, or opening.

At the PO stage, unless authorized in writing and in advance by WHO, the WHO guidance applies Points to consider for setting the remaining shelf-life of medical products upon delivery Annex 8, WHO Technical Series 1044, 2022<sup>3</sup>

### 2.2. STORAGE CONDITIONS ALONG THE SUPPLY CHAIN

Particular storage conditions (temperature, pressure, humidity, etc.) shall be clearly stated. Labelling of the products shall be according to the WHO Technical Report Series 953, 2009, Annex 2, Appendix 3 (Recommended labelling statements)<sup>4</sup>.

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<sup>3</sup> <https://www.who.int/publications/m/item/trs-1044-annex-8-shelf-life-medical-products-delivery>

<sup>4</sup> [https://www.who.int/publications/i/item/WHO\\_TRS\\_953](https://www.who.int/publications/i/item/WHO_TRS_953)

Statements such as “Store at room temperature” or “This product does not have special storage requirements” are not acceptable, the numerical temperature storage conditions shall be specified on quotation, product leaflets and any relevant shipping documents. It is crucial for supplier to take note of the transit and end destination of the supply chain and highlight any precautionary conditions to be complied for optimum storage conditions.

For all temperature sensitive products (biologics and pharmaceuticals) purchased as a result of the solicitation, suppliers shall ensure that the storage and distribution of the products comply with the TRS 961 - Annex 9: Model guidance for the storage and transport of time and temperature sensitive pharmaceutical products.<sup>5</sup>

### 2.3. STABILITY STUDIES

WHO supplies many countries with pharmaceutical products. Due to the weather conditions in some countries, long-term stability studies performed under Zone IVB conditions are required. Therefore, in order to ensure the product quality is maintained throughout the product shelf-life, WHO requires that all medicines undergo stability studies under  $30 \pm 2^\circ\text{C}$ /  $75 \pm 5\%$  RH. Only in exceptional cases, when bidders provide sound scientific justifications, the studies do not need to be performed, e.g. product is unstable at the indicated study temperatures. A commitment to start and complete stability studies under  $30 \pm 2^\circ\text{C}$ /  $75 \pm 5\%$  RH is acceptable. (WHO Technical Report Series 953, 2009, Annex 2, Appendix 1<sup>6</sup>).

### 2.4. PATIENT INFORMATION LEAFLETS AND PACKAGE INSERTS

During the bidding process and if requested by WHO, bidders shall submit the Patient Information Leaflets (PILS), instructions, etc. in two languages (English and French). It is possible that the translation into other languages is required in the ITB. Once contracted, the supplier shall supply the health technology with manuals or instructions sheets (providing instructions for safe installation, set up, assembly, usage, recommended storage conditions and maintenance of the product) in two languages (English and French) along with the shipment. It is possible that the translation in other languages is required in the contract.

### 2.5. PRODUCT PICTURE AND SAMPLES

Bidders might be requested to submit a picture or an artwork of the products in PDF/JPEG format. When this is the case, the picture must be properly filed and labelled with the product item number and product name.

Bidders might be requested to submit samples of requested products.

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<sup>5</sup> <https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport>

<sup>6</sup> [https://www.who.int/publications/i/item/WHO\\_TRS\\_953](https://www.who.int/publications/i/item/WHO_TRS_953)

## 2.6. QUALITY OF GOODS

Once contracted, goods supplied from different sources of supply other than from the approved manufacturers must be technically cleared, in writing, by WHO.

The supplier shall inform WHO of the renewal of every ISO and GMP certificate of the approved manufacturers during the entire term of the Agreement, including any extension period.

The supplier shall ensure that the pharmaceutical products supplied are recently produced, with a minimum shelf life as described under chapter 2.3 at time of delivery to consignee. See Points to consider for setting the remaining shelf-life of medical products upon delivery Annex 8, WHO Technical Series 1044, 2022<sup>7</sup>

The name of the manufacturer must be stated on the physical product or the primary packaging of the physical product by the manufacturer printed. In addition, the address of the manufacturer must be stated on the physical product or the primary packaging of the physical product. If there are any exceptions to this due to National or Regional Legislation, please provide evidence of such.

