INVITATION TO BID

ITB-IDA/GDF - TB/2018/003

Issue date: 14 August 2018

IDA Foundation (IDA), as the contracted Procurement Agent of the Stop TB Partnership/Global Drug Facility (GDF), wishes to procure ANTI-TUBERCULOSIS MEDICINES for the treatment of drug sensitive and drug-resistant forms of tuberculosis (TB) for the period 1st November 2018 – 31 March 2019

IMPORTANT – ESSENTIAL INFORMATION

Deadline for the electronic submission of Technical and Financial Bids: **10 September 2018 at 16:00h IST (India Standard Time)**

Public opening of Financial Bids at IDA Foundation's Mumbai Office on **11 September 2018 at 13:30h IST (India Standard Time)**

The reference **ITB-IDA/GDF – TB/2018/003** should be shown on Technical and Financial Bids and in all correspondence related to this ITB

This ITB document consists of the following:

ANNEXES

Annex A1: Technical TB Bid Response Form (Excel spreadsheet)

Annex A2: Financial TB Bid Response Form (Excel spreadsheet)

Annex B: List and technical specifications of products

Annex C: Response Form for TB medicines registration

Annex D: IDA model long-term agreement (LTA)

Annex E: IDA general terms and conditions

Annex F: IDA code of conduct

Annex G: GDF access to WHO PQP/ERP supplier information

Annex H: Indicative non-binding estimated quantities

Annex I: GMSDs address list

Annex J: Global Drug Facility packaging guidelines

Annex K: ITB checklist

Annex X: Form for Requests for Clarifications or Complaints after ITB awarding

SECTION 1: INTRODUCTION

1.1. GDF's mission and vision

Today, the Global Drug Facility (GDF) is the largest supplier of quality-assured anti-tuberculosis (TB) products in the public sector worldwide. Since its inception and as of 31 March 2018, GDF has supported and increased access to critical quality-assured TB treatments and diagnostics to 139 countries. During this period, it has delivered: 29.3 million adult first-line drugs (FLDs) treatments; 2 million paediatric FLDs treatments (including 429,694 new paediatric formulations treatments); 332,733 multidrug-resistant TB (MDR-TB) treatments; 13,429 treatment courses of Bedaquiline; and 3,856 treatment courses of Delamanid.

The key added value of GDF is to offer a full package of services for ensuring market availability, affordability and provision of quality-assured TB products and diagnostics to countries in need, as well as to offer country support for facilitating access to and uptake of new medicines and diagnostic tools.

GDF's services include active market shaping, strategic procurement solutions, innovative logistics approaches, Strategic Rotating Stockpile, pre-shipment inspection and quality control services, capacity building and technical assistance.

GDF's mission and vision

GDF's mission is to support and promote equitable access to TB medicines and diagnostics worldwide. Its vision for success foresees that:

- All people requiring TB diagnostics and medicines are able to access them. Global markets are optimized to meet public health needs.
- Markets are able to reliably deliver innovative, internationally quality-assured, appropriately adapted, affordable, sustainably priced TB medicines and diagnostics.
- Investments in research and development continue according to target product profiles, with a shift from single-drug-medicine to regimen development, clear specifications for multiplatform diagnostics, and a more coordinated end-to-end approach across the entire portfolio of TB products.
- International organizations coordinate long-term, targeted technical assistance to countries in a manner that ensures supply chains get products to the places where people seek care.
- Global and national finances are sufficient to support the introduction and scale-up of new TB innovations as they emerge from the pipeline.
- Countries transition from the Global Fund TB financing in a manner that not only ensures ongoing access to TB services in country, but also supports global market strategies.
- Stakeholders work transparently and collaboratively in a coordinated fashion towards collective goals in order to avoid duplication, leverage resources and optimize efficiency.

1.2. Objective of the ITB

The purpose of this ITB is to select a panel of suppliers who will enter into long-term agreements (LTAs) with IDA Foundation (IDA), the contracted Procurement Agent of the Stop TB Partnership/Global Drug Facility, to supply anti-TB medicines specified in Annex B of this ITB document. According to clause 2.9.2b of this ITB document, GDF/IDA launches this ITB following the recent approval of new suppliers for the sole sourced of anti-TB medicines specified in Annex B, and with the aim to ensure effective competition and best value for money for the benefit of the TB patients.

1.3. The ITB and award process

The ITB and award process consists of six steps:

- In Step 1, Bidders prepare and submit Bids according to the terms and conditions stated in this ITB document, particularly in sections 3.1, 3.2 and 3.3;
- In Step 2, GDF/IDA opens and screens the Technical Bids in order to check the eligibility of the Bidders and products offered, as stated in sections 2.4 and 3.4;
- In Step 3, there is a public opening of the Financial Bids at IDA Foundation's Mumbai Office, as stated in section 3.5;
- In Step 4, GDF/IDA evaluates the Technical and Financial Bids of eligible Bidders/products, as outlined in section 3.7;
- In Step 5, GDF/IDA adjudicates and allocates the market share per awarded Bidder, as stated in section 3.8;
- In Step 6, eligible Bidders are notified of the awards, as stated in section 3.9.

