INVITATION TO BID

ITB-IDA/GDF INDIA 2015/005

IDA foundation, as contracted Procurement Agent of the
Stop TB Partnership/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

IMPORTANT AND ESSENTIAL INFORMATION

The reference ITB-IDA/GDF INDIA 2015/005 must be shown on your bid.

Bids should be sent electronically to: bids@idafoundation.org

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

Emailed bids must be received by latest **16.00 hours Indian Standard Time (IST) on 27th January 2015.** Bids received after the stipulated date and time will be excluded.

Bids will be publicly opened at IDA Mumbai office on **28th January 2015 at 10.00 hours IST.**

Bids will only be accepted in **US DOLLARS (USD)**. Bids received in any other currency will be rejected.

This invitation to bid has been:

Prepared By:	Suzanne de Jongh Programme Manager GDF, IDA Foundation
Verified By:	Kaspars Lunte, Team Leader Sourcing and Special Projects, GDF Fabienne Jouberton, Team Leader Procurement, GDF Nigorsulton Muzafarova, Quality Assurance Officer, GDF

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SECTION 1: OBJECTIVE

The purpose of this ITB is to select a panel of suppliers who will supply first tranche of 2015 medicines requirements (further in text: medicines), as requested by the Revised National TB Control Programme (RNTCP) in India under The Global Fund funding. It is estimated that 50% of MDR quantities and 100% of XDR quantum will constitute 1st delivery which is planned in April/May 2015 and the balance in August 2015.

SECTION 2: SCOPE OF WORK

2.1 The GDF strategy

The Global Drug Facility (GDF) aims to ensure timely access to quality assured, affordable TB drugs and diagnostics and contribute to the development of sustainable TB drug management capacity for countries in need. In developing its strategy, the GDF has determined the following key principles:

- Saving lives by ensuring an uninterrupted supply of quality-assured, affordable anti-TB drugs and diagnostics to population in need

- Contributing to TB commodities market shaping by linking strategic interventions on the demand and supply sides with stakeholders/partners, focusing on market analysis, supply security, suppliers engagement, affordable and sustainable prices, innovation and new products introduction/uptake by countries

- Maximizing impact and value for money by enhancing efficiency/effectiveness of operations focusing on quality of services and clients/partners feedback

2.2 Technical Specifications/ Product list

To translate the strategic principles into an executable strategy, the following criteria have been defined:

2.2.1. The medicines selected are the ones indicated in **Annex C and Annex G.**

2.2.2. The total demand for the products will be allocated to a limited number of suppliers, whose selection will be based on the outcomes of this ITB.

2.3 Products volume

2.3.1 Actual quantities to be ordered in 2015 can vary due to RNTCP demand fluctuations. IDA/GDF is not in the position to make any guarantees in this regard.

2.4 Contract management

2.4.1 Purchase Orders under this ITB will be concluded with bidders of compliant products offering a combination of price, production lead time, shelf life, and total number of API sources and (WHO PQed) API sources. The goods must be commercially, technically and quality acceptable, and the bid in compliance with this ITB. 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 2015

2.4.2 This IDA/GDF ITB for India will complement the forthcoming general ITB for all markets for the year 2015 (Rest of the World (ROW) ITB).
Therefore, the Ex-Works prices in USD that a supplier will bid in this IDA/GDF ITB per basic unit (tablet, ampoule, vial or capsule) will also be valid for the forthcoming ITB for ROW, unless lower Ex-Works prices for equivalent products will be offered for the ROW ITB.

2.4.3 Performance monitoring
IDA will be measuring awarded bidders, focusing on production lead time as stated in the bid. In addition, quality compliance (e.g. on-time providing of documents, compliance to QC and PSI requirements) will be monitored and measured. Outcomes of these performance measurements will be used for future ITBs and for discussion on improvement of performance.

SECTION 3: CONDITIONS OF PARTICIPATION

3.1 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 (http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp).

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 ITB evaluation.

3.2 However, 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.

3.3 Where items offered are not exactly in compliance with specifications indicated by GDF, or wherever alternatives are offered, the Bidder shall re-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.

3.4 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. All ERP products can only be sourced after obtainment of no-objection certificate from The Global Fund.