Any Goods delivered to WHO that do not meet the specifications outlined in the LTA or Purchase Order shall be replaced promptly by the supplier, inclusive of all inland or air/sea freight and any destruction costs at no charge to WHO.

In the event that the supplier decides to discontinue the manufacture of any Goods covered under the LTA, or to change its production lines or products, the supplier shall provide at least 90 days' notice to WHO prior to the effective date of discontinuation, in order to allow WHO sufficient time to make alternative arrangements.

## 2.7. AUDITS

WHO reserves the right to conduct audits or technical visits along the supply chain if an award is issued. To ensure the quality standard of the products, WHO reserves the right to request for random independent sampling and testing at any time.

The supplier shall grant WHO, or its authorized agent, access to its facilities at all reasonable times to appraise the production, testing and packing of goods, and shall provide WHO, or its authorized agent, during such appraisals, with all necessary assistance including the submission of copies of any test results or quality control reports as may be necessary.

Should there be any Out of Specifications (OOS) results, an independent WHO Quality Control Laboratories (QCL) services that are WHO prequalified or accredited in accordance with ISO 17025, will conduct and document an investigation. In cases where the OOS is confirmed as failing to meet the specifications (as per the Agreement); the

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<sup>7</sup> <https://www.who.int/publications/m/item/trs-1044-annex-8-shelf-life-medical-products-delivery>

supplier will be required to investigate the discrepancies and report. And shall replace the goods, pay for the freight cost and the re-inspection fee at cost. Test results submitted by WHO's appointed laboratories are final and binding.

## 2.8. SUPPLIER'S RESPONSIBILITY FOR REJECTED OR RETURNED PRODUCTS

Once contracted, should any product fail the pre- or post-shipment inspection and testing, the supplier shall be responsible for disposal of and/or the return of the rejected goods to the country of origin. The supplier shall bear the cost of all related activities, including product recall, product replacement, freight and re-inspection cost.

In case of non-compliance, either in the quality, performance, safety of the product or in agreed packaging or labelling, the supplier will be requested to replace the complete batch at supplier's own cost or reimburse WHO and take appropriate actions to eliminate public health risks for users.

Should any part of the goods fail to meet the requirements of the specifications, the supplier shall replace the items within the time specified for delivery, or granted extension.

Inspection does not relieve the supplier from its contractual obligations and the goods are subject to final acceptance after delivery.

Depending on the nature of non-compliance, the replacement from the same source may no longer be acceptable. In such a case, WHO reserves the right to cancel or terminate the contract with the supplier (in addition to other rights, such as the right to claim damages) and/or remove the supplier from the WHO list of accepted-in-principle suppliers of essential medicines and other health products.

## 2.9. MANAGING PRODUCT RECALLS

WHO reserves the right to suspend procurement of products in case of identification of inferior quality and inform publicly when applicable, the NMRA and patients who may be affected.

In the event that WHO in co-operation with NRA in supplied countries decides on product recall, the supplier shall organize this recall and necessary associated activities at the cost of the supplier. Any additional recall expenditure incurred by WHO shall be compensated by the supplier.

In case an essential medicine is found substandard or falsified, the supplier/manufacturer is bound to replace the item within a reasonable time.

## 3. PACKAGING AND PALLETIZATION

Packaging must be suitable for the mode of transport indicated, shall conform with national/regional/international rules and regulations and best practices, shall account for special requirements related to the transportation and storage of dangerous goods and/or perishables.

The supplier shall ensure that packaging materials shall be of good quality, capable of providing adequate protection to the goods for carriage by air, sea, rail and/or road to final destinations worldwide, including remote locations.

Packaging materials are strong, able to be stacked to a height of 2 meters, and resistant to puncturing, suitable for shipment, storage and use inworld-wide, including destinations with elevated temperatures and humidity, adverse climatic and storage conditions, unless otherwise stated.

All wooden packaging, including pallets and boxes, shall undergo heat treatment, impregnation or fumigation, and shall be appropriately marked as having undergone such process. A certificate of conformity has to be provided to the Forwarder, if any, together with shipping documents.

