Technical Requirements for pharmaceutical products
In ITBs/RFQs

September 2017
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1. General

WHO seeks to provide timely access to affordable quality of pharmaceutical products according to the WHO Quality assurance policy (www. Website).

WHO pharmaceutical products are aligned with normative standards and guidelines and designed to facilitate rational use at the different health care services. WHO Model of Essential Medicines List (EML) and disease specific treatment guidelines inform our product selection. WHO technical guidance informs specifications and requirements for procured products, including non-standard items.

The pharmaceutical products to be procured are for WHO’s programmes located worldwide.

2. Product Information

2.1. Product identification

The product(s) supplied shall be compliant with the WHO technical specifications provided in the MS Excel Product Form (see annex X).

Whenever the offered item(s) are not in compliance with WHO specifications or alternatives are offered, it is the supplier’s responsibility to provide a full descriptive specification and documentation of such items in the Bid. These item(s) shall be clearly marked as not being in compliance with specifications stated in the MS Excel Product Form (see Annex X). 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; further references can be found in WHO TSR 957 (p62) 2010 http://www.who.int/medicines/publications/pharmprep/en/index.html;
5. Specification of the route of administration e.g IM, IV, SC, PO, 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. (http://www.who.int/medicines/areas/quality_safety/quality_assurance/MQAS-Inter-AgencyFPP-questionnaire-QAS13-556_06082013.pdf).
2.2. Manufacturing sites

For each product, the supplier shall indicate the name and current valid address of the manufacturing and provide corresponding GMP valid certificate in English. In addition, the supplier shall provide a valid manufacturing license provided by the NRA.

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 WHO/CPS. 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 LTA and any pending orders.

2.3. Shelf life

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 the shelf-life should be established based on complete long term data at 30°C ±2°C/75% RH ±5% RH (Zone IVb). When possible, total Shelf life of 36 months or longer is preferred. If the product requires a diluent, the diluent shall have at least the same shelf life as the corresponding product.

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

Unless authorized in writing and in advance by WHO, the remaining shelf life at time of delivery point to consignee shall not be less than 75 percent of the total product’s shelf life for pharmaceuticals and biologicals, and for vaccines not less than 18 months.

2.4. 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.

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.

For all products requiring cold chain storage (biologicals and pharmaceuticals) purchased as a result of the solicitation, suppliers shall ensure that the storage and distribution of the products comply with WHO Model guidance for the storage and transport of temperature-sensitive pharmaceutical products:

1 Exceptions may be granted for vaccines with a total product’s shelf life of 24 months or less.
Additionally, suppliers shall include one WHO PQS electronic temperature monitoring device with USB interface per shipping carton for temperature measurements (http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/). The content of the device shall be readable without the need of special software of any kind (please refer to the Guidelines on International Packaging and Shipping of Vaccines: http://whqlibdoc.who.int/hq/2005/WHO_IVB_05.23_eng.pdf).

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

2.5. 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 ±2°C/ 75 ±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 ±2°C/ 75 ±5% RH is acceptable.

2.6. 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.

2.7. 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.

2.8. 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.
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.

2.9. 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) will conduct and document an investigation. In cases where the OOS is confirmed as failing to meet the specifications (as per the Agreement); the 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.

2.10. 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 of the product or appropriate packaging or agreed 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.
2.11. 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 NMRA 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.

Substandard Drugs: In case a drug is found substandard, the supplier/manufacturer is bound to replace the item within 8 working days.

3. Kit Packing Information

3.1. Packing of Goods for International Delivery

The cost of packing and the packing material cost shall be included in the items bid price.

Packaging of the product shall comply with WHO GMP standards.

- Primary packaging –
  - 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. For item with tablets/capsules or less, it shall be preferably in blister pack.
  - Glass containers will not be accepted above a maximum of 250 ml. 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 – to protect the primary packaging – e.g. cardboard, rigid wrapping

- 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 with vaginal pessaries

3.2. Marking and labelling

The labelling of the product shall meet the following requirement:

a. The Manufacturer’s name and manufacturing site address shall be imprinted on the secondary packaging.

b. Summary of Product Characteristics, package inserts and Patient information leaflets. The content should be in line with WHO SPC template which may be accessed at http://apps.who.int/prequal/WHOPAR/WHOPARGUIDE/file04a_Annotated_SPC_template.pdf

c. Primary packaging shall be imprinted with the following:
   i. Name of manufacturer;
   ii. Address of manufacturer’s manufacturing site;
   iii. Article reference of the manufacturer and the supplier;
   iv. Details to identify device (in English, French and Spanish): description, composition as appropriate;
   v. Batch number prefixed by the word “LOT” or equivalent harmonized symbol
   vi. Items with limited shelf life: expiry date using the words “use before (month)/(year) or prefixed by “EXP” or equivalent harmonized symbol (month)/(year)
   vii. Items without expiry date: the date of manufacture (year) prefixed by the harmonised symbol, unless information already incorporated into the batch number or serial number
   viii. For single use items, the words “DO NOT RE-USE” or “FOR SINGLE USE” or equivalent harmonized symbol
   ix. For sterile items, the word “STERILE” or equivalent harmonized symbol, plus a warning which advises to “check the integrity of the sterile packaging before use.”

