

**INVITATION TO BID**  
**ITB-IDA/GDF INDIA 2013/003**

**October 29, 2013**

**IDA FOUNDATION**  
**As Contracted Procurement Agent of the WHO/Global Drug Facility (GDF)**  
**WISHES TO PROCURE SECOND AND THIRD LINE ANTI -TUBERCULOSIS (TB)**  
**MEDICINES for the Revised National TB Control Programme (RNTCP) in India**

**Bids should be sent electronically to:**

***bids@idafoundation.org.***

**Attention: Bid Opening Team**

**IMPORTANT - ESSENTIAL INFORMATION**

**The reference ITB-IDA/GDF INDIA 2013/003 must be shown on your bid.**

The bid response form must be used when replying to this invitation. Failure to submit your bid in the attached bid response form, or failure to complete the details as requested, shall result in rejection.

Emailed bids **MUST** be received by latest **16.00 hours Indian Standard Time (IST) on 18<sup>th</sup> November 2013**. Bids received after the stipulated date and time will be excluded.

Bids will be publicly opened at IDA Mumbai office on **19<sup>th</sup> November 2013 at 11.30 hours India time**

Bids will only be accepted in **US DOLLARS** as stated in the enclosures to the invitation. Bids received in any other currency will be rejected.

This invitation to bid has been:

**Prepared By:**

Wendy Eggen  
Manager Large Programmes  
Ida Foundation

**Verified By:**

Kaspars Lunte  
Team Leader MDR-TB Supply, GDF  
Nigorsulton Muzafarova, Quality Assurance Officer, GDF

## **CONTENTS**

SECTION 1: INSTRUCTIONS TO BIDDERS.....	3
1 MARKING AND RETURNING BIDS .....	3
2 DEADLINES FOR THE SUBMISSION OF BIDS AND BID OPENING .....	3
3 PUBLIC OPENING OF BID .....	3
4 REQUEST FOR INFORMATION .....	3
5 ELIGIBILITY CRITERIA AND SPECIFICATIONS.....	3
6 MODIFICATION AND WITHDRAWAL .....	4
7 VALIDITY OF BIDS.....	4
8 PRICES AND DISCOUNTS .....	4
9 INCOTERMS .....	5
10 PACKING .....	5
11 DELIVERY PERIOD.....	5
12 DESTINATIONS .....	5
13 SAMPLES .....	5
14 SUBCONTRACTING.....	5
15 BIDDER REQUIREMENTS .....	6
16 GROSS WEIGHT AND VOLUME .....	6
17 RIGHTS OF IDA/GDF.....	6
18 AWARD/ADJUDICATION OF BIDS.....	6
19 BIDDER REGISTRATION AND EVALUATION .....	7
20 ERROR IN BID .....	8
21 COUNTRY OF ORIGIN .....	8
SECTION 2: CONTRACTUAL PROVISIONS.....	9
SECTION 3: TECHNICAL PROVISIONS .....	10
1 DRUG PRODUCT SPECIFICATIONS .....	10
2 CONTRACT MANUFACTURER .....	10
3 QUALITY CONTROL .....	10
4 MARKETING AUTHORIZATION.....	10
5 STABILITY .....	11
6 REMAINING SHELF LIFE AT THE TIME OF DELIVERY.....	11
7 CERTIFICATE OF ANALYSIS .....	11
SECTION 4: BID RESPONSE FORM.....	12

## **ANNEXES**

- Annex A: Bid response form Excel spread sheet
- Annex B: List consignees for India programme
- Annex C: List of quantities required for India programme
- Annex D: Model of Purchase order
- Annex E: IDA Terms and Conditions
- Annex F: IDA Code of Conduct
- Annex G: Technical Specifications
- Annex H: Disclosure Letter or Access to information

## **SECTION 1: INSTRUCTIONS TO BIDDERS**

### **1 MARKING AND RETURNING BIDS**

1.1 **BIDS** must be submitted by email to ***bids@idafoundation.org***, addressed to the Bid Opening Team and stating the reference **ITB-IDA/GDF INDIA 2013/003**.

1.2 **Bids received without the Bid reference number or to any other address than *bids@idafoundation.org*, will be rejected.**

### **2 DEADLINES FOR THE SUBMISSION OF BIDS AND BID OPENING**

2.1 Bids must be submitted by email to ***bids@idafoundation.org***, by **16.00 hours Indian Standard Time (IST) hours on 18<sup>th</sup> November 2013**. Bids received after this deadline will be rejected.