SECTION 4: BID FROM AND BID RESPONSE FORM / INSTRUCTIONS TO BIDDERS

4.1 MARKING AND RETURNING BIDS

4.1.1 Bids must be submitted by email to bids@idafoundation.org addressed to the Bid Opening Team and stating the reference ITB-IDA/GDF INDIA 2015/005.

4.1.2 Bids received without the Bid reference number or to any other address than

bids@idafoundation.org will be rejected.

4.1.3 BID FORM (SECTION 9) and BID RESPONSE FORM (ANNEX A) must be completed, signed and returned to IDA.
BID RESPONSE FORM (ANNEX A) must preferably be provided in both high resolution easily readable PDF and EXCEL electronic format.

4.1.4. Bid must be made in accordance with the instructions contained in this Invitation to Bid.

4.2 DEADLINES FOR THE SUBMISSION OF BIDS AND BID OPENING

4.2.1 Bids must be submitted by email to **bids@idafoundation.org by 16.00 hours Indian Standard Time (IST) on 27th January 2015.** Bids received after this deadline will be rejected.

4.2.2 The Bid Opening Team will open Bids publicly on **28th January 2015 at 10.00 hours** India time in IDA Mumbai office.

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

4.3 PUBLIC OPENING OF BID

Bidders, or their authorized representatives, 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.

4.4 REQUEST FOR INFORMATION

4.4.1 Any request for information should be forwarded to Ms Suzanne De Jongh at sdejongh@idafoundation.org, Kaspars Lunte at kasparsL@stoptb.org, Fabienne Jouberton at fabiennej@stoptb.org and Nigorsulton Muzafarova at nigorsultonM@stoptb.org , latest by close of business 16th January 2015.

4.4.2 Responses to requests for information will be sent to all bidders within three working days from after closing date of the request for information.

4.5 MODIFICATION AND WITHDRAWAL

4.5.1 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.

4.5.2 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.

4.6 VALIDITY OF BIDS

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

4.7. PRICES AND DISCOUNTS

Bidders are requested to:

4.7.1 Provide unit prices in US Dollars only, which will remain firm.
Failure to quote in US Dollars will lead to invalidation of the bid. Bids will be evaluated in US Dollars only.

4.7.2. Advise as to additional discounts applicable for high-volume purchases.

4.7.3 Any discounts for any reason other than those mentioned on the Bid Response Form must be stated on the Bid (Annex A).

4.8. INCOTERMS

4.8.1 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 2015

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

4.9. GROSS WEIGHT AND VOLUME

Bidders are required to state the estimated gross weight and volume of the items offered in accordance with the Bid Response Form (Annex A).

4.10. PACKING

4.10.1. The bidder shall ensure that the cost of packing is included in the price offered for the item(s).

4.10.2 GDF will directly or through IDA submit pdf samples of the latest standard packaging requirements including GDF logo file to all suppliers, upon request.

4.11. SAMPLES

4.11.1 IDA/GDF reserves the right to request the bidder for free, non-returnable samples of medicines under this ITB. The 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.

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

4.11.3 GDF directly or through IDA and upon request will submit technical specifications or its changes, as received from RNTCP on the packaging and marking.

4.12. COUNTRY OF ORIGIN

Goods produced in countries other than that of the Bidder must be indicated, stating clearly 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.

4.13. CONTRACT MANUFACTURING

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

4.14. BIDDER REQUIREMENTS

4.14.1 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 LTA or Purchase Order;
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 the ensure integrity of the product;
d) It has not and shall not enter into any agreement or arrangement that restrains or restricts the 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 LTA or Purchase Order;
e) The bidder and any of its affiliates shall minimize greenhouse emissions in their activities to the extent possible;
f) The RNTCP will provide the Customs Duty Exemption Certificate/Excise Duty Exemption Certificate to the contractor for the products along with the Purchase Order. The contractor shall specifically indicate in this regard the exact details of such exemptions that are needed for the finished Pharmaceutical Products and/or for the API that might be needed for manufacture of such finished Pharmaceutical Products proposed to be covered under such purchase orders. The vendors are advised to specifically indicate the details of such certificates needed while responding to the Bid.

4.14.2 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.

4.15. RIGHTS OF IDA/GDF

4.15.1 IDA/GDF reserves the right to cancel this 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. The IDA/GDF may also, unless otherwise specified by IDA/GDF or by the Bidder, accept any item in the Bid.

4.15.2 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.

4.16. ERROR IN BID

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 package price, the basic unit price (tablet, capsule, vial etc) shall govern.

SECTION 5: EVALUATION CRITERIA AND ADJUDICATION

5.1 Bid evaluation criteria and point allocation shall be as follows; with highest points awarded to the lowest price offered for the first category (e.g. 1 – 1100 units) as per Bid Response Form (Annex A) and additional criteria, as follows:

CRITERIA	**MAXIMUM POINTS**
Price (lowest)	70
Production lead time (Shortest)	15
Shelf life (longest)	10
Number of API source(s) (highest)	2,5
Number of WHO PQ API source(s) (highest)	2,5

5.2 The competitive range of the bids quoted is considered within a maximum delta of +15% from the lowest price. Suppliers outside the competitive range will not be considered for evaluation

5.3 Bid evaluation will be carried out by a bid Evaluation Committee which will comprise at least 2 members, with at least 1 representative each from the GDF and IDA Foundation. The Evaluation Committee will operate by consensus.

5.4 In case a formal complaint with regard to the outcomes of the bidding process is lodged by a Bidder, a Review Committee will be set up and will comprise representatives of both GDF and IDA Foundation. Complaints will need to be filed to IDA and GDF within maximum 1 week after the outcomes of the bidding have been communicated to bidders.
The recommendation made by the Review Committee regarding the complaint in question shall be final and the award, if necessary, modified accordingly.

5.5 Prior to the expiration of the period of bid validity, IDA Foundation will notify the successful Bidder(s) in writing that its bid has been accepted. If, after notification of award, a Bidder wishes to ascertain the grounds on which its bid was not selected, it should address its request to the Procurement Agent. IDA Foundation will promptly respond in writing to the unsuccessful Bidder.

5.6 IDA/GDF may issue new Invitations to Bid for a specific product schedule in a case where A) current suppliers are deemed unable to meet the orders coming from the market (e.g. due to insufficient capacity), or B) where a product had none or only one supplier eligible at the time of bid and additional sources achieve the necessary

regulatory approval during the LTA period, or a combination of A) and B), or other unforeseen exceptional circumstances.

5.7 The production lead time, i.e. the length of time required for manufacture from the date an order is received until date of goods and shipping documents readiness at supplier premises for pre shipment inspection, must be stated. This parameter will be taken into account in the Bid evaluation.

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

5.9 IDA and GDF reserve the right, unless this information has already been provided within the previous 12 months, to request bidders to submit their most recent Audited Financial Statement, Statutes, Registry excerpt from the respective Chamber of Commerce and Quality System Certificate. This information may be used by IDA/GDF for evaluation and approval purposes before making an award. It is in the interest of the bidders, if requested, to provide information as complete as possible.

5.10 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 activity, including copies of any test results or quality control reports as may be necessary.

SECTION 6: CONTRACTUAL PROVISIONS

For contractual provisions, please see Contractual Provisions for Purchase Order IDA's Terms and Conditions and Code of Conduct (ANNEXES D, E and F).

SECTION 7: TECHNICAL PROVISIONS

For all Technical Provisions reference is made to Annex G: Technical Specifications

SECTION 8: TECHNICAL SPECIFICATIONS / PRODUCTS

For all Technical Specifications / products reference is made to ANNEX G. ANNEX C refers to List of quantities required for India programme.

TERMS AND CONDITIONS OF CONTRACT

Any Purchase Order resulting from this ITB shall contain IDA's General Terms and Conditions and Code of Conduct (as per ANNEXES E and F).

INFORMATION

Any request for information concerning this ITB, must be forwarded in writing by email, to the persons mentioned in Section 1.4.1, with specific reference to the ITB number.

SECTION 9: BID FORM

DECLARATION

The undersigned, having read the Terms and Conditions of **ITB-IDA/GDF INDIA 2015/005** set out in the present 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 this document.

Supplier Name: _____

Postal Address: _____

Telephone No.: _____

Fax No.: _____

Email Address: _____

Validity of Offer (not less than 60 days from the submission date): _____

Name of authorized representative: _____

Title: _____

Signature: _____

Date: _____