1.4. Timeline of the ITB

Activity	Scheduled Time – Deadline
ITB launch/web-publishing	Tuesday 14 August 2018
Request for clarification on the ITB (section 3.1.9)	Deadline: Tuesday 21 August 2018, 16:00h IST (India Standard Time)
GDF/IDA responses to requests for clarification on the ITB (section 3.1.10)	Deadline: Friday 24 August 2018, 16:00h IST (India Standard Time)
Electronic submission (via email) of Technical and Financial Bids, in separate emails (sections 3.2.4 and 3.2.5)	Deadline: Monday 10 September 2018, 16:00h IST (India Standard Time) *Bids received after the stipulated date and time will be rejected.*
Opening and screening of Technical Bids (section 3.4)	Monday 10 September 2018, 16:30h IST (India Standard Time)
Public opening of Financial Bids (section 3.5)	Tuesday 11 September 2018 at 13:30h IST (India Standard Time) at IDA Foundation's Mumbai Office
Evaluation of Technical and Financial Bids (section 3.7)	From Tuesday 11 September to Thursday 13 September 2018
Adjudication and market share allocation (section 3.8)	Friday 14 September 2018
Notification of awards to Bidders (section 3.9)	by Wednesday 19 September 2018

1.4.1. GDF/IDA reserves the right to cancel this ITB, change the scheduled times of the ITB's key activities, revise the ITB and any of its schedules, or not make any awards by issuing an amendment to this ITB. GDF/IDA will not be held liable for any compensation demanded by Bidders for the costs involved in Bid preparation.

1.4.2. All amendments to this ITB will be posted on the GDF website at http://www.stoptb.org/gdf/drugsupply/procurement_notice.asp and the IDA website at https://www.idafoundation.org/blog

1.4.3. It is the Bidder's responsibility to consult the GDF and IDA websites to ensure that they are aware of any amendments to and additional information regarding this ITB.

1.5. Contacts for the ITB

All correspondence in relation to this ITB should be sent to:

- Mrs Suzanne de Jongh, Director Procurement Services GDF, IDA Foundation, at sdejongh@idafoundation.org, with copy to
- Dr Magali Babaley, GDF Strategic Procurement and Business Intelligence Manager, at magalib@stoptb.org
- Mrs Nigorsulton Muzafarova, GDF Lead Product Quality Officer, at nigorsultonm@stoptb.org
- Dr Kaspars Lunte, GDF Global Sourcing Officer, at kasparsL@stoptb.org

ATTENTION: ITB Bids should NOT be submitted to the above staff emails! For Bid submission please use the two (2) dedicated email addresses as given in sections 3.2.4 and 3.2.5.

SECTION 2: SCOPE OF THE ITB

2.1. The GDF/IDA procurement strategy

The GDF/IDA procurement strategy for TB medicines and related products has been developed with specific key objectives to support Goal 3 of the Stop TB Partnerships Operational Strategy 2016-2020. This Goal seeks to ensure uninterrupted access to quality-assured TB products at the optimum price, while simultaneously maintaining a sustainable and competitive market.

The GDF/IDA procurement strategy consolidates the results of market analysis and discussions with manufacturers, GDF clients, the Global Fund and GDF donors and technical partners. The principles of the GDF/IDA procurement strategy are:

a. to maintain a sustainable and predictable supply of the needed TB medicines and related products;
b. to maintain sufficient suppliers in the market through sourcing strategies, by understanding and supporting suppliers' interests, and by encouraging new suppliers to enter the market;
c. to ensure affordable and competitive pricing through competitive, fair and transparent tenders, supplier engagement strategies and the minimization of supplier production costs through improved GDF/IDA forecasts and procurement planning;
d. to ensure reliable supply through improved suppliers performance;
e. to increase supplier engagement in sufficient production capacity by improving demand visibility through improved GDF/IDA forecasts;
f. to enable supply flexibility through a reduction in supplier production lead times;
g. to limit the risk of expirations and write-offs by encouraging suppliers to extend product shelf life (to 48 months where applicable);
h. to reduce supply chain risks by encouraging suppliers to register their products in countries.

2.2. Implementation of the GDF/IDA procurement strategy

GDF/IDA has analyzed the list of needed TB medicines and related products against its procurement strategy and has defined different priorities per product. While affordability and delivery performance remain priorities for GDF/IDA, supplier production capacity and delivery lead times, product shelf life and storage conditions, and the number of countries in which the products are registered have also emerged as priorities. Addressing these priorities will allow GDF/IDA to improve supply flexibility and client satisfaction, and decrease supply chain risks.

