INVITATION TO BID

ITB-IDA/GDF - FLD/2014/001

IDA FOUNDATION,
As contracted Procurement Agent of the Stop TB Partnership/Global Drug Facility (GDF),
WISHES TO PROCURE FIRST LINE
ANTI-TUBERCULOSIS (TB) MEDICINES

Attention: Bid Opening Team

IMPORTANT – ESSENTIAL INFORMATION

The reference ITB-IDA/GDF - FLD 2014/001 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 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 IST on 14th of November 2014.** Bids received after the stipulated date and time will be excluded.

Bids will be publicly opened at IDA Mumbai office on **17th November 2014 at 10.00 hours IST.**

Bids will only be accepted in **US DOLLARS**. 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:
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 enter into Long-term agreements (LTAs) with IDA Foundation, the selected Procurement Agent of the Global Drug Facility for the supply of First Line Anti-TB drugs.

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 First line Anti-TB products and medical devices selected are the ones indicated in **Annex B.**

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 and allocation scheme

2.3.1 The total forecasted volume covered by this ITB is indicated in **Annex H**. Forecasts are subject to change and shall not be considered as volume commitment. Actual quantities to be ordered in 2015 can vary due to countries demand fluctuations. IDA/GDF is not in the position to make any guarantees in this regard.

2.3.2 The products ordered will be allocated to the limited number of suppliers following a volume allocation scheme as indicated in section 5.5.

2.4 Contract management

2.4.1 IDA Foundation intends to sign Long-term Agreements (LTAs) with awardee(s) under this ITB. The LTAs will be awarded to bidders of compliant products offering a combination of price, supplier performance, production lead time, shelf life, product registration, 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. Bids will be adjudicated on an EXW basis as elaborated hereunder.

2.4.2 LTAs shall be valid for an initial term of 12 months). IDA Foundation shall be entitled to renew an LTA for a further term of 6 or 12 months and on the same terms and conditions, by giving the Contractor written notice of its intention to renew the LTA not less than 30 days prior to the expiry date, provided however that the Contractor shall be entitled to review its prices 12 months after the commencement date of the LTA, and not less than 90 days prior to expiry of the 12 month period shall advise IDA Foundation in writing as to price maintenance or proposed price increases/reductions. In case of price increase, well documented justification needs to be provided to IDA/GDF. The IDA Foundation shall notify the Contractor in writing within 60 days of receipt of the notice, whether it agrees to the revised prices.

2.4.3 Performance monitoring
After conclusion of LTA, IDA will be measuring awarded bidders, focusing on lead time (promised date of delivery versus actual date of delivery) and production lead time as stated in the bid. In addition, on time order confirmation and 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 during the LTA period. Please also see clauses 5.1 and 5.14.

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 (published at 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 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.

All suppliers who expect their products to be compliant by the time of bid opening can submit bids in the ITB, and those that achieve approval by bid opening will be assessed according to that status, if relevant confirmation is provided to IDA/GDF latest 3 hours before bid opening in writing.

If during the ITB period, the submitted product has ERP approval, it cannot be eligible for market share allocation if there are 2 or more products fully approved by WHO PQP or SDRA as per GDF's Quality Assurance policy and procedures (published http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp)

However, if the status of these ERP products will change as fully approved by WHO PQP or SDRA until the day and time of the bid opening, these will be considered for market share allocation during bid evaluation.

Manufacturer concerned shall immediately inform Suzanne de Jongh, Programme Manager GDF, IDA Foundation at sdejongh@idafoundation.org, with copy to Fabienne Jouberton, GDF Team Leader at joubertonf@who.int and Nigorsulton Muzafarova, GDF QA officer, at muzafarovan@who.int about such status change latest 3 hours before the time of bid opening, otherwise this will not be considered during bid evaluation.

3.3 For the new paediatrics formulations (section 8-schedule 2, items 4 and 5) bidders are invited to offer a bid or to express their interest (EoI). Bidders can express their EoI by stating this on the

Bid Form (SECTION 9).
If after the closure of the ITB, mentioned products become eligible according to GDF QA Policy, bidders that expressed their interest at the time of this ITB will be invited to 1) make an offer (if only 1 supplier is eligible) or 2) to bid (if more than 1 supplier is eligible). Terms and conditions will be the same this ITB. The LTA will only be signed when all conditions are met.

3.4 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.

3.5 If the bidder submits product in compliance with the GDF's Quality Assurance policy, but in other packaging as required by this ITB, it can be considered for bid evaluation, however without any market share allocation.

3.6 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. No 'ERP Category 3' product will be considered for market share allocation.

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 - FLD/2014/001.

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, p.13) and BID RESPONSE FORM (ANNEX A) must be completed, signed and returned to IDA. Bidder is requested to also return the Response form for Registration (in High Burden Countries) (ANNEX C) and Disclosure Letter for Access to Information (ANNEX G).

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 IST on 14th of November 2014.** Bids received after this deadline will be rejected.

4.2.2 The Bid Opening Team will open Bids publicly on **17th of November 2014 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 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.

