

## **INVITATION TO BID**

**ITB-IDA/GDF - FLD/2016/002**

**Issue date: 18 October 2016**

**IDA FOUNDATION, as contracted Procurement Agent of the Stop TB Partnership/Global Drug Facility (GDF), wishes to procure FIRST LINE ANTI-TUBERCULOSIS (TB) MEDICINES (FLDs) AND RELATED PRODUCTS for the treatment of Drug Sensitive forms of TB**

### **IMPORTANT – ESSENTIAL INFORMATION**

**Deadline for electronic submission of Technical and Financial Bids: 16 November 2016 at 16.00 hours IST (India Standard Time)**

**Public opening of the Financial Bids at IDA Foundation Mumbai office on 23 November 2016 at 10.00 IST (India Standard Time)**

The reference **ITB-IDA/GDF - FLD/2016/002** shall be shown on Technical and Financial Bids and in all correspondence related to this ITB

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## **SECTION 1: INTRODUCTION**

### **1.1. GDF mission and vision**

Today the Global Drug Facility (GDF) is the largest supplier of quality assured anti-tuberculosis products worldwide in the public sector. Since its inception in 2001, GDF delivered a total of 26.5 million adult patient treatments for sensitive tuberculosis (FLDs), 1.53 million pediatric patient treatments and 218,466 patient treatments for multi-drug resistant tuberculosis (SLDs) to 133 countries and since 2008, GDF has contributed to active case-finding by procuring diagnostics worth US \$135 million to more than 82 countries as of June 2016.

The key GDF added value 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 needs as well as country support for facilitating access and uptake of new medicines and diagnostic tools. The GDF services include but are not limited to, 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 mission and vision

GDF's mission is to support and promote worldwide, equitable access to TB medicines and diagnostics. 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 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, the contracted Procurement Agent of the Stop TB Partnership/Global Drug Facility (GDF) to supply the First Line Anti-TB medicines (FLDs) and related products specified in Annex B of this ITB document for the treatment of Drug Sensitive forms of TB

### 1.3. ITB and award process

The ITB and award process will take place in six steps:

- Step 1 is the preparation and submission of Bids by the Bidders according to the terms and conditions stated in the ITB document and in particular in art 3.1; art 3.2 and art 3.3
- Step 2 is the opening and screening of technical Bids by GDF/IDA to check the eligibility of the Bidders and products offered as stated in art 2.3, art 3.4
- Step 3 is the public opening of financial Bids in IDA Foundation Mumbai Office as stated in art 3.5
- Step 4 is the evaluation of technical and financial Bids of eligible Bidders/products by GDF/IDA as stated in art 3.7
- Step 5, is the adjudication and market share allocation per awarded Bidders by GDF/IDA as stated in art 3.8
- Step 6 is the notification of the awards to all Bidders as stated in art 3.9

### 1.4. Timeline of the ITB

	Activity	Schedules time - Deadline
	ITB Launch/web-publishing	Tuesday 18 October 2016
	Request for information on ITB (Art 3.1.9)	Deadline: Friday 21 October 2016, 16.00 hours IST (India Standard Time)
	Responses to requests for information on ITB (Art 3.1.10)	Deadline: Tuesday 25 October 2016, 16.00 hours IST (India Standard Time)
	Electronic submission (via e-mail) of the Technical and Financial Bids, in <u>separate emails</u> (Art 3.2.4 and 3.2.5)	Deadline: Wednesday 16 November 2016, 16.00 hours IST (India Standard Time). Bids received after the stipulated date and time will be rejected.
	Opening and screening of Technical Bids (Art 3.4)	From Thursday 17 to Tuesday 22 November 2016
	Public opening of Financial Bids (Art 3.5)	Wednesday 23 November 2016 at 10.00 hours IST (India Standard Time) at IDA Foundation Mumbai Office
	Evaluation of Technical and Financial Bids (Art 3.7)	From Wednesday 23 to Thursday 24 November 2016
	Adjudication and market share allocation (Art 3.8)	Friday 25 November 2016
	Notification of Awards to Bidders (Art 3.9)	Wednesday 30 November 2016

1.4.1. GDF/IDA reserves the right to cancel this ITB, change the scheduled time of the key activities of this ITB, or revise this 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](http://www.stoptb.org/gdf/drugsupply/procurement_notice.asp) and IDA website at <http://www.idafoundation.org/news-events/news.html>

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

## 1.5. Contacts for the ITB

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

- Suzanne de Jongh, Programme Manager GDF, IDA Foundation at [sdejongh@idafoundation.org](mailto:sdejongh@idafoundation.org), with copy to
- Magali Babaley, GDF Strategic Procurement and Business Intelligence Manager at [magalib@stoptb.org](mailto:magalib@stoptb.org)
- Nigorsulton Muzafarova, GDF Product Quality Assurance Officer, at [nigorsultonm@stoptb.org](mailto:nigorsultonm@stoptb.org)
- Kaspars Lunte, GDF