INVITATION TO BID

ITB-IDA/GDF 2013/005 *29th October 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

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

Attention: Bid Opening Team

IMPORTANT – ESSENTIAL INFORMATION

The reference ITB-IDA/GDF 2013/005 must be shown on your bid.

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 18th of November.** Bids received after the stipulated date and time will be excluded.

Bids will be publicly opened at IDA Mumbai office on **19th November 2013 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:
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Manager Large Programmes, IDA Foundation

Verified By:
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Nigorsulton Muzafarova, Quality Assurance Officer, GDF

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Annex B: List of High Burden Countries

Annex C: Example of Artwork and GDF logo

Annex D: IDA Code of Conduct

Annex E: IDA Model Long-term Agreement

Annex F: IDA General Terms and Conditions

Annex G: GDF QA Policy

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Annex I: 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 2013/005 .**

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 t**o bids@idafoundation.org** by **16.00 hours IST on 18th of November 2013.** Bids received after this deadline will be rejected.

2.2 The Bid Opening Team will open Bids publicly **on 19. November 2013** at **10.00 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 Wendy Eggen Manager Large Programmes, IDA Foundation, at weggen@idafoundation.org, with copy to Kaspars Lunte, GDF Team Leader MDR-TB supply at luntek@who.int and, Nigorsulton MUZAFAROVA, GDF QA officer 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 three 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) 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 ITB 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 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 currently 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 at www.stoptb.org/gdf).
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 Wendy Eggen Manager Large Programmes, IDA Foundation, at weggen@idafoundation.org, with copy to Kaspars Lunte, GDF Team Leader MDR-TB supply at luntek@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.

5.4 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.

5.5 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.

5.6 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.

5.7. This IDA/GDF ITB is the main bidding exercise, which might be complemented by specific ITBs for major countries, such as India. Therefore, the prices that a supplier bids in in the IDA/GDF ITB per basic unit (tablet, ampoule, vial or capsule) will prevail if they are lower than the Ex Works equivalent prices that supplier bids of the other ITBs. Therefore higher pricing per basic unit in specific ITBs will not be accepted. Due to additional volumes, it is expected that additional volume discounts and discounted pricing will be offered for the additional ITB in India.

5.8 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.

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 only,** which will remain firm, subject to the right to review as outlined in ITB clause 17.2 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.

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

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

(d) Advise as to 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 **FCA (Free Carrier (named place)).** The bids will be evaluated on the basis of EXW, but FCA prices are also requested for information purposes.

9. 2 Failure to quote in accordance with the requested INCOTERMS will lead to exclusion of the bid.

10. SAMPLES

10.1 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.

10.2 GDF directly or through IDA will submit pdf sample of the latest standard packaging, Vectorized GDF logo file can be provided upon request.

10.3 Failure to provide, in a timely manner, samples or documentation requested by the IDA

/GDF shall be sufficient ground to reject a bid.

11. CONTRACT MANUFACTURING

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

12. PACKING

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

13. BIDDER REQUIREMENTS

13.1 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 them;
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.

13.2 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.

14 DELIVERY PERIOD

14.1 The required delivery period, i.e. the estimated length of time required for manufacture from the date an order is received and until date of goods and shipping documents readiness at supplier premises, must be stated. These parameters will be taken into account in the Bid evaluation. Please refer to Clause 17.3 for additional details.

14.2 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. GDF at its own discretion may change market allocation in case the

performance of the successful bidder(s), in comparison with guaranteed minimum lead time indicated in their bid(s), is not satisfactory.

15 GROSS WEIGHT AND VOLUME

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

16 RIGHTS OF IDA/ GDF

16.1 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.

16.2 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.

17 AWARD/ADJUDICATION OF BIDS

17.1 The Procurement Agent 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, guaranteed lead time (minimum), supplier performance on delivery time, minimum order quantity (lowest), quality assurance status, product registration and shelf life (climatic Zone IV studies promoted). 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.

17.2 LTAs shall be valid for an initial term of 12 months(s). The Procurement Agent shall be entitled to renew an LTA for a further term of 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 the Procurement Agent 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 Procurement Agent shall notify the Contractor in writing within 60 days of receipt of the notice, whether it agrees to the revised prices.

17.3 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*)	75
Guaranteed lead time (minimum)	7
Supplier performance on delivery time*	7
Technical compliance:	11
▪ Quality assurance status (WHO PQ/SRA or ERP)1	(3)
▪ Minimum order quantity (lowest)**	(2)
▪ Product registration (most)	(3)
▪ Shelf life (longest) ▪	(3)

**- 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*

17.4 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 17.1 above.