d. In addition, the primary packaging for pharmaceutical products shall be labelled with the following:
   x. Name of drug;
   xi. Pharmaceutical dosage form;
   xii. Active pharmaceutical ingredient(s); type and amount;
   xiii. Name and amounts of excipients with relevant medical and pharmaceutical effects e.g. preservatives, sugar content;
   xiv. Net quantity per unit;
   xv. Instructions/direction for use;
   xvi. Batch number;
   xvii. Expiry date;
   xviii. Storage conditions including warnings and precautions ;
   xix. If reconstitution is required, the storage conditions after reconstitution and shelf-life;
   xx. Name of manufacturer;
xxi. Address of manufacturing site (For contract manufacturer, indicate clearly that:
manufactured by A for Company Y).

e. Secondary packaging for pharmaceutical products shall be imprinted with the following:
   i. Name of manufacturer;
   ii. Address of manufacturing site;
   iii. Labelling same as on primary packaging;
   iv. Any special storage conditions and or handling conditions;
   v. Instructions for use in English, French and Spanish.

3.3. Transport of temperature sensitive pharmaceuticals

WHO procures pharmaceuticals which are to be stored at 2-8° 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,
TRS961Annex9.pdf]

Containers:

- The container should protect the product from mechanical damage and any anticipated ambient
temperature range during transportation and transit
- Materials such as dry ice, thermal jacket may be used to maintain the desired temperature;
- The shipping carton should be strong enough to prevent breakage;
- The container shall be tamper proof and allow for the recipient to establish that
the product has not been tampered with while in transportation and transit.

Temperature monitoring:

- The temperature in the container during transportation and transit should be monitored using
appropriately calibrated monitoring devices;
- The monitoring device should reflect the temperature inside the container;
- Temperature monitoring devices used for WHO shipments must be prequalified as per the
Performance, Quality and Safety (PQS) process (PQS). No other temperature monitoring devices
are acceptable.
   a. For cold chain consignment

       Each cold chain box shall contain one temperature monitoring device;

   b. For temperature sensitive goods air consignment

       Each shipment shall contain one electronic temperature monitoring device, placed
randomly in one of the shipment boxes;

   c. For temperature sensitive goods sea consignment (containers)
For containerized cargo, each container shall contain 2 electronic temperature monitoring devices placed in two different shipment boxes, one located at the top and the other at the bottom of the container. The country logistic team must be informed of the location of the electronic temperature devices.

4. Request for Change of Product(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 of the product as approved in the LTA is not negatively affected. The risks of using different specifications and/or manufacturer must be carefully and thoroughly assessed by the supplier and a risk management plan provided.

5. 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 turnover 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.

6. Kitting Service

Once contracted, the supplier may be requested to pack the goods in the form of a kit. Details of such arrangements shall be provided in the ITB Requirements.

Labelling and packaging of the WHO emergency Health kit should be aligned with WHO recommendations. For additional information refer to Quality Information Memo 2017/01 (annex X).

7. Delivery information

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 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 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 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.

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.

7.4. Handover 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);
- Pro-forma 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, the supplier shall submit the following documents to the WHO appointed Forwarder:

- 2 Sets of Original Invoice and Packing List;
- 1 Original copy of the Certificate of Origin;
- 1 copy of Certificate of Analysis.
The WHO appointed Forwarder will then send out the original and copies to the respective recipients / Notify party

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

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

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

In reference to the section 6 of the Interagency Pharmaceutical Product questionnaire (IAFPPQ), please ensure that all documents necessary to enable the objective technical evaluation of your product are attached. For emergency Health kit please detail each items proposed.

This checklist may not be exhaustive, please provide the following for each item proposed:

- **GMP certificate from the country of origin**;
- Recent/valid GMP certificates/letter from SRA or PICs;
- **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 for the last three batches released**;
- Copy of product registered and currently marketed - License no;
- 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 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;

If requested,

• Artwork (primary and secondary packaging)
• Package insert/leaflet
• Patient information leaflet;
• Samples of the product
• Picture of the product
ANNEX 2 : BID CONFIRMATION FORM

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<thead>
<tr>
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<th>Date:</th>
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<tr>
<td><strong>To:</strong></td>
<td>WHO [Insert name of Office &amp; contact person]</td>
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<td><strong>From:</strong></td>
<td>[Company name]</td>
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<td>[Postal address]</td>
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<tr>
<td><strong>Subject:</strong></td>
<td>ITB No.:</td>
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</tbody>
</table>

YES, we intend to submit a bid.

NO, we are unable to submit a bid in response to the above mentioned Invitation to Bid due to the following reason(s):

( ) The requested products are not within our range of supply

( ) We are unable to submit a competitive bid for the requested products at the moment

( ) The requested products are not available at the moment

( ) We cannot meet the requested specifications

( ) We cannot offer the requested type of packing

( ) The information provided for quotation purposes is insufficient

( ) Your ITB is too complicated

( ) Insufficient time is allowed to prepare a quotation

( ) We cannot meet the delivery requirements

( ) We cannot adhere to your terms and conditions (please specify: payment terms, request for performance security, etc)
( ) Our production capacity is currently full
( ) We are closed during the holiday season
( ) We had to give priority to other clients’ requests
( ) Other (please specify)

If WHO has questions to the bidder concerning this NO BID, WHO should contact Mr./Ms._______________, phone/email _______________, who will be able to assist.