2.2 The Bid Opening Team will open Bids on **19. November 2013 at 11.30 hours India time in IDA Mumbai office**.

2.3 IDA will accept no responsibility for the premature opening of a Bid which is not properly addressed or marked.

### **3 PUBLIC OPENING OF BID**

3.1 Bidders, or their authorized representative, may attend the public opening of the Bid at the time, date and location specified. No more than two physical representatives per bidder shall be allowed. Bidders should note that the Bid Opening is the only time and place where information related to pricing from competitors is available.

### **4 REQUEST FOR INFORMATION**

4.1 Any request for information should be forwarded to Ms Wendy Eggen , at *weggen@idafoundation.org*, Kaspars Lunte at *luntek@who.int* and Nigorsulton MUZAFAROVA at *muzafarovan@who.int*, latest by close of business 8th of November 2013.

4.2 Responses to requests for information will be sent to all bidders within 3 working days from receipt of the request.

### **5 ELIGIBILITY CRITERIA AND SPECIFICATIONS**

5.1 This Invitation to Bid is open to bidders whose products have been deemed eligible for inclusion in the tender in compliance with the GDF's Quality Assurance policy and procedures (published at [www.stoptb.org/gdf](http://www.stoptb.org/gdf)) and who have been shortlisted accordingly. A bid submitted for a product for which the bidder has not received regulatory approval status in accordance with the GDF Quality Assurance policy and procedures shall not be considered in the evaluation.

5.2 Bidders whose products shall be prospectively compliant in the near future may be conditionally invited to bid for the product(s) in question at the discretion of IDA /GDF.

5.3 Where items offered which are not exactly in compliance with specifications indicated by GDF, or wherever alternatives are offered, it is the Bidder's responsibility to clearly state in the Bid full specifications offered and how these differ from the specifications requested by GDF. IDA/GDF reserves the right to reject any bid that does not conform to the technical specifications.

5.4 This IDA/GDF ITB for India complements the general ITB for all markets as per main bidding exercise for the year 2014. Therefore, the prices that a supplier bids in the main general IDA/GDF ITB per basic unit (tablet, ampoule, vial or capsule) will prevail if they are lower than the Ex Works equivalent prices that that supplier bids in this ITB. Therefore higher pricing per basic unit in this specific India ITBs will not be accepted. Due to additional volumes, it is expected that additional volume discounts and discounted pricing will be offered for India as per this ITB.

5.5 Quality assurance status 'ERP Category 3' means that the product does not meet all quality requirements and it is only recommended if the risk of not treating the disease is higher than the quality risk. Awards are therefore made only in exceptional circumstances for 'ERP Category 3' products.

## **6 MODIFICATION AND WITHDRAWAL**

6.1 All changes to a Bid must be received by email to ***bids@idafoundation.org*** prior to the closing time and date. It must be clearly indicated that it is a modification and supersedes the earlier Bid, or state the changes from the original Bid.

6.2 Bids may be withdrawn on written request received from Bidders prior to the bid submission deadline. Negligence on the part of the Bidder confers no right for the withdrawal of the Bid.

## **7 VALIDITY OF BIDS**

7.1 Bids should be valid for a period of not less than 60 days after bid submission date.

## **8 PRICES AND DISCOUNTS**

8.1 Bidders are requested to:

(a) Provide unit prices in **US Dollars**, which will remain firm, subject to the right to review as outlined in clause 2. Failure to quote in **US Dollars** will lead to invalidation of the bid. Only one DAP price should be quoted per product for all destinations (i.e to various State Drug Stores), including all required documentation. Delivery should be to the consignees as specified in Annex B.

(b) DAP prices should be quoted excluding customs and excise duties.

(c) Advise as to additional discounts applicable for high-volume purchases

(d) Advise as to additional discounts for payment within a specified period of time.

(e) Any discounts for any reason other than those mentioned on the Bid Response Form (Annex

A) must be stated on the Bid.

## **9 INCOTERMS**

9.1 Bidders are requested to quote unit prices in accordance with the following delivery terms (INCOTERMS 2010): **EXW (Ex-Works)** and **DAP (Delivered at Place)**. The bids will be evaluated on the basis of **DAP** but for information purposes EXW prices are also required, to allow basic unit costs comparison with the general ITB for the year 2014.