GDF/IDA also recognizes that it needs to further develop its supplier engagement strategy in order to improve its partnership and collaborative activities with suppliers and thus create additional value for both parties.

2.3. WHO Prequalification fees and price reasonableness

2.3.1. GDF is carefully monitoring new market developments, specifically the introduction and application of the WHO Prequalification Programme's (PQP) new fee structure. This new fee structure was implemented in January 2017 and applies to both new product applications and the maintenance of products on the WHO's List of Prequalified Medicines.

GDF held numerous discussions with WHO officials and presented multiple case studies and scenarios to WHO PQP regarding the introduction of fee waivers, especially for the most vulnerable products.

Thanks to joint efforts, WHO PQP accepted the fee waiver system for many TB products in order to ensure long-term price security. The list of products eligible for fee waivers has been published at https://extranet.who.int/prequal/sites/default/files/documents/PQ_Fees_Annex_092017.pdf (and may be amended from time to time by WHO PQP). Given that manufacturers of listed products may apply for a waiver of the annual fees, GDF will not consider WHO Prequalification fees to be an additional cost burden for manufacturers.

2.3.2. The supplier base for TB products is stable, and in general GDF expects to see trends towards sustainable or reduced pricing. Hence, in cases where a higher price is offered for a product, GDF reserves the right to evaluate the reasonableness of the price.

2.4. Conditions/eligibility for ITB participation

2.4.1. This ITB is open to Bidders who are authorized by relevant regulatory authorities to manufacture, distribute and export medicines.

2.4.2. IDA and GDF reserve the right to verify the financial soundness of Bidders, unless this information has been provided within the previous 12 months; for example, the ratio of current assets/liabilities for the previous 3 years must be greater than 1, as substantiated by audited financial reports. GDF/IDA may request Bidders to submit their most recent audited financial statements, statutes, registry excerpts from the respective chamber of commerce, and quality and environmental management system certificates. It is in the interest of the Bidders, if requested, to provide information that is as complete as possible. This information may also be used by GDF/IDA in the Bid adjudication process.

2.4.3. Only Bidders with products that comply with the GDF Quality Assurance Policy (http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp) are eligible to participate in this ITB.

2.4.4. A Bid submitted for a product that has not received regulatory approval in accordance with the GDF Quality Assurance policy will not be considered for the ITB evaluation.

2.4.5. All Bidders who expect their product(s) to be compliant with the GDF Quality Assurance policy by the time of the public opening of the Financial Bids can submit Bids in this ITB. However, Bidders must provide relevant confirmation of the compliance of their product(s) in writing to

the contacts indicated in section 1.5 at the latest 3 hours before the public opening of the Financial Bids. Bids will then be assessed according to the updated status.

2.4.6. This ITB should not be construed as a contract or a commitment of any kind. This ITB in no way obligates GDF/IDA to award a contract, nor does it commit GDF/IDA to pay any costs incurred in the preparation and submission of the Bid(s).

2.4.7. Bidders shall be responsible for and bear their own costs, expenses and liabilities arising in connection with the preparation and submission of a Bid and their involvement in the ITB process. GDF/IDA will under no circumstances be held liable for any such costs incurred by Bidders, whether direct or indirect, regardless of the outcome of the procurement process or whether the procurement process is cancelled, altered or postponed for any reason.

2.4.8. Bidders are not required to bid for all products. However, Bidders are encouraged to bid for as many eligible products as possible.

2.4.9. By participating in this process, Bidders agree to the legal terms and conditions as stated in this ITB document. There is no arrangement or understanding between GDF/IDA and any Bidder with respect to this ITB other than what is outlined in this document.

2.4.10. Bidders shall comply with IDA's code of conduct for suppliers.

2.5. Bidder ethics requirement

2.5.1. GDF/IDA requires that all Bidders maintain the highest standard of ethics throughout the entire ITB process, as well as for the duration of any LTA that may be signed as a result of this process.

2.5.2. Therefore, all Bidders must represent and warrant that they:

(i) have not unduly obtained or attempted to unduly obtain confidential information in connection with the ITB process;

(ii) have no conflict of interest that would prevent them from entering into a contract with GDF/IDA;

(iii) have not engaged or attempted to engage in any Proscribed Practices in connection with this ITB process or the LTA that may be awarded as a result of this process. For the purposes of this provision, Proscribed Practices are defined as corrupt, fraudulent, coercive, collusive and unethical practices, and obstruction.

2.6. List and technical specifications of products

2.6.1. Bidders are invited to submit Bids for the products that are listed and specified in Annex B – List and technical specifications of products.

2.6.2. The products listed in Annex B will be allocated to selected suppliers based on the outcomes of this ITB.

2.7. Product quantity estimations

2.7.1. The total estimated quantity of products covered by this ITB is indicated in Annex H. Please note that the estimations provided in Annex H are indicative only and should not be considered a volume commitment. Actual quantities to be ordered can vary, and GDF/IDA is not in a position to make any guarantees in this regard.