Deliveries should be packed/palletized (pallet 120 x 80 cm with 15 cm ground clearance), with a maximum height of 160 cm (ALL IN) for AIRFREIGHT and 210 cm (ALL IN) for SEA FREIGHT, in the most cost-effective way for the indicated mode of shipment to minimize freight costs.

### 3.1 KIT PACKAGING SPECIFICITY

To facilitate country logistics and the identification of the WHO kit by the end-user, the below general labelling and packing recommendations are applicable to all WHO kits. These requirements should be taken into account in the offers.

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#### 3.1.1. CONTENT LIST AND PACKING LIST

- General packing list should contain the following information:
  - i. Product description;
  - ii. Unit of measure;
  - iii. Quantity;
  - iv. Lot/Batch number(s) (when applicable) with the date(s) of expiration of the finished product(s), including diluent (when applicable).
  - v. P.O number;
- Two copies of the packing list shall be inserted in a self-adhesive plastic pouch firmly attached to the box#1 of each module/set and easily accessible (more copies could be requested on case by case);
- One copy of the packing list shall be affixed on the carton box (in addition to the pouch envelope);
- A content list of the module/set, as per WHO current version, shall be placed inside the carton box#1 on the top of the goods;
- The packing list shall be send in Excel format along with shipping documents;

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#### 3.1.2. KIT LABEL

- The kit label shall be affixed on the top right corner of one side of the box. (QA Memo 2017/3)
- The kit label on the box shall mention the following:
  - i. The full name of the WHO Kit, *e.g. Inter-Agency Health Kit-2024.*, *Font Arial(Body) 24;*

- ii. The full name of the WHO module or set, e.g. ((IEHK 2024 BASIC) UNIT, MEDICINE AND RENEWABLES (1.1) *Font Arial(Body)* 36;
- iii. The WHO code , e.g. *KMEDIEHK2O1--A1. Font Arial (Body)* 20;
- iv. The Box number. *e.g. BOX 1/4 indicates the first box of a module of a total of four boxes. Font Arial (Body)* 72;
- v. The assembly date of the kit. *Font Arial (Body)* 20 ;
- vi. The date of the first item to expire in the box. *Font Arial (Body)* 20;
- vii. The weight and volume of each box. *Font Arial (Body)* 20;
- viii. WHO logo will be provided in jpg. or eps format and shall not be modified.;

The above listed (i-viii) shall be organized as described in annex 1;

- Colour of the kit label : As per WHO colour coding
- Size and quality of the kit label: The label size is A5, water resistant and self-adhesive in order to prevent detachment during transport and storage in tropical climate;
- Specific label: when applicable, a label shall indicate the presence inside the carton box of thermo-sensitive product or of an electronic temperature monitoring device (data logger);

Under no circumstances shall labels include any of the following: “donation” or “free medicine.” And Re-labelling or over-labelling is not acceptable, unless agreed to in writing by WHO.



### 3.1.3. KIT STANDARD BOX REQUIREMENTS

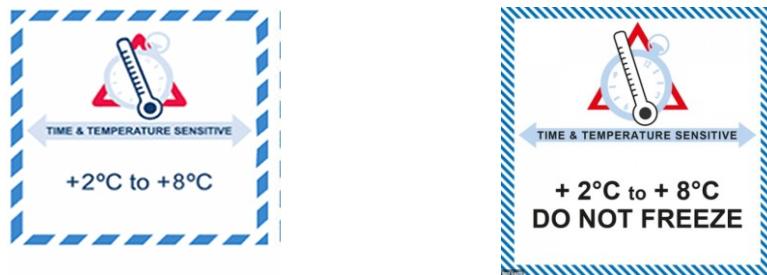
- The box material shall be sturdy export quality, resistant to puncturing and have a minimum of 3-layers and 4 (four) straps;

- The cardboard shall be of virgin base materials and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity;
- The boxes shall not exceed 25 kg;
- The supplier shall use sustainable packaging in accordance with sustainability standards.