4.4 REQUEST FOR INFORMATION

4.4.1 Any request for information should be forwarded to Suzanne de Jongh, Programme Manager GDF, IDA Foundation at sdejongh@idafoundation.org, with copy to Fabienne Jouberton, GDF Team Leader at joubertonf@who.int and Nigorsulton Muzafarova, GDF QA officer at muzafarovan@who.int, latest by close of business 31th of October 2014.

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 i.e. on 5th of November 2014.

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, subject to the right to review as outlined in ITB clause 2.4.2 and in clause 4 of the model Long-term Agreement (LTA). Failure to quote in US Dollars will lead to invalidation of the bid. Bids will be evaluated in US Dollars only.

4.7.2 Provide staircase pricing as per Annex A Bid Response Form Spread Sheet (i.e. varying prices according to quantity of units purchased per Purchase Order).

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

4.7.4 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: EXW (Ex-Works) (INCOTERMS 2010).

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.

4.12. 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 bidder shall obtain any export license or other governmental authorization which may be necessary. It will be the sole responsibility of the bidder to obtain such license or authorization. IDA /GDF may provide assistance upon request.

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 extension price, unit price 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)	60
Supplier performance on delivery time (highest)*	20
Production lead time	5
Shelf life (longest)	5
Product registration (most)	5
Number of API source(s) (highest)	2,5
Number of WHO PQ API source(s) (highest)	2,5

**Historical performance on lead time (promised date of delivery versus actual date of delivery) will be used in the bid evaluation for performance on delivery time. Performance is measured per order (line) and for this ITB performance is measured of the full period of the validity of the last LTA (i.e. 1 January 2013 - 31 October 2014) will be used.*

This will ensure points awarded are based on an objective and equitable input.

In cases where there is no supply history for a specific product/supplier, 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 product in question), the overall performance of the supplier across all other relevant products 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 product.

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 may be awarded with LTAs without any market share allocation.

5.3 IDA/GDF shall make multiple awards as it is deemed to be in IDA/GDF's 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 and third lowest, etc. acceptable bid which meets the requirements in paragraph 2.4.1 above.

5.4 IDA/GDF intends to award contracts or orders based on market share allocation based on the results of this ITB, with possible modifications as per point 5.5 below. Please note, that the below allocations are target allocations only and only for fully approved products under WHO PQP or SDRA, and actual allocations may deviate due to unforeseeability and volatility of procurement requests from countries. Market allocations are also subject to fulfilment by suppliers of respective order requirements, such as but not limited to quality assurance status, importation requirements, in-country registration status, production capacity and lead time in accordance with the Agreement entered with the supplier, as well as client preferences (e.g. in regard to packaging).

5.5 The allocation is indicative based on the primary/secondary/tertiary supplier status awarded based on evaluation of this ITB, and is implemented per formulation and anticipated total quantity over the contract period as follows:

- 100% for primary/sole supplier
- 65%/35% for primary/secondary/auxillary suppliers
- 60%/25%/15% for primary/secondary/tertiary/auxillary suppliers

For the new paediatrics formulations, the initial volume allocation is 100% if there is only one eligible supplier. If after the initial allocation meanwhile more than one supplier becomes eligible, based on the evaluation of the ITB, above scheme will be applicable (see also 3.3).

5.6 The market allocation amounts given above will be re-assessed quarterly, based on performance of suppliers (including but not limited to compliance with lead time, responsiveness etc.). Allocations may be adjusted at the discretion of GDF/IDA as required. In the event of significant underperformance of a supplier, IDA reserves the right to suspend or cancel a long-term agreement and/or reallocate quantities to the other contracted supplier(s).

GDF/IDA reserve the right to modify the allocation percentages if circumstances so require, e.g. with respect to production capacity.

5.7 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.

5.8 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.

5.9 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.

5.10 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.

5.11 Successful bidders shall register their products in the countries for which they are ordered where registration is mandatory, and in High Burden TB Countries The most recent information on HBTCs can be found on http://www.stoptb.org/countries/tbdata.asp
and can be used to fill in Annex C.

5.12 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.

5.13 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, must be stated. This parameter will be taken into account in the Bid evaluation.

5.14 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. GDF at its own discretion may change market allocation in case the performance of the successful bidder(s), in comparison with production lead time indicated in their bid(s) is not satisfactory.

5.15 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.

5.16 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 model Long-term Agreement, 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 model LTA (ANNEX G)

Bidder confirms by offering a BID that all First line TB medicines offered are compliant with the model LTA requirements e.g. Quality Status, GMP compliant manufacturing site, Quality Control, Shelf Life, Marketing Authorization, COA, Packaging etc. etc.

SECTION 8: TECHNICAL SPECIFICATIONS / PRODUCT LIST

For all Technical Specifications / product list reference is made to ANNEX B.

TERMS AND CONDITIONS OF CONTRACT

Any Purchase Order or Contract 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-FLD/2014/001** 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): _____

EXPRESSION OF INTEREST TO SUBMIT AT A LATER STAGE _____
Offers for Products in section 8 - schedule 2, items 4 & 5

Name of authorized representative: _____

Title: _____

Signature: _____

Date: _____