2.8. Contracting

2.8.1. On behalf of GDF, IDA intends to sign LTAs with awarded suppliers as per the results of the ITB.

2.8.2. For contractual and technical provisions, LTAs with suppliers will be issued according to the model LTA (Annex D), IDA's general terms and conditions (Annex E) and IDA's code of conduct (Annex F).

2.8.3. Any purchases will be made against purchase orders issued by IDA in accordance with the terms and conditions of the LTA.

2.8.4. While Bids will be adjudicated on an EXW (EX-Works) basis, as stated in section 3.1.6.2, LTAs with three INCOTERMS (2010) will be issued by IDA: EXW (Ex-Works), FCA (Free Carrier Alongside) and DAP prices (Delivered at Place) for Indian supplies to Government Medical Store Depots (GMSDs) situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkatta and Guwahati. Detailed GMSD addresses are provided in Annex I.

2.8.5. LTAs will be valid for an initial term until 31 March 2019. They will begin on the commencement date and expire at midnight on the expiry date, unless there is early termination in accordance with the provisions of the LTA. For Expert Review Panel (ERP)-approved products, the LTA will be subject to early termination if the product's ERP approval is not renewed or is cancelled.

2.8.6. After the initial term, IDA will be entitled to renew the LTA for a further term of up to 12 months, based on the same terms and conditions. IDA will give the supplier written notice of its intention to renew the LTA no less than 60 days prior to the LTA's expiry date. GDF/IDA will provide the supplier with product forecast(s) for the next period. Based on the new forecasts:

a) The supplier shall notify IDA in writing, within 30 days of receiving the forecasts, about the price maintenance or proposed price increase/reduction. If the supplier proposes a price increase, it must provide a well-documented justification to GDF/IDA for consideration.
b) IDA shall notify the supplier in writing within 20 days of receiving the above notice as to whether it agrees to the revised prices. In the case of a price increase, GDF/IDA will be entitled to revise existing market share allocations.
c) If parties agree to the revised prices, the LTA shall be amended accordingly; if the parties do not agree to the revised prices, the LTA shall not be extended.

2.9. Contract management

During the LTA period:

2.9.1. GDF/IDA will monitor and report every 3 months on the suppliers' performance, focusing on delivery lead time (promised date of goods readiness versus actual date of goods readiness) and compliance to the production lead time stated by suppliers in the Bid. Production lead time is defined as the length of time from when a purchase order is placed with the supplier to when

the products are available for dispatch at the premises of the supplier along with the shipping documents invoice, packing list, COA and other documents as specified in the PO (including but not limited to production planning, purchase of API, packaging materials, manufacturing period, batch release). In addition, GDF/IDA will monitor and measure that suppliers confirm the purchase orders and provide documents on time, and are in compliance with Quality Control and Pre-Shipment Inspection requirements. Outcomes of supplier performance measurements will be used to discuss performance improvements with suppliers, to re-assess market share allocation during the LTA period (section 3.8.8)

2.9.2. GDF/IDA may issue new ITBs for specific products when:

a) current supplier(s) are deemed unable to deliver the orders due to insufficient production capacities, or
b) a product had only one eligible Bidder at the time of the ITB, but additional quality sources have become available during the LTA period, or a combination of a) and b), or
c) GDF/IDA and suppliers fail to agree on a proposed price increase, or
d) There are other unforeseen exceptional circumstances, at the discretion of GDF/IDA.

2.9.3. GDF/IDA may conduct investigations related to any aspect of the ITB award at any time during the term of the LTA and for a period of 3 years following the expiration or termination of the LTA. The supplier shall provide its full and timely cooperation with any such inspections, audits or investigations. Such cooperation includes the supplier making available its personnel and any relevant documentation, including copies of any test results or quality control reports, at reasonable times and on reasonable conditions, and granting access to the premises used for the production, testing and packaging of the products and to its personnel. The supplier shall require its agents, including its attorneys, accountants or other advisers, to reasonably cooperate with any inspections, post-payment audits or investigations carried out by GDF/IDA.

SECTION 3: INSTRUCTIONS FOR BIDDERS

3.1. Preparation of Bids

3.1.1. Bidders shall complete the following Forms and provide the requested documents:

- ✓ Annex A1 – Technical TB Bid Response Form (Excel spreadsheet)
- ✓ Annex A2 – Financial TB Bid Response Form (Excel spreadsheet)
- ✓ Annex C – Response Form for TB medicines registration
- ✓ Declaration (Section 4 of the ITB document)
- ✓ Annex K - ITB checklist

3.1.2. **Technical specifications of products offered**: In Annex A1 – Technical TB Bid Response Form, Bidder is requested to:

3.1.2.1. Provide the technical specifications of the products offered, including INN, dosage, form (e.g., tablet, capsule), specification (e.g., coated, colour, breakable), primary packaging specification (e.g., Alu/PVC/PVDC film blister, vial, ampule) and secondary packaging size. In cases where the items do not comply exactly with the given technical specifications (Annex B) or where alternatives are offered, the Bidder should detail how the specifications offered differ from the specifications requested by GDF/IDA. GDF/IDA reserves the right to reject any Bid that does not conform to the technical specifications outlined in Annex B.