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#### 3.1.4. KIT COLD CHAIN PACKAGING

- The mode of shipment for all cold chain modules in the WHO kits will be by air in active cold chain.
- The different items of the module must be placed in a validated cold chain container keeping temperature between 2-8°C, for a minimum duration of 96 hours. This to guarantee the quality, prevent quick degradation and shorter shelf life of the different products;
- A temperature monitoring device used for WHO shipments must be prequalified as per the Performance, Quality and Safety (PQS) process. And each cold chain box shall contain one PQS temperature monitoring device and one freeze tag® ( Berlinger, Switzerland).
- The Cold Chain box shall be clearly identified. The Cold chain box running the risk of damage in freezing conditions shall include the following warning label: “Do not freeze”. And the IATA Time and Temperature Sensitive Label (see below) or an equivalent shall be affixed to all boxes that are time and temperature sensitive, indicating the external transportation temperature range of the shipment and shelf life. The Cold Chain label shall indicate the presence of an electronic temperature monitoring device (data logger) inside the carton box.



- When several modules are requested on the same PO, consolidation of the different modules in one shipment is possible. However, each module should be clearly identifying and labeled before being placed in the cold chain container, some example below.



#### 4. TRANSPORT OF TEMPERATURE SENSITIVE PHARMACEUTICALS

WHO procures pharmaceuticals which are to be stored at (-)20°C, (+)2-8°C and (+)15-25°C. These pharmaceutical products also require controlled temperatures during transportation as indicated in the Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products: WHO TRS 961, Annex 9<sup>8</sup>.

For all WHO ad hoc tenders, potential suppliers are requested to price data loggers recording temperature during transport as per general requirements below. Such requirements will be included with immediate effect in tender documentation and shall form an integral part of the Purchase Order/Contract that governs the conditions of packaging and transportation. Suppliers should consider data logger (s), as well as the cost of cold chain container when applicable, as part of their export packaging cost submitted in their offer, in accordance with the guidelines provided in this document.

The cost of the data logger and additional export packaging must be included at prorate to the price of each item proposed. Such extra cost will not be charged afterwards at PO or shipping stage.

The number of data loggers requested is in accordance with the nature of the goods, the mode of transport and the total order quantity, as described below:

<sup>8</sup> <https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport>

## Summary of the recommendations

		-20 °C	2-8°C	15-25°C (medicines ONLY)
By Air	Commercial flight	1 data logger per carton box/pallet shipper	1 data logger + 1 freeze tag per carton box/pallet shipper	1 data logger per shipment
	Chartered flight	1 data logger per carton box/pallet shipper	1 data logger per carton box/ pallet shipper	1 data logger per 30 pallets
By Sea	Full container load	n/a	n/a	1 data logger per container
	Shared container	n/a	n/a	1 data logger per shipment
By Road	Full container load	1 data logger per carton box/pallet shipper	1 data logger + 1 freeze tag per carton box/pallet shipper	1 data logger per container
	Shared space load	1 data logger per carton box/pallet shipper	1 data logger + 1 freeze tag per carton box/pallet shipper	1 data logger per shipment

*RDTs, even prequalified one, can be shipped as general cargo, no reefer container needed, but one data logger per shipment for sea shipment.*

Appropriate IATA labels, indicating the storage temperature range should be affixed to the shipping cartons.

## 5. REQUEST FOR CHANGE OF PRODUCT(S) OR PRICE(S) AFTER AWARD

The change of products is allowed only under exceptional instances when the supplier is not able to provide a product according to the specifications included in the Long Term Agreement (LTA). In those instances, it is important that the quality and price of the product as approved in the LTA is not negatively affected and alternative sources are subject to Quality Assurance acceptance by WHO.

## 6. STOCKS

The supplier shall maintain a stock or make other arrangements at its own risk and cost in order to ensure timely delivery.

The supplier shall ensure that products manufactured for specific Purchase Orders are from a continuous manufacturing batch. The supplier is not to break up orders unless expressly requested by WHO. Each Purchase Order shall contain individual order instructions.

For stockholding, if applicable, the supplier shall ensure turn over to guarantee appropriate shelf life. The supplier shall provide monthly stock reports using the provided template and certify that the relevant stock is maintained for the sole use of WHO.