9.2 Failure to quote in accordance with the requested INCOTERMS will lead to exclusion of the bid.

## **10 PACKING**

10.1 The bidder warrants that the cost of packing is included in the price offered for the items.

10.2 The successful bidder shall ensure that products with specific temperature requirement will be packed and stored in appropriate conditions.

## **11 DELIVERY PERIOD**

11.1 The required delivery period, i.e. the estimated length of time required for manufacture from the date an order is received and until it can be delivered to the consignee, must be stated. These parameters will be taken into account in the Bid adjudication.

11.2 Successful bidders are requested to note that IDA/GDF will monitor and measure the performance of the successful bidder(s), in comparison with guaranteed minimum lead time indicated in their bid(s). Accordingly, bidders are requested to state realistic guaranteed minimum lead times.

## **12 DESTINATIONS**

12.1 For direct distribution to consignees, as Indicated in Annex B.

## **13 SAMPLES**

13.1 IDA/GDF reserves the right to request to the bidder free, non-returnable samples of medicines under this ITB. Those samples shall be labelled and printed according to the latest standard specimen, for approval by GDF. IDA will facilitate coordination prior to placement of any order.

13.2 GDF directly or through IDA will submit technical specifications from RNTCP on the packaging and marking upon request.

13.3 Failure to provide, in a timely manner, samples or documentation requested by IDA/GDF shall be sufficient ground to reject a bid.

## **14 SUBCONTRACTING**

14.1 Bidders MUST identify on their bid any finished products which may be offered by themselves, but originate from another supplier and/or country.

## **15 BIDDER REQUIREMENTS**

15.1 The successful bidder warrants that:

- (a) It has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources to perform its obligations under any resulting Purchase Orders;
- (b) The items offered shall be new and factory packed, and free from defects in workmanship and materials;
- (c) The items offered shall be contained or packaged in a manner adequate to protect them;
- (d) It has not and shall not enter into any agreement or arrangement that restrains or restricts IDA /GDF or the ultimate recipient's rights to use, sell, dispose of or otherwise deal with any item that may be acquired under any resulting Purchase Orders;
- (e) It its affiliates shall minimize greenhouse emissions in their activities to the extent possible.

15.2 The successful bidders will be required to acknowledge that:

- (a) IDA /GDF may further distribute the goods supplied to their clients;
- (b) The benefit of any warranties provided and liabilities entered into with IDA, shall be passed on by IDA to its clients.

## **16 GROSS WEIGHT AND VOLUME**

16.1 Bidders are required to state the estimated gross weight and volume of the items offered in accordance with Annex A.

## **17 RIGHTS OF IDA /GDF**

17.1 IDA /GDF reserves the right to cancel the ITB or not to make any award(s) and cannot be held liable for any compensation demanded by bidders for the costs involved in bid preparation. IDA /GDF may also, unless otherwise specified by IDA /GDF or by the Bidder, accept any item in the Bid.

17.2 IDA /GDF reserves the right to invalidate any Bid received from a Bidder who, in the opinion of IDA/GDF, is not in a position to perform the contract.

## **18 AWARD/ADJUDICATION OF BIDS**

18.1 The contract will be awarded to bidders of compliant products offering a combination of price, lead time, quality assurance status, shelf life, batch quantity and production capacity; whose goods are commercially, technically and quality acceptable, and whose bid is in compliance with this IDA/GDF ITB, provided the bid is reasonable and it is in the interest of IDA /GDF to accept it. Bids will be adjudicated on an DAP basis.

18.2 Bid evaluation criteria and point allocation shall be as follows; with highest points awarded to the lowest price offered as per Bid Response Form (Annex A), and additional criteria, as follows:

<b>CRITERIA</b>	<b>MAXIMUM POINTS</b>
Price ( <i>lowest</i> )	75
Guaranteed lead time (minimum)	8
Supplier performance on Delivery time ( <i>lowest</i> )*	7
Technical compliance:	10
▪ Quality assurance status (WHO PQ/SRA or ERP <sup>1</sup> )	(3)
▪ Minimum order quantity ( <i>lowest</i> **)	(3)
▪ Shelf life ( <i>longest</i> )	(4)

\*- historical performance will be used in the bid evaluation for delivery time. This will help ensure that points awarded are based on an objective and equitable input. In cases where there is no supply history, the following methodology will be used for assigning a performance score.