3.1.2.2. Provide information related to the finished products, as required.

3.1.2.3. Indicate whether the finished products are produced in countries other than the country of the Bidder; if so, the Bidder must clearly state the country of origin. The Bidder may be required to submit a Certificate of Origin of Products issued by the Chamber of Commerce or other equivalent authority.

3.1.2.4. Indicate whether the finished products originate from another supplier; if so, the Bidder must state which supplier.

3.1.2.5. Provide commercial information, as required.

3.1.2.6. Failure to provide all information requested in the Technical TB Bid Response Form may lead to rejection of the Bid.

3.1.3. **GDF packaging**: For all information regarding GDF packaging requirements, the Bidder is invited to refer to Annex J – GDF packaging guidelines and sections 11 and 12 of Annex D – IDA model LTA.

3.1.4. **Samples**: IDA/GDF reserves the right to ask the Bidder for free, non-returnable samples of products (secondary packaging) for the purposes of this ITB. Failure to provide, in a timely manner, samples or documentation requested by GDF/IDA may lead to rejection of the Bid.

3.1.5. **Prices and discounts**: In Annex A2 – Financial TB Bid Response Form, the Bidder is requested to:

3.1.5.1. Provide unit prices of the packaging offered, in US Dollars only. Bids will be evaluated in US Dollars only. Failure to quote in US Dollars may lead to rejection of the Bid. The Bidder must ensure that the cost of transportation packaging (shrink wrapping) is included in the price offered for the item(s).

3.1.5.2. Unit prices provided will remain firm but subject to the right to review, as outlined in section 2.8.6 of the ITB and in clause 4 of the model LTA (Annex D).

3.1.5.3.

3.1.5.4. Advise if additional discounts are applicable for high-volume purchases; if so, these should be specified.

3.1.5.5. Advise if any other discounts other than those mentioned in section 3.1.5.3 are applicable; if so, these should be specified.

3.1.6. **INCOTERMS:**

3.1.6.1. The Bidder is requested to quote unit prices in accordance with the following delivery INCOTERMS (2010): EXW (Ex-Works), FCA (Free Carrier Alongside) and DAP[1] prices (Delivered at Place) for Indian supplies to Government Medical Store Depots (GMSDs) situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkatta and Guwahati. Detailed GMSD addresses are provided in Annex I.

3.1.6.2. EXW prices will be used to assign points for the Financial Bid evaluation, as stated in section 3.7.3.

3.1.6.3. Products for which the Bidder does not provide a DAP price for India may not be considered for Indian supplies; therefore, the Bidder may not be considered for full market share allocations as awarded.

3.1.6.4. Failure to quote in accordance with the requested INCOTERMS (EXW, FCA and DAP) may lead to rejection of the Bid.

3.1.7. **Annex C – Response Form for TB medicines registration**: Bidders must include a copy of a valid registration certificate for TB medicines, issued by the relevant regulatory authority. If the

[1] DAP excluding taxes. Please note that when this item is proposed for India, IDA will contact the supplier to provide duties and import taxes if applicable

certificate is issued in English, Russian or French, Bidders should verify the copy by signing and stamping it. If the registration certificate is issued in a language other than English, Russian or French, Bidders must provide an English translation of the registration certificate. Validity of the registration must be clearly indicated on the certificate; if not, the Bidder should provide an explanation letter attached to the certificate.

3.1.8. **Validity of the Bids**: Bids should be valid for a period of no less than 90 days from the Bid submission date.

3.1.9. **Bidders requests for clarification related to this ITB**: Any requests for information in relation to this ITB should be sent by email to the contacts provided in section 1.5, by the deadline stated in section 1.4.

3.1.10. **GDF/IDA responses to requests for clarification related to this ITB**: IDA will respond to any requests for clarification received prior to the deadline stated in section 1.4 in one joint email response to all Bidders within 3 working days following the closing date for clarification requests.

3.2. Submission of Bids

3.2.1. The **Technical Bid** should contain the following documents:

- ✓ Annex A1 – Technical TB Bid Response Form, duly completed (Excel spreadsheet)
- ✓ Annex A1 – Technical TB Bid Response Form in PDF, duly dated, signed and stamped
- ✓ Annex C – Response Form for TB medicines registration, duly completed, dated, signed and stamped
- ✓ Copy of valid country registration certificates + translations of the registration certificates as required in section 3.1.7
- ✓ Annex K: ITB checklist, duly completed
- ✓ Annex G: GDF access to WHO PQP/ERP supplier information

Bidders should ensure that PDF documents are high-resolution and easily readable.