## 7. DELIVERY INFORMATION

The delivery of the goods must comply with the delivery date mentioned in the purchase order. If the delivery date cannot be met, the supplier must inform GSC Shipping unit (gscshipping@who.int) of the new delivery date. Any impediment to deliver must be advised in writing to WHO and to the appointed forwarder, if any, as soon as possible. No delivery shall take place before agreement is received from WHO's appointed forwarder, if any. No partial delivery will be accepted without written agreement by WHO.

### 7.1. DELIVERY LEAD TIME

Bidders shall indicate the guaranteed maximum lead time for delivery of each product. Bidders are advised to state realistic lead times since WHO shall monitor and evaluate delivery performance (one of the Key Performance Indicator(s) (KPIs) of the contract agreement) in comparison with guaranteed minimum lead time indicated in the Bid.

The supplier performance is evaluated against the timeliness of delivery with reference to the PO Due Date.

The agreed LTA lead time should take into consideration the time required for a potential pre-shipment inspection.

The Purchase Order (PO) Due Date is defined as the “Ready for shipment Date” and the WHO appointed Forwarder should be contacted by the supplier at or before the “Ready for shipment date”.

No partial deliveries shall take place unless written approval has been obtained from the WHO. The Purchase Orders will contain individual delivery instructions.

### 7.2. RECEIPT AND CONFIRMATION OF PURCHASE ORDER (PO)

Once contracted, the supplier shall acknowledge receipt and acceptance of the WHO Purchase Order within **one to three (1-3) business days** (for non-emergency orders) from the receipt of the WHO Purchase Order to WHO procurement (via email).

The supplier must confirm that all items supplied are from the approved manufacturer sources as per the LTA or accepted Offer.

### 7.3. NOTICE OF DELAY OF DELIVERY

In the event of a delay in the delivery time of a Purchase Order, the supplier shall immediately and not later than one week notify the WHO via email, requesting an extension of the delivery time, clearly stating the nature of the delay (including supporting documentation) and the proposed new delivery time. For delay of emergency order or anticipated delay of more than thirty (30) days on standard order, supplier is required to propose alternative solution for WHO's approval to expedite deliveries. Delay in delivery would be monitored and documented closely as record for performance evaluation.

#### 7.4. HANOVER OF THE GOODS TO WHO APPOINTED FORWARDER

For every Purchase Order, the supplier shall scan and send via email a Ready for shipment note to the WHO appointed Forwarder. The Note shall contain the following information and documents:

- PO reference;
- Packing list with complete information on packing dimensions (LxWxH) and gross weight n kilograms and volume in cubic meters;
  - Item description and quantity, weight and dimensions in cm per parcel
  - Total gross weight in kilograms and volume in cubic meters
  - In case of perishable or dangerous items: full details with temperature degree,
  - UN No, Class no. Flashpoint are to be clearly indicated on the packing list and in the invoice.
- Invoice;
- Certificate of Origin;
- Certificate of Analysis;
- Any other Certificates specified in the PO.

The supplier is responsible for obtaining at its own risk and expense any export license or other official authorization required and to carry out all customs formalities necessary for the export of the goods.

#### 7.5. CUSTOM AND SHIPPING DOCUMENTS

When the shipment is arranged by the WHO's appointed Forwarder, for all modes of transport, except for Sea freight, the Shipping Documents should be sent together with the shipment. For Sea freight shipments, the supplier shall mail the documents to the consignee by special courier such as TNT, DHL or similar and email copies to WHO's appointed forwarder.

The supplier shall submit the following documents:

- 2 Sets of **Original** Invoice and Packing List;
- 1 **Original** Certificate of Origin;
- 1 copy Certificate of Analysis.

When shipment is arranged by the supplier, it shall submit the following:

- 2 Sets of **Original** Invoice and Packing List to the consignee and one copy to WHO procurement/logistics;
- 2 Sets of **Original** Bill of Lading/Airway Bill (stamped “freight prepaid”) to the consignee and one copy to WHO procurement/logistics;
- 1 **Original** copy of the Certificate of Origin to the consignee and one copy to WHO procurement/logistics;
- 1 copy of Certificate of Analysis to the consignee and one copy to WHO procurement/logistics;

Depending of the country of destination additional types of documents will be mentioned in WHO PO such as: Certificate of Fumigation, Export License, Import License, Quality control Certificate, Release Certificate by the National Authority, WHO Donation Letter.