17.5 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 17.6 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

[1] WHO PQ / SRA: 3 points; ERP Cat. 1 or 2: 1 points.

(refer to GDF quality assurance policy, www.stoptb.org/gdf), 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).

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

- 65%/35% for primary/secondary suppliers
- 60%/25%/15% for primary/secondary/tertiary suppliers
- 55%/20%/15%/10% for primary/secondary/tertiary/quaternary suppliers

While GDF offers medicines in bulk packaging to a very limited degree, sales of bulk products cannot be guaranteed and are not included in the market allocation scheme where blistered products are available.

17.6 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). Allocations may be adjusted at the discretion of GDF /IDA as required. In the event of significant underperformance of a supplier, the Procurement Agent 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 also modify the allocation percentages if circumstances so require, e.g. with respect to production capacity.

17.7 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.

17.8 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.

17.9 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 the Procurement Agent. The Evaluation Committee will operate by consensus.

17.10 In case a formal complaint with regard to the outcome of the bidding process is lodged by a Bidder, a Review Committee will be set up and will comprise representatives of both GDF and Procurement Agent. The recommendation made by the Review Committee regarding the complaint in question shall be final and the award, if necessary, modified accordingly.

17.11 Prior to the expiration of the period of bid validity, the Procurement Agent 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. The Procurement Agent will promptly respond in writing to the unsuccessful Bidder.

17.12 Successful bidders shall register their products in the countries for which they are ordered where registration is mandatory, and in High Burden TB Countries (as outlined in Annex B).

17.13 "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 tender period, or combination of A) and B), or other unforeseen exceptional circumstances .

18 SUPPLIER REGISTRATION AND EVALUATION

18.1 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 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.

19 ERROR IN BID

19.1 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.

20 COUNTRY OF ORIGIN

20.1 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 contractual provisions, please see attached model Long-term Agreement, the Procurement Agent's general terms and conditions and Code of Conduct (Annexes E, F and D).

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) formulation;
- 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 manufacturers 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 GDF/Procurement Agent'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/Procurement Agent Standard Operating Procedure for PSI and testing will be applied.

4 MARKETING AUTHORIZATION

4 .1 A WHO-certificate issued by 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 under which the FFP was approved.

5.2 Containers for all pharmaceuticals must conform to the latest edition of the BP, USP, EP or IP, whenever 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, 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 the date of presentation for pre-shipment inspection, a remaining shelf life as follows:

Total shelf life	**Minimum remaining shelf life at Pre-shipment inspection date**
24 - 36 months (2 - 3 years)	85% shelf life remaining of the total specified shelf life.
36 - 48 months (3 - 4 years)	30 months or 80 % shelf life remaining of the total specified shelf life, whichever is longer
> 48 months (> 4 years)	36 months or 75 % shelf life remaining of the total specified shelf life, whichever is longer.

6.2 Shelf life and storage conditions: if supported stability data has been submitted and accepted, 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 along 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) Batch quantity
e) Date of manufacture;
f) Expiry date;
g) Date of test;
h) Description (clarity, colour, etc.);
i) 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.
j) Conclusion
k) 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.

8 BLISTER PACKAGING

8.1 IDA /GDF have adopted standards for blister design including layout, materials, and markings. Due to operational advantages for the TB programme, most clients require medicines to be supplied in blister packaging. GDF will focus on blister packaging as follows:

a. Alu/PVC/PVdC Blister cards of 10 tablets/ capsules]
b. Alu/Alu continuous strips of 10 tablets/ capsules]
c. Specific packing for India TB programme.

SECTION 4: TECHNICAL SPECIFICATIONS

NOTE: The estimated Global needs for the products below are provided in Annex H of this ITB. Actual quantity to be ordered in 2014 can vary due to countries demand fluctuations. IDA/GDF make no guarantees in this regard.

SCHEDULE No. 1: Oral solid dosage forms: Fluoroquinolones

- **Item No. 1: Ofloxacin 200mg tablet (blister)**

General Description: Ofloxacin 200 mg film-coated tablets.

Technical Specifications: Each tablet should contain Ofloxacin 200mg and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging[2].: Al/PVC/PVDC film blister pack of 10 tablets x 10 blisters in a carton box

Shelf life and storing conditions[3]: minimum accepted 24 months shelf life. Store below 30 C degrees, in a dry place, protected from light.