3.2.2. The **Financial Bid** should contain the following documents:

- ✓ Annex A2 – Financial TB Bid Response Form (Excel spreadsheet), duly completed
- ✓ Annex A2 – Financial TB Bid Response Form in PDF, duly dated, signed and stamped
- ✓ Declaration (Section 4 of the ITB document), duly completed, dated, signed and stamped

Bidders should ensure that PDF documents are high-resolution and easily readable.

3.2.3. Failure to submit the documents requested for the Technical and/or Financial Bids may result in rejection of the Bid.

3.2.4. The "Technical Bid" should be sent in a separate email to GDFtechnicalBid@idafoundation.org by the electronic submission deadline in accordance with section 1.4. The subject of the email should be "supplier name + ITB-IDA/GDF – TB/2018/003 – Technical Bid". The email should contain all of the documents listed in section 3.2.1 above.

3.2.5. The "Financial Bid" should be sent in a separate email to GDFfinancialBid@idafoundation.org by the electronic submission deadline in accordance with section 1.4. The subject of the email should be "supplier name + ITB-IDA/GDF–TB/2018/003– Financial Bid". The email should contain all of the documents listed in section 3.2.2 above.

3.2.6. Failure to follow the instructions given in sections 3.2.4 and 3.2.5 may result in rejection of the Bids received.

3.3. Modification and withdrawal of Bids

3.3.1. Bidders are expected to examine all schedules and instructions pertaining to the Bid. Failure to do so will be at the Bidder's own risk. Bidders acknowledge that GDF/IDA, its directors, employees and agents make no representations or warranties (expressed or implied) as to the accuracy, correctness or completeness of this ITB or any other information provided to the Bidders.

3.3.2. Any changes to the Technical and/or Financial Bids must be sent by email to the relevant email addresses (refer to sections 3.2.4 and/or 3.2.5) prior to the deadline for electronic submission as stated in section 1.4. Bidders must clearly indicate that it is a modification that supersedes the earlier Bid or clearly state the changes from the original Bid.

3.3.3. Bidders may withdraw their Technical and/or Financial Bids through a written request prior to the deadline for electronic submission stated in section 1.4. After the deadline, Technical and/or Financial Bids will remain valid and open for eligibility for the entire Bid validity period, as may be extended.

3.4. Opening and screening of Technical Bids

3.4.1. After the deadline to electronically submit Technical Bids, GDF/IDA will open and screen the Technical Bids to confirm that:

- ✓ All documents requested in section 3.2.1 have been provided;
- ✓ Each document submitted is complete and valid as requested in sections 3.1.2 and 3.1.7;
- ✓ Each document is dated, signed and stamped as requested;
- ✓ Bidders and products offered are eligible according to section 2.4.

3.4.2. GDF/IDA may reject any Bids that do not comply with the requirements listed in section 3.4.1.

3.4.3.Bids that are rejected during the screening of the Technical Bids will not be considered for evaluation. Consequently, the corresponding Financial Bids will not be opened during the public opening of Financial Bids.

3.5. Public opening of Financial Bids

3.5.1. GDF/IDA will organize a public opening of the Financial Bids for Bidders at IDA Foundation's office in Mumbai at the date and time specified in section 1.4. No more than two representatives per Bidder should attend the public opening of the Financial Bids. IDA will ensure remote connection via telephone or internet if requested 3 working days prior to the public opening.

3.5.2. Representatives of the UN, non-governmental organizations and donor organizations may send an email request to participate in the Financial Bid opening to the contacts listed in section 1.5.

3.5.3. Bidders should note that the public opening of Financial Bids is the only occasion on which information related to competitors' pricing per product will be publicly announced.

3.6. Minor informalities, errors or omissions

3.6.1. Provided that a Bid is substantially compliant, GDF/IDA may waive any minor informalities, errors or omissions in the Bid, as long as they are a matter of form and not substance and can be corrected or waived without being prejudicial to other Bidders.

3.6.2. Provided that a Bid is substantially compliant, GDF/IDA may ask the Bidder to submit the necessary information or documentation within a reasonable period of time in order to rectify minor informalities, errors or omissions in the Bid.

3.7. Evaluation of Technical and Financial Bids

3.7.1. A Bid Evaluation Committee will carry out the evaluation and assignment of scores according to the evaluation criteria for the Technical and Financial Bids. This Committee will consist of at least three members, with at least one representative from IDA and two representatives from GDF. The Committee will convene at the scheduled time stated in section 1.4.

3.7.2. Evaluation will be conducted based on the cumulative analysis of the Technical and Financial Bids, with a weighting of 50% and 50% respectively for the Technical Bid and the Financial Bid.

3.7.3. The total number of points Bidders may receive for their Bid is as follows:

- ✓ Technical Bid: 50 points
- ✓ Financial Bid: 50 points

3.7.4. The evaluation criteria used to determine the number of points that Bidders may receive for their Technical and Financial Bids are as follows:

TECHNICAL EVALUATION CRITERIA (maximum 50 points)
Total Shelf life of product
Guaranteed production lead time *
Product registration
Minimum Order Quantity (MOQ)
FINANCIAL EVALUATION CRITERIA (maximum 50 points)
Price per unit (tablet, vial…) **

**The guaranteed production lead time is defined as the length of time from when a purchase order is placed with the supplier to when products are available for dispatch at the premises of the supplier along with the shipping documents invoice, packing list, COA and other documents as specified in the PO (including but not limited to production planning, purchase of API, packaging material, manufacturing period, batch release, etc.). The longest lead time will be considered if a range is provided.*

***Price per unit (tablet, vial) offered for the EXW INCOTERM.*

3.7.5. The number of points allocated per evaluation criterion for the technical evaluation of products is at the discretion of GDF/IDA and according to the GDF procurement strategy as described in section 2.1 and 2.2.

3.7.6. GDF/IDA will be under no obligation to reveal or discuss with any Bidder how the Technical and Financial Bids were assessed, or to provide any other information related to the selection process. GDF/IDA will only communicate how the points were allocated between the Technical

and Financial Bids, as stated in section 3.7.3. Bidders whose Bids are not selected will be notified in writing of this fact and shall have no claim whatsoever to any kind of compensation or justification.

3.7.7. The competitive range of the Bids quoted is considered to be within a maximum delta of +15% from the lowest price. Suppliers that quote a price per unit that falls outside of the competitive range may still be awarded LTAs but with no market share allocation.

3.7.8. If it is the opinion of GDF/IDA that the prices offered by a supplier for particular product(s) are not reasonable as described in section 2.3.2, the supplier may be requested to provide proper justification for such increase along with substantiated evidence within 1–2 working days.

3.7.9. GDF/IDA expressly reserves the right without liability or penalty to any party to:

a) reject any or all Bids;
b) invalidate any Bid received from a Bidder who, in the opinion of GDF/IDA, is not in a position to perform the contract;
c) accept part of a Bid;
d) waive informalities and minor irregularities in Bids or price submissions received.

3.8. Bid adjudication and market share allocation

3.8.1. The Bid adjudication will be carried out by a Bid Adjudication Committee. This Committee will consist of at least two members, with a least one representative from IDA and one representative from GDF. The Committee will convene at the scheduled time stated in section 1.4. Additional independent parties may be invited to observe the adjudication process under a strict confidentiality agreement with GDF/IDA.

3.8.2. The Bid Adjudication Committee will make its final decision based on the Bid evaluation outcomes presented by the Bid Evaluation Committee. The Bid Adjudication Committee will operate by consensus. If consensus cannot be reached, GDF's representative will decide the final outcome.

3.8.3. Although GDF/IDA will make multiple awards in order to maintain enough suppliers in the market to ensure a sustainable supply of quality-assured products to its clients, there is no guarantee that all eligible Bidders will be considered for market share allocation.

3.8.4. Market share allocation is indicative, based on a primary/secondary/tertiary and auxiliary supplier status as per the outcomes of the ITB; it is implemented per product based on anticipated total quantity to be purchased over the contract period, as follows:

a) 100% for primary/sole suppliers
b) 60%/40% for primary/secondary suppliers
c) 50%/30%/20% for primary/secondary/tertiary suppliers
d) 0% for auxiliary suppliers.

3.8.5. For sole suppliers, GDF/IDA reserves the right to negotiate the terms of the agreement irrespective of the ITB cycle, including the price.

3.8.6. While auxiliary suppliers will sign LTAs without market share allocation, they may receive purchase orders based on specific country requests or as deemed otherwise necessary by GDF/IDA.

3.8.7. GDF/IDA's principles for market share allocation are as follows :

a) If there is no WHO PQP/SRA-approved product, but ERP-approved product(s), the ERP-approved product(s) will be considered for market share allocation.
b) When there are at least two WHO PQP/SRA-approved products, ERP-approved product(s) will not be considered for market share allocation, except in cases where the production capacity of the WHO PQP/SRA-approved products is insufficient to cover the estimated quantities in the necessary timeframe.
c) In other cases, including but not limited to the case where only one WHO PQP/SRA-approved product is available and there are ERP-approved product(s), the market share allocation between WHO PQP/SRA and ERP-approved products will be at the sole discretion of the Bid Adjudication Committee.
d) When a product has been offered in a different package size than requested, the supplier may be awarded auxiliary supplier status without market share allocation; however, the supplier may receive purchase orders based on specific country requests.