Some destinations would also request for **3 original copies of Bill of Lading (BL)** instead of the normally required 2 original BL. On the event this happens, it will be specified in the WHO PO.

## 7.6. CARGO TRANSPORT

The shipments for cargo which requires temperature control shall be arranged as followed :

- Pharmaceutical products with temperature requirement of +2°C - +8°C are solely shipped by Air. WHO will not ship above mentioned products by Sea.
- Pharmaceutical products with temperature requirement of 15°C - +25°C : shipped by reefer container for sea freight shipments as per clear instructions from WHO to the freight forwarder. Any exception to that decision must be granted by WHO.

The temperature requirements are always mentioned in the PO; suppliers and freight forwarders are obliged to comply.

## 8. TECHNICAL DOCUMENTS TO BE SUBMITTED AS ANNEXES BY BIDDERS

For bulk items or for emergency Health kits please detail each items proposed in the technical documents. Below checklist may not be exhaustive, but following documents should be available for each item proposed uploaded on a USB stick.

### MEDICINE:

- **GMP certificate from the country of origin;**
  - Recent/valid GMP certificates/letter from WHO listed Authority (WLA)<sup>9</sup> or PICs participating authorities<sup>10</sup> ;
- **Certificate of pharmaceutical product (CPP)** according to the WHO Certification Scheme (WHO Technical Report Series, No. 863). An earlier version is not acceptable;
- **Copy of the certificate of analysis (COA) for the last three batches released;**
- Stability studies
- In vivo/ in vitro bioequivalence studies, if applicable
- Copy of product registered and currently marketed licence

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<sup>9</sup> <https://www.who.int/initiatives/who-listed-authority-reg-authorities>

<sup>10</sup> PICs participating authorities <https://picscheme.org/en/members>

- Copy of the relevant WHO Prequalification approval letter signed by your company;
  - WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product;
  - Letter/agreement sent by Inter Agency Pharmaceutical Group (IAPG);
  - Reference to the External Review Panel (ERP) list of recommended product and or letter issued by The Global Fund or relevant ERP client;
- Certification that the proposed product is exactly the same as the prequalified/ approved one;
- Artwork (primary and secondary packaging )
- Package insert/leaflet
- Patient information leaflet;
- Picture of the product

If requested:

- Sample of the product

## **MEDICAL DEVICES**

- Quality management system ( ISO 13485 or ISO 9001) for manufacture & subcontractor
- EC certificate converting the directive 93/42/ECC for medical devices or FDA approval with 510k clearance ( or permanent approval PMA for some class II device)
- Declaration of conformity + cE mark
- Manufacturing license + free Sale Certificate
- Prequalified by an international organisation ( WHO, UNICEF, UNFPA)
- Environment ( ISO14001, ISO50001)
- Item specific safety standards: proof of conformity required
- Biocompatibility evaluation report depending on the risk associated ISO 10993
- Risk assessment ISO 14971
- Extractable and leachables depending on the risk ( ISO10993)
- Compliance to products specific standards ( e.g.ISO4074)
- Specific ISO for sterility and stability (e.g ISO 11135- ETO sterilisation,11137-gamma irradiation, 17665-steam sterilisation, 20857-dry heat, 14937-for other sterilisation methods.
- The model, product code, and/or manufacturer reference should be shown explicitly.
- Different presentations need to be clearly identifiable.
- Installation, spare parts and services repair when applicable
- Training and support
- Warranty
- Reusable product clear information / instruction provided on cleaning/ disinfecting/ sterilization methods and types for the device

- Electrical devices indicate the voltage and plug type, which should be supplied according to the country of destination
- Methods for safe disposal / decommissioning of the device where appropriate
- Picture of the product offered.
- Genuine catalogue and/or commercial brochure that clearly identify the product offered containing information on material, sizes and the presentations available.

If requested:

- Sample of the product