- **Item No. 2: Ofloxacin 400mg tablet (blister)**

General Description: Ofloxacin 400 mg film-coated tablets.

Technical Specifications: Each tablet should contain Ofloxacin 400mg and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: Al/PVC/PVDC film blister pack of 10 tablets x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 30 C degrees, in a dry place, protected from light.

- **Item No. 3:Levofloxacin 250 mg tablet (blister)**

General Description: Levofloxacin 250mg film-coated tablets.

Technical Specifications: Each tablet should contain Levofloxacin 250mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

[2] The number of blisters in a carton box is the preferred number and/or indicative. The number of blisters in a carton should be ideally sufficient for the duration of treatment.
[3] The preferred storage condition for all GDF medicines is "do not store above 30° C".

Packaging Al/PVC/PVDC film blister pack of 5 x 4 tablets x 5 blisters in a carton box or 10 tablets x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 30 C degrees, in a dry place, protected from light.

- **Item No. 4: Levofloxacin 500 mg tablet (blister)**

General Description: Levofloxacin 500mg film-coated tablets.

Technical Specifications: Each tablet should contain Levofloxacin 500mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: Al/PVC/PVDC film blister pack of 5 x 4 tablets x 5 blisters in a carton box or 10 tablets x10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 25 C[4] degrees, in a dry place, protected from light.

- **Item No. 5: Moxifloxacin 400 mg tablet (blister)**

General Description: Moxifloxacin 400mg film-coated tablets.

Technical Specifications: Each tablet should contain Moxifloxacin 400mg and should be biconvex film coated tablets.

Packaging: Al/PVC/PVDC or Alu/Alu film blister pack of 5 tablets x 1 blister in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 25 C degrees, in a dry place, protected from light.

[4] The preferred storage condition for all GDF medicines is "do not store above 30° C".

SCHEDULE No. 2: Oral solid dosage forms: Bacteriostatic Second Line Drugs

- **Item No. 1: Ethionamide 250 mg tablet (blister)**

General Description: Ethionamide 250mg film-coated tablets.

Technical Specifications: Each tablet should contain Ethionamide 250mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: Al/PVC/PVDC and Alu/Alu strips of 10 tablets x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 2: Protionamide 250 mg tablet (blister)**

General Description: Protionamide 250mg film-coated tablets.

Technical Specifications: Each tablet should contain Protionamide 250mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: Al/PVC/PVDC film blister of 10 tablets x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 3: Protionamide 250 mg tablet (loose)**

General Description: Protionamide 250 mg film-coated tablets.

Technical Specifications: Each tablet should contain Protionamide 250mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: 50 tablets on LPDE bag placed in HDPE container (with a silica gel bag and sealed with and aluminium tagger seal) and a screw cap.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 25 C degrees, in a dry place, protected from light.

Loose product will be ordered only in case of specific requirement by the client. No market share can be allocated for loose products.

- **Item No. 4: Cycloserine 250 mg capsules. (blister/strip)**

General Description: Cycloserine 250mg hard capsules.

Technical Specifications: Each hard capsule should contain Cycloserine 250mg.

Packaging: Al/PVC/PVDC or Alu/Alu strip pack of 10 capsules x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 5: Cycloserine 250 mg capsule (loose)**

General Description: Cycloserine 250mg hard capsules.

Technical Specifications: Each hard capsule should contain Cycloserine 250mg.

Packaging: 40 or 50 or 100 capsules on LPDE bag placed in HDPE container (with a silica gel bag and sealed with and aluminium tagger seal) and a screw cap.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

Loose product will be ordered only in case of specific requirement by the client. No market share can be allocated for loose products.

- **Item No. 6: PAS Acid granules (sachet)**

General Description: P-aminosalicylic acid (PAS) 4 g enteric coated delayed-release granules in sachets.

Technical Specifications: Each sachet should contain aminosalicylic acid 4 g.

Packaging: 30 Alu/PET/Alu/LLDPE sachets / 1 carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store in a dry place below 15 °C (in a refrigerator).

- **Item No. 7: PAS Sodium powder for oral solution (sachet)**

General Description: P-aminosalicylate sodium salt powder for oral solution 5.52 g sachet.

Technical Specifications: Each laminated sachet contains power P-aminosalicylate sodium salt equivalent to 4 g of PAS.

Packaging: Alu/PET/Alu/LDPE laminated sachets in a carton box. The following quantities are preferable: 25 sachets in one carton box; 300 sachets in one carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 8: PAS Sodium enteric coated granules (container)**

General Description: P-aminosalicylate sodium enteric coated delayed-release granules 60% w/w, 100 g HDPE container.