3.8.8. IDA will award LTAs based on the market share allocation resulting from the ITB. However, GDF/IDA reserves the right to adjust or cancel the market share allocation awarded to suppliers over the valid period of the LTA and/or to suspend or terminate the LTA and reallocate quantities to other contracted suppliers at its sole discretion for any of the following reasons:
a) The supplier's inability to deliver against agreed lead times for any reason, including a Force Majeure event;
b) The lapse of necessary regulatory approval or certification;
c) The occurrence of any unforeseen event because of which the GDF/IDA determines and establishes a tangible risk that the supply or price continuity cannot be maintained;
d) The supplier's failure to meet performance standards (including but not limited to compliance with actual lead times, responsiveness, production capacity, importation requirements, registration status). IDA will assess supplier performance quarterly. If a supplier is underperforming, GDF/IDA may issue an order for only a limited quantity until satisfactory performance can be established;
e) A change in the WHO-recommended treatment regimens, the enactment of which will materially impact the demand profile for the supplied products during the LTA period;
f) Failure in quality of the supplied products;
g) The supplier's uncured material breach(es) of the LTA or violation of the IDA code of conduct;
h) Client preferences, including but not limited to packaging and shelf life.

3.9. Notification of awards to Bidders

3.9.1. IDA will notify all Bidders in writing of the outcomes of the ITB prior to the expiration of the period of Bid validity and at the scheduled time stated in section 1.4.
3.9.2. If a correction in the awards is required, this will be communicated to all awardees.
3.9.3. The awards of this ITB will supersede the awards of the previous ITBs for identical products, and relevant LTAs will be amended accordingly.

3.10. Requests for Clarifications and/or Complaints after ITB awarding

3.10.1. After the outcomes of the ITB have been communicated to Bidders, the Bidder has right to file a Request for Clarification or to file a Formal Complaint on the outcomes of the ITB. If a correction in the awards is published at a later stage, a shortened deadline for Request for Clarification or Formal Complaint may be announced by GDF/IDA.
3.10.2. The Request for Clarification or the Formal Complaint should be sent only to the contacts as listed in section 1.5 and it should be filed within 5 working days after the outcomes of the ITB have been communicated.

3.10.3. Only Annex X shall be used for the submission of a Request for Clarification or a request for a Formal Complaint.

3.10.4. If a Request for Clarification is filed by the bidder within the deadline as per section 3.10.2, IDA shall, on behalf of GDF/IDA, provide written response to the Bidder within 10 working days after submission deadline of the Request for Clarification.

3.10.5. If a Formal Complaint is filed by the bidder within the deadline as per section 3.10.2, GDF/IDA will establish a Complaint Review Committee. This Complaint Review Committee will comprise of independent representatives from both GDF and IDA that were not members of the Bid Evaluation or Adjudication Committees. If required, the Complaint Review Committee may also include representatives from other agencies or external independent experts.

3.10.6. The Complaint Review Committee will review the complaint and provide its decision to the bidder within 15 working days after receipt of the Formal Complaint. The decision of the Complaint Review Committee is final, and the Complaint Review Committee will be under no obligation to reveal the details of the review. If deemed necessary, GDF/IDA will modify the ITB outcomes/awards in line with the decision of the Complaint Review Committee.

3.10.7. Formal complaints must only be filed by bidders, complaints filed by third parties will not be considered.

3.11. Bidder warranties

3.11.1. If successful, the Bidder warrants that:

a) It has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources needed to fulfil its obligations under any resulting LTA or purchase order;

b) The items offered shall be new, factory packed, and free from defects in workmanship and materials;

c) The items offered shall be contained or packaged to ensure the integrity of the product and to fully comply with valid regulatory approvals;

d) It has not and shall not enter into any agreement or arrangement that restrains or restricts the GDF/IDA's or ultimate recipient's rights to use, sell, dispose of or otherwise deal with any item that may be acquired through any resulting LTA or purchase order;

e) It and any of its affiliates will seek to minimize greenhouse emissions in their activities to the extent possible;

f) It will obtain any export license or other governmental authorization that may be necessary. It will be the sole responsibility of the Bidder to obtain such license or authorization. GDF/IDA may provide assistance upon request;

g) It will register its products in the countries for which it has received orders and where this registration is mandatory;

h) All TB medicines and related products offered are identical in all aspects of manufacturing and quality to that approved by WHO PQP/SRA for the country, including formulation, method and site of manufacture, sources of active and excipient starting ingredients, quality control of the product and starting material, packaging, shelf life, and product information.

3.11.2. The successful Bidders will be required to acknowledge that:

a) GDF/IDA may further distribute the products 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.

SECTION 4: DECLARATION

The undersigned, having read the Terms and Conditions of **ITB-IDA/GDF-TB/2018/003** 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.

Bidder Name:

_____

Postal Address:

_____

_____

Telephone: _____

Email: _____

Validity of Bid (not less than 90 days from the deadline for the electronic submission of Bids):

_____ days.

Name of authorized representative:

_____

Title:

Date:

Signature/Stamp: