Template Emergency ITB document

United Nations Population Fund
UNFPA - Yemen
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Sanaa'a.,Yemen
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Date: 23/09/2024

Invitation to Bid (ITB) No. YEM/2024/006

Dear Sir/Madam,

We hereby solicit your Bid for the supply of the following items with the following technical specifications as stated in **Annex 6:**

Commodity LOT 1: MHPSS MEDICINES SUPPLIES

Bid Submission:

If you are interested in submitting a bid for these items/services, kindly fill in the attached submission forms and send to the secure email address indicated below/ not later than **13/10/2024, 15:00 (Sana'a time).**

Please ensure to mark your email subject with the ITB reference number:

"ITB/YEM/2024/006 – Medicines –Required Documentation"

Pre-shipment inspection will be conducted at supplier's warehouse before transporting to UNFPA Aden warehouse.

Bidding shall be conducted through ONE envelope. The technical bid containing the technical specifications and the financial bid containing the price information shall be submitted together.

Questions or Clarifications related to the Bid:

Any questions or clarifications relating to the Bid process and/or to the attached documents shall be sent to: Dr. Gamil Zaid at emails: zaid@unfpa.org, no later than **06/10/2024**.

Note: Do not submit or cc your bid/proposal submission to the contact person's email address mentioned in this section!

Documents to be submitted with the bid:

DOCUMENT CHECKLIST - Please remember to submit the following documents:

No.	DOCUMENT NAME	
1	**Annex 1** - Bid Submission Form - Completed and Signed	●
2	**Annex 2** - Bidders Identification Form - Completed	●
3	**Annex 3** - Product Item Overview Form - Completed	●
4	**Annex 5** - Price Schedule Form - Completed and Signed	●
	Annex 7 - Requirements for the Procurement	●
5	A statement whether any import or export licenses are required in respect of the goods to be purchased including any restrictions on the country of origin, use/dual-use nature of goods or services, including and disposition to end users;	●
6	- Latest Business Registration Certificate; - Latest Internal Revenue Certificate / Tax Clearance; - Manufacturer's Authorization of the Company as a Sales Agent (if Bidder is not the manufacturer);	●
7	Certificate of Exclusive Distributorship in the country (if applicable, and if Bidder is not the manufacturer);	●
8	Complete documentation, information and declaration of any goods classified or may be classified as "Dangerous Goods"	●
9	Patent Registration Certificates (if any of technologies submitted in the quotation is patented by the Supplier)	●
10	Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List	●
11	Complete Technical bid submission, including detailed technical specifications, product catalogue, technical data sheets and schematic drawings (when applicable) to demonstrate that specification and quality of the products are in line with the requirements listed in the bidding document.	●
12	**Quality Assurance Documents to be submitted:** Below are Guidelines describing the minimum documentation required to be submitted by the bidders, and can be found in the tables below of pharmaceuticals items. All certificates and approvals must be valid at the time of bid submission.	
12.1	**Documents to be submitted for Pharmaceuticals:** ● **Annex 4.1** - Fast Track Procurement Questionnaire for Pharmaceuticals - duly	●

	completed by bidder and signed for each of the items included in the submission. ● Evidence that the product is registered in the country of intended use ● Evidence that the product is included in the Country National list of essential medicines. ● GMP certificate for Finished Pharmaceutical Product (FPP) manufacturer ● Certificate of analysis for at least one recently released batch. ● Package insert if applicable and patient information leaflet (PIL). ● Photos of the finished pharmaceutical product and labeling. ● Signed declaration that the product to be supplied meets the locally approved specifications and is manufactured under cGMP	
12.2	* Any product registered for "Research Use Only" or "For Export Only" is not acceptable, unless specifically authorized in writing by UNFPA.	●

Partial Bids:

Partial bids are not **allowed** under this ITB. Note: Partial bids mean that the bidder does not have to offer all requested commodity types in order to submit a complete bid. However, within each commodity type, full quantities/items must be offered.

UNFPA reserves the right to make multiple arrangements for any item(s) where, in the opinion of UNFPA, the lowest Bidder cannot fully meet the delivery requirements or if it is deemed to be in UNFPA's best interest to do so.

INCOTERMS 2020:

- Freight cost **DAP** (UNFPA Aden Warehouse)

Validity of Bid:

The prices of the bid shall be valid for *90 days depending* after the closing date of bid submission as specified by UNFPA. A bid valid for a shorter period shall be rejected by UNFPA.

Delivery Time:

The maximum allowed delivery time is **3 weeks** upon issuing of purchase order.

Evaluation of Bids:

UNFPA shall compare all substantially responsive bids to determine the lowest priced substantially responsive bid.

A substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the bidding documents without material deviation, reservation, or omission. A material deviation, reservation, or omission is one that:

a. affects in any substantial way the scope, quality, or performance of the goods and related services specified in the contract; or

b. limits in any substantial way, inconsistent with the bidding documents, UNFPA's rights or the bidder's obligations under the contract; or

c. if rectified would unfairly affect the competitive position of other bidders presenting substantially responsive bids.

d. Bidder's full acceptance of the UNFPA General Terms and Conditions.

e. Adherence to the requested Delivery Time in this Bid document.

f. Physical inspection of registered office, facilities/warehouses will be conducted for the potential suppliers under consideration

Contract Award:

UNFPA shall award the contract to the lowest priced bidder(s) whose bid has been determined to be substantially responsive with the bidding documents, including the maximum allowable lead time. Note: if partial bids are allowed, the lowest evaluated bidder will be evaluated by **commodity** type.

Note: Current UNFPA supplier policies apply to this solicitation and can be found at: http://www.unfpa.org/suppliers.

Attachments:

- **Annex 1 - Bid Submission Form**
- **Annex 2 - Bidders Identification Form**
- **Annex 3 - Product Item Overview Form**
- **Annex 4 - Fast Track Procurement Questionnaire**
- **Annex 5 - Price Schedule Form**
- **Annex 6 – Technical Specification**
- **Annex 7 - Requirements for the Procurement of Medicines**

Annex 1 - Bid Submission Form

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/006

Name of Bidder: _____

Contact Person: _____

Title: _____

Email Address: _____

Telephone Number: _____

Date of Bid: _____

Bid No: _____

Currency of Bid price: _____

Delivery time *(days from receipt of order till dispatch):* _____

(Note: maximum number of days is: 3 weeks)

Expiration of Validity of Bid/Proposal *(The bid shall be valid for a period of at least 90 days after the Closing date.):* _____

Vendor's Comments:

I hereby certify that this company, which I am duly authorized to sign for, accepts the General Terms and Conditions of UNFPA http://www.unfpa.org/resources/unfpa-general-conditions-contract **and we will abide by this bid/proposal until it expires.**

We undertake, if our bid/proposal is accepted, to commence and complete delivery of all items in the contract within the time frame stipulated.

We understand that you are not bound to accept any bid you may receive and that a bidding contract would result only after final negotiations are concluded on the basis of the technical and price bids proposed.

_____ _____

Name and title **Date and Place**

Annex 2 - Bidders Identification Form
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1. **Organization**

Company/Institution Name	
Address, City, Country	
Telephone/FAX	
Website	
Date of establishment	
Legal Representative: Name/Surname/Position	
Legal structure: natural person/Co.Ltd, NGO/institution/other (please specify)	
Organizational Type: Manufacturer, Wholesaler, Trader, Service Provider, etc.	
Areas of expertise of the organization	
Current Licenses, if any, and permits (with dates, numbers, and expiration dates)	
Years supplying to UN organizations	
Years supplying to UNFPA	
Production Capacity	
Subsidiaries in the region (please indicate names of subsidiaries and addresses, if relevant to the bid)	
Commercial Representatives in the country: Name/Address/Phone (for international companies only)	

2. **Quality Assurance Certification**

International Quality Management System (QMS)	
List of other ISO certificates or equivalent certificates	
Presence and characteristics of in-house quality control laboratory (if relevant to bid)	

3. **Expertise of Staff**

Total number of staff	
Number of staff involved in similar supply contracts	

4. **Client Reference List**

Please provide references of main client details.

Name of company	Contact person	Telephone	E-mail
1.			
2.			
3.			

5. **Previous Experience and Similar main projects**

Project	Country/Region	Type of Commodity	Project value in USD
1.			
2.			
3.			

6. **Contact details of persons that UNFPA may contact for requests for clarification during bid evaluation**

Name/Surname	
Telephone Number (direct)	
Email address (direct)	

P.S.: This person must be available during the next two weeks following receipt of the bid

Annex 3 - Product Item Overview Form
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Product's adherence with specifications
The product supplied by manufacturers (and Suppliers, if different from the manufacturer) shall conform with the UNFPA technical specifications or be similar. Bidders are to state clearly in the below table, whether each criteria of the technical specifications matches or not and clearly state the Bidder's specifications in the below field for each item. It is essential that the full specifications are provided.
The bidder SHOULD NOT copy and paste UNFPA's specifications.

Item No.	Description and minimum /mandatory specifications *[Detailed description to be completed by UNFPA]*	Description of items offered and Bidder's statements on deviations (To be completed by the bidder)	Compliant? (Y/N) (To be completed by UNFPA during evaluation)
1	**[...]**		
2	**[...]**		
3	**[...]**		
...			

(Use the spreadsheet "Product Item Overview Form.xls" if a large number of items need to be compared.)

Annex 4 - FTP Questionnaires

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/006

Bidders to complete and submit the below Questionnaires:

➔ **Annex 4.1 - Fast Track Procurement Questionnaire for Pharmaceuticals**

UNFPA Questionnaire for

Pharmaceutical Products under FTP

Please complete all the fields in the questionnaire as required and attach the requested supporting documents. Please fill out one form separately for each pharmaceutical product.

1) MANUFACTURER DETAILS

Name of manufacturer:

Physical address (include Block number, line number etc.):
Postal address:

City: Country:

Telephone: Fax:

E-mail: Website:

A. Include a copy of registration certificate or evidence that the product is registered in the country of intended use.

2) FINISHED DRUG PRODUCT

2.1. IDENTIFICATION

Content	Active Pharmaceutical Ingredient	Amount in dosage form or amount per unit (Strength)
Active Ingredient 1		
Active Ingredient 2 (if applicable)		

Inactive Ingredients (excipients) of medical/pharmaceutical relevance (e.g. sugar, allergens such as preservatives, lactose) amount in dosage form or per dosage unit (e.g. Contains Alcohol 10%):

Brand/trade name (if any):

Dosage form (select below):

- □ **Tablets**
  - ○ Uncoated
  - ○ Sugar coated
  - ○ Film coated
  - ○ Enteric coated
- □ **Capsules**
- □ **Syrup/oral liquids**

- □ **Injection**
  - ○ Microcrystalline suspension
  - ○ Oily solution
  - ○ Aqueous solution
  - ○ Powder for injection
- □ **Implants**

Route of administration (select below):

☐ Oral ☐ I.M. ☐ I.V. ☐ S.C. ☐ Other (Please specify)

2.2PACKAGING

Number of dosage units per unit packs:

Description of primary packaging materials:

B. Attach package insert and/or patient information leaflet (PIL).

C. Picture/photo of the finished pharmaceutical product and labelling.

D. Certificate of analysis for at least one recently released batch (not more than 1 year old).

2.3SHELF LIFE and STORAGE CONDITIONS

Shelf life as it appears on the packaging:

Temperature:

Light:

Humidity:

Other (Specify):

2.4.REGULATORY STATUS

Registration Number of Pharmaceutical Product: Valid until:

Regulatory issued by (Name of Agency): Country:

E. Valid GMP certificate for Finished Pharmaceutical Products (FPP).

3) DECLARATION BY BIDDER/MANUFACTURER

F. Filled out declaration from bidder/manufacturer.

[*Company letterhead*]

Declaration by bidder/manufacturer

I, the undersigned certify that all the information in this declaration and all accompanying documentation is correct and updated. I further certify that I have examined the following statements and I attest to their accuracy.

1. The holder of the national registration follows national requirements for handling adverse reactions on its products.
2. The holder of the national registration follows national requirements for handling batch recalls of its products.
3. The formula to be supplied is exactly the same as the formula approved by the National Regulatory Authority (NRA), SBDMA The strength, specifications (API, excipients and FPP), etc. are exactly the same as the formula approved NRA.
4. The primary packaging is exactly the same in all aspects, including specifications, as the primary packaging approved for use in the same product as approved by the NRA.
5. The secondary packaging is exactly the same in all aspects, including specifications, as the primary packaging approved for use in the same product as approved by the NRA.
6. The information in the questionnaire/dossier submitted to UNFPA contains information which is the same as the information in the dossier which is approved by the NRA.
7. The package inserts, summary of product characteristics, patient information leaflet submitted in the submission are the same as those approved by the NRA.
8. Where there are any differences in any aspect of the product including formula, manufacturing site of API, manufacturing site of FPP, specifications of primary packaging, specifications of secondary packaging, package insert, summary of product characteristics, patient information leaflet, I have stipulated these and the justification for the changes in a separate document and submitted to UNFPA.

Name: Signature:

Position in Company: Date:

Annex: Checklist of attachments required

Please ensure that all documents necessary to enable objective evaluation of your product are attached. This checklist may not be exhaustive.

☐ A. Copy of the registration certificate or evidence that the product is registered in the country of intended use.

☐ B. Package insert and patient information leaflet (PIL).

☐ C. Picture/photo of the finished pharmaceutical product and labelling.

☐ D. Certificate of analysis for at least one recently released batch (not more than 1 year old).

☐ E. Valid GMP certificate for Finished Pharmaceutical Product (FFP).

☐ F. Filled out declaration from bidder/manufacturer.

Annex 5 - Price Schedule Form

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/006

Name of Bidder: _____

Date of Bid: _____

Bid No: _____

Currency of Bid price: _____

Delivery time *(days from receipt of order till dispatch):* _____

(Note: maximum number of days is: 3 weeks)

Expiration of Validity of Bid/Proposal *(The bid shall be valid for a period of at least 90 days months after the Closing date.):* _____

You can include an Excel spreadsheet instead of this format. The table columns should be modified as appropriate for the specific case.

Item No.	price/unit	Quantity	Total FCA/FOB (Destination)	Transportation cost to destination (specify mode of)	Total DAP (Destination)	Delivery schedule (days/weeks upon order)

Vendor's Comments:

PROVIDED THAT A PURCHASE ORDER IS ISSUED BY UNFPA **WITHIN THE REQUIRED BID VALIDITY PERIOD**, THE UNDERSIGNED HEREBY COMMITS, SUBJECT TO THE TERMS OF SUCH PURCHASE ORDER, TO FURNISH ANY OR ALL ITEMS AT THE PRICES OFFERED AND TO DELIVER SAME TO THE DESIGNATED POINT(S) WITHIN THE DELIVERY TIME STATED ABOVE.

_____ _____

Name and title **Date and Place**

Annex 6 – Technical Specification

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/006

LOT 1 Medicines

SN	Item Name	UOM	Pack size	National EML	Quantity requirement	Duration in months
1	Amisulpride 200mg	Packet/ Tab	**30**	**yes**	1500	12
2	Amitriptyline HCL 25 mg	Packet/ Tab	**30**	**yes**	2000	12
3	Aripiprazole 15mg	Packet/ Tab	**30**	**yes**	3000	12
4	Carbamazepine 200mg	Packet/ Tab	**50**	**yes**	3000	12
5	Chlorpromazine 100mg	Packet/ Tab	**30**	**yes**	1500	12
6	Clomipramine 25mg	Packet/ Tab	**30**	**yes**	1150	12
7	Clonazepam 2mg	Packet/ Tab	**100**	**yes**	1500	12
8	Diazepam 5mg/ml amp 2ml	Packet/ Ampoule	**10**	**yes**	1500	12
9	Fluoxetine HCL 20mg	Packet/cap	**30**	**yes**	1500	12
10	Fluphenazine Decanoate 25 mg/1ml	Packet/ Ampoule	**5**	**yes**	3000	12
11	Haloperidol 5mg	Packet/ Tab	**30**	**yes**	3000	12
12	Levetiracetam 500mg	Packet/ Tab	**100**	**yes**	3000	12
13	Lorazepam 2mg/2ml	Packet/ Ampoule	**5**	**yes**	350	12
14	Mirtazapine 15 mg	Packet/ Tab	**30**	**yes**	1300	12
15	Olanzapine 10mg	Packet/ Tab	**30**	**yes**	3000	12
16	Olanzapine 5mg	Packet/ Tab	**30**	**yes**	3000	12
17	Promethazine 25mg/2ml	Packet/ Ampoule	**25**	**yes**	2000	12
18	Risperidone 2 mg	Packet/ Tab	**30**	**yes**	3000	12
19	Risperidone 3 mg	Packet/ Tab	**30**	**yes**	3000	12
20	Sertraline 50 mg	Packet/ Tab	**30**	**yes**	5000	12
21	Trihexyphenidyl HCL 2mg	Packet/ Tab	**100**	**yes**	3000	12
22	Valproic acid 200mg	Packet/ Tab	**30**	**yes**	3000	12
23	Valproic acid 500mg	Packet/ Tab	**30**	**yes**	1500	12

Annex 7

Table 1: - Requirements for the Procurement of Medicines Supplies for the Vendors.

No	Requirements
1	Fast Track Procurement Questionnaire for Pharmaceuticals for each item.
2	GMP (Food and Drug Administration) certificate for Finished Pharmaceutical Product (FPP) manufacturer
3	Certificate of analysis for at least one recently released batch.
4	The supplier shall bear transportation costs to UNFPA warehouses Aden governorates.
5	The Supplier must provide necessary certifications and documentation to prove the Products meet these standards.
6	The suppliers must ensure properly licensed to distribute pharmaceuticals and medical supplies from the locally authorized Supreme Board of Drugs and Medical Appliances (SBDMA).
7	Vendors to Ensure that all medicines and supplies have adequate shelf life upon delivery. (75% of the shelf life).
8	UNFPA may procure all items in the attached lists or some of them.