- If there is no or inadequate product-specific history (i.e., the supplier has been part of the GDF/IDA programs but has not previously supplied the formulation in question), the overall performance score of the supplier across all other relevant formulations will be considered.

- If there is no or inadequate supplier history (i.e., the supplier is new to the GDF/IDA programs or has not supplied any products during the evaluation period), a Supplier Performance Score will be assigned reflecting the mean score of all eligible suppliers for that formulation.

\*\* - lowest minimum order size that a manufacturer commits to service within the guaranteed lead time

18.3 IDA /GDF shall make awards as it is deemed to be in IDA /GDF best interests to ensure that quality products can be delivered to clients in a timely manner. Any arrangement under this condition will be made on the basis of the lowest, second lowest acceptable bid which meets all the requirements in paragraph 13.1 above.

18.4 In case of an award, Bidders who have not previously received Purchase Orders from IDA may receive an order for a limited quantity until satisfactory performance is established.

18.5 Successful bidders shall permit GDF representatives access to their facilities at any reasonable time to inspect the premises that will be used for the production, testing and packaging of the goods, and will provide reasonable assistance to the representatives for such inspection, including copies of any test results or quality control reports as may be necessary.

## **19 BIDDER REGISTRATION AND EVALUATION**

19.1 IDA and GDF reserve the right, unless this information has already been provided within the

---

<sup>1</sup> WHO PQ/SRA: 3 points; ERP Cat 1 or 2: 1 point

previous 12 months, to request bidders to submit their most recent Audited Financial Statement and Quality System Certificate. This information will be used by IDA/GDF for evaluation and approval purposes before making an award. It is in the interest of the bidders to provide information as complete as possible.

## **20 ERROR IN BID**

20.1 Bidders are expected to examine all Schedules and all Instructions pertaining to the Bid. Failure to do so will be at Bidders own risk. In case of errors in the extension price, unit price shall govern.

## **21 COUNTRY OF ORIGIN**

21.1 Goods produced in countries other than that of the Bidder must be indicated, stating the country of origin. Bidders may be required to submit a Certificate of Origin of Goods issued by the Chamber of Commerce or other equivalent authority.

## **SECTION 2: CONTRACTUAL PROVISIONS**

For the contractual provisions, please see attached model of Purchase Order, the procurement agent terms and conditions and the Code of Conduct (Annexes D, E, F)

## **SECTION 3: TECHNICAL PROVISIONS**

### **1 DRUG PRODUCT SPECIFICATIONS**

1.1 The bidder confirms that all anti-TB medicines offered are identical in all aspects of manufacturing and quality to that approved by the WHO Prequalification Programme (WHO PQP) and/or the relevant Stringent Regulatory Authority (SRA) and/or the Expert Review Panel –ERP. This includes, but is not limited to, the following:

- Finished Pharmaceutical Product (FPP);
- Method and site of manufacture;
- Source and specifications of active and excipient starting ingredients;
- FPP specifications;
- Materials and specifications of the packing (primary, secondary, pack size, label and package insert);
- Shelf life and storage condition;
- Product information.

### **2 CONTRACT MANUFACTURER**

2.1 All sites of contract manufacture and the name of the contract manufacturer must have been reviewed and approved by WHO PQP and/or the relevant SRA and/or the Expert Review Panel.

### **3 QUALITY CONTROL**

3.1 All anti-TB medicines offered must be manufactured and conform for quality standards at least to the latest edition of the International Pharmacopoeia, British Pharmacopoeia, US Pharmacopoeia or, exceptionally, in-house method, only in cases where the product in question has no monograph as mentioned before. If there is no monograph available in any of the three of the referenced pharmacopoeias, the approved manufacturer's specifications with supported and validated data shall be submitted within 2 weeks following the notification of contract award by IDA /GDF, if already not provided to GDF/Procurement Agent's Quality Control Agent earlier. Supplier In-house methods should be validated according to ICH guidelines. Failure to submit the documents on time might result in nullification of contract award. If a method is subsequently published by the International Pharmacopoeia, British Pharmacopoeia or US pharmacopoeia, the supplier shall change its testing methods and switch to use of the pharmacopoeial method within 120 days.

3.2 Batches and/or consignments are subject to pre-shipment inspection (PSI), sampling and/or quality control testing performed by the IDA /GDF's Quality Control Agent. In case of the detection of a defective product either in the testing of the product or during the pre-shipment inspection the Supplier will be requested to replace the complete batch at its own cost. The valid GDF/PA Standard Operating Procedure for PSI and testing will be applied.

### **4 MARKETING AUTHORIZATION**

4.1 A WHO Certificate issued by the National Health Authorities, authorizing the manufacture and sale of a given product (WHO Technical Report Series No 863, 1996. Earlier version is NOT acceptable) must be provided upon request.

## **5 STABILITY**

5.1 For products approved with 24 months shelf life, manufacturers shall commit to complete and submit stability studies to support minimum or beyond 36 months of shelf life either to WHO PQP or SRA depending on the mechanism which approved the FFP.

5.2 Containers for all pharmaceuticals must conform to the latest edition of the BP, USP, EP or IP, whichever is applicable. In particular, packaging must be suitable for delivery and use in countries having adverse climatic and storage conditions (Zone IV as specified in Annex 5 in WHO Technical Report Series No 863, 1996) and additionally should be suitable for shipment, storage and use worldwide at elevated temperatures and humidity, unless otherwise stated.

5.3 The size of the container should be proportional to its contents with the addition of appropriate padding to prevent damage to the product during shipment. All containers should be tamper-proof. For tablets or capsules the preferred containers are: Alu/PVC blister cards in carton boxes. For vials small glass bottle colourless, clear, with closed with a rubber stopper and a metal cap are required. For ampoules, glass bottle, colourless and clear, or plastic ampoules of polyethylene, watertight, light and unbreakable and does not react with the water, twist off top pods are required.

## **6 REMAINING SHELF LIFE AT THE TIME OF DELIVERY**

6.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry. The bidder further warrants that all goods supplied, will have, upon arrival at the consignee's warehouse, a remaining shelf life as per Technical Specifications in Annex G and your ERP approval as attached in the Covering Letter.

6.2 Shelf life and storage conditions: if supported stability data has been submitted and accepted by WHO PQP, SRA or ERP, products can be offered with longer shelf life and approved storing conditions.

## **7 CERTIFICATE OF ANALYSIS**

7.1 A Certificate of Analysis from manufacturer's own quality control laboratory covering each batch delivered is to be submitted together with shipping documents.

7.2 The Certificate of Analysis shall include:

- a) Generic name (INN) of product;
- b) Pharmacopoeial reference and/or In-house method;
- c) Batch number;
- d) Date of manufacture;
- e) Expiry date;
- f) Date of test;
- g) Description (clarity, colour, etc.);
- h) All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia and/or In-house method. Both the actual results and the limits for the individual tests should be given.
- i) Conclusion
- j) Qualified signatures

7.3 A certified copy of the original Certificate of Analysis in English should be sent by email to the GDF contracted quality control laboratory.

**SECTION 4: BID RESPONSE FORM**

BID FORM must be completed, signed and returned to IDA. Bid must be made in accordance with the instructions contained in this Invitation to Bid.

**TERMS AND CONDITIONS OF CONTRACT**

Any Purchase Order or Contract resulting from this invitation shall contain IDA's General Terms and Conditions (as per Annex E).

**INFORMATION**

Any request for information concerning this invitation, must be forwarded in writing by email, to the persons mentioned in Section 1 § 4.1, with specific reference to the ITB number.

**DECLARATION**

The undersigned, having read the Terms and Conditions of **ITB-IDA/GDF INDIA 2013/003** set out in the attached document, hereby offers to supply the goods specified in the schedule at the price or prices quoted, in accordance with the specifications stated and subject to the Terms and Conditions set out or specified in the document.

**Name of authorized representative:** \_\_\_\_\_

**Title:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Bidder Name:** \_\_\_\_\_

**Postal Address:** \_\_\_\_\_

**Telephone No.:** \_\_\_\_\_

**Fax No.:** \_\_\_\_\_

**Email Address:** \_\_\_\_\_

**Validity of Offer (not less than 60 days from the submission date):** \_\_\_\_\_

**Currency of Offer:** **USD**

Please indicate after having read Payment & Discount stated under Instructions to Bidders, which of the following payment terms are offered by you:

- 10 days - 3.0% discount of product price
- 15 days- 2.5% discount of product price
- 30 days -2.0% discount of product price
- 45 days net

**BID RESPONSE FORM SPREADSHEET**

**KINDLY SEE ANNEX A (please submit Annex A in both pdf and excel electronic formats)**