Technical Specifications: Each granule contains P-aminosalicylate sodium salt.

Packaging: 100gr in LPDE bag placed in a triple laminated Alu/PET/Alu sachet further packed in HDPE container.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light

- **Item No. 9: PAS Sodium enteric coated granules (sachet)**

General Description: P-aminosalicylate sodium enteric coated delayed-release granules 60% w/w, 9.2 g sachets.

Technical Specifications: Each granule contains P-aminosalicylate sodium salt.
Packaging: 30 PET/Alu/LLDPE sachets of 9.2 g/ 1 carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 10: Terizidone 250 mg capsule (blister)**

General Description: Terizidone 250 mg capsules

Technical Specifications: Each hard capsule should contain Terizidone 250 mg.

Packaging: Al/PVC/PVDC blister pack of 10 hard capsules x 10 blister in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light.

SCHEDULE No.3: Parenteral Injectables

- **Item No. 1: Capreomycin 1 g injectable- powder (vial/ampoule)**

General Description: Capreomycin 1 g powder for injection.

Technical Specifications: Each vial/amp should contain Capreomycin 1 g.

Packaging: 1 vial/ampoule in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 2: Capreomycin 0.75 g injectable- powder (vial/ampoule)**

General Description: Capreomycin 0.75 g powder for injection.

Technical Specifications: Each vial/amp should contain Capreomycin 0.75 g.

Packaging: 1 vial/ampoule in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light

- **Item No. 3: Capreomycin 0.5 g injectable- powder (vial/ampoule)**

General Description: Capreomycin 0.5 g powder for injection.

Technical Specifications: Each vial/amp should contain Capreomycin 0.5 g.

Packaging: 1 vial/ampoule in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 4: Kanamycin 1 g injectable -powder (vial/ampoule)**

General Description: Kanamycin 1 g powder for injection.

Technical Specifications: Each vial/amp should contain kanamycin 1 gram as sulphate.

Packaging: 1, 10, 50, 100 vials/ampoules in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 5: Kanamycin 0.75 g injectable- powder (vial/ampoule)**

General Description: Kanamycin 0.75 g powder for injection.

Technical Specifications: Each vial/amp should contain kanamycin 0.75 gram as sulphate.

Packaging: 10, 50, 100 vials/ampoules in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 6: Kanamycin 0.5 g injectable- powder (vial/ampoule)**

General Description: Kanamycin 0.5 g powder for injection.

Technical Specifications: Each vial/amp should contain kanamycin 0.5 gram as sulphate.

Packaging: 10, 50, 100 vials/ampoules in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 7: Kanamycin 1 g injectable- solution (vial/ampoule)**

General Description: Kanamycin 1 g solution for injection (4 ml)

Technical Specifications: Each vial/amp should contain kanamycin 1 gram as sulphate.

Packaging: 10 or 20 or 50 or 100 vials/ampoules in a carton box.

Shelf life and storing conditions: 36 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 8: Amikacin 500 mg injectable - powder (vial/ampoule)**

General Description: Amikacin 500mg powder for injection

Technical Specifications: Each vial/amp should contain Amikacin 500mg

Packaging: 10 or 20 or 50 or 100 vials/ampoules in a carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No.9: Amikacin 500 mg injectable –solution (vial/ampoule)**

General Description: Amikacin 500mg solution for injection (2 ml)

Technical Specifications: Each vial/amp should contain Amikacin 500mg.

Packaging: 10 or 20 or 50 or 100 vials/ampoules in a carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

SCHEDULE No.4: Oral solid dosage forms: Third line anti-TB

- **Item No. 1: Amoxicillin Clavunalate 875 + 125 mg tablet (blister)**

General Description: Amoxicillin Clavunalate 875+ 125 mg film coated tablets

Technical Specifications: Each tablet should contain 1004.0 mg Amoxicillin Trihydrate equivalent to Amoxicillin based 875.0 mg + 297.8 mg Clavunalate potassium equivalent to clavulanic acid 125.0 mg.

Packaging: Al/PVC/PVDC film blister pack of 7 tablets per blister x 2 blisters or 10 tablets per blister x 10 blisters /1 carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light,

- **Item No. 2: Amoxicillin Clavunalate 500 +125 mg tablet (blister)**

General Description: Amoxicillin Clavunalate 500+ 125 mg film coated tablets

Technical Specifications: Each tablet should contain 625 mg Amoxicillin Trihydrate equivalent to 500 mg Amoxicillin based and mg Clavunalate potassium equivalent to clavulanic acid 125 mg.

Packaging: Al/PVC/PVDC film blister pack of 10 tablets per blister x 2 blisters or 10 tablets per blister x 10 blisters / 1 carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light,

- **Item No. 3: Amoxicillin Clavunalate 250 +125 mg tablet (blister)**

  General Description: Amoxicillin Clavunalate **2**50+ 125 mg film coated tablets

  Technical Specifications: Each film coated tablet should contain Amoxicillin Trihydrate equivalent to 250 mg of Amoxicillin based and potassium clavulanic equivalent to 125 mg of clavulanic acid.

  Packaging: Al/PVC blister pack of 7tablets per blister x 2 blisters or 5 tablets per blister x 3 blisters.

  Shelf life and storing conditions: minimum accepted shelf life 24 months. Do not store above 25º C degrees, keep in a dry place and protect from light.

- **Item No. 4: Amoxicillin Clavunalate 250 mg powder for oral suspension**

Technical Specifications: 250 mg/62.5 per 5 ml powder for oral suspension. White to off-white powder for reconstitution with water. Each 5 ml of reconstituted suspension contains Amoxicillin Trihydrate equivalent to 250 mg of amoxicillin and potassium clavunalate equivalent to 62.5 mg of clavulanic acid.

Packaging: Glass bottles with aluminium screw caps or a ROPP, internally lacquered closure, containing a Polymer (PVC) liner, containing powder for reconstitution to 100ml.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Do not store above 25º C degrees; store in original container to protect from moisture. Reconstituted suspension to store between 2º and 8ºC for 7 days. Do not freeze.

- **Item No. 5: Clarithromycin 250 mg tablet (blister)**

General Description: Clarithromycin 250 mg film-coated tablets

Technical Specifications: Each tablet should contained clarithromycin 500 mg, film-coated tablets.
Packaging: Al/PVC/PVDC film blister pack of 7 tablets per blister x 2 blisters or 10 tablets per blister x 2 blisters /1 carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 6: Clarithromycin 500 mg tablet (blister)**

General Description: Clarithromycin 500 film-coated tablets

Technical Specifications: Each tablet should contained clarithromycin 500 mg, film-coated tablets.

Packaging: Al/PVC/PVDC film blister pack of 7 tablets per blister x 2 blisters or 10 tablets per blister x 10 blisters /1 carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 7: Imipenem / Cilastatin 500 mg + 500 mg injectable –powder for solution for IV (vial/ampoule)**

General Description: Imipenem / Cilastatin 500 mg + 500 mg powder for solution for IV infusion

Technical Specifications: Each vial/amp 500 mg should contain 500 mg of Imipenem monohydrate and 500 mg of Cilastatin sodium.

Packing: 20, 50, 100 vials in a carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 8: Linezolid 600 mg tablet (blister)**

General Description: 600 mg film-coated tablets

Technical Specifications: Each film coated tablet contains linezolid 600 mg. White oval shaped bevel edged, boconvex film coated tabs, debossed with “L” on one side and “22” on the other side

Packaging: Al/PVC/PVDC film blister pack of 10 tablets per blister x 2 blisters /1 carton box; 20 HDPE container pack

Shelf life and storing conditions: minimum accepted shelf life 24 months. Do not store above 30º C degrees, keep it in a dry place, protected from light.

SCHEDULE No.5: Oral solid dosage forms: first line anti-TB drugs

- **Item No. 1: Rifabutin (Rfb) 150 mg capsules (blister)**

General Description: Capsules for oral administration containing 150 mg of rifabutin along with the inactive ingredients microcrystalline cellulose and etc.

Technical Specifications: Each hard gelatin capsules contains 150 mg of rifabutin.Rifabutin is chemically designated as 4-deoxo-3,4-[2-spiro-(N-isobutyl-4-piperidyl)- 2,5-dihydro-1H-imidazo]-rifamycin S

Packaging: Al/PVC/ blister package of 30 capsules

Shelf life and storing conditions: minimum accepted shelf life is 24 months. Store below 25 C degrees, in a dry place, protected from light.

SECTION 5: 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 and Code of Conduct (as per Annexes F and D).

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 2013/005** 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.

Name of authorized representative: _____

Title: _____

Signature: _____

Date: _____
Supplier 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 high resolution (easily readable) pdf and Excel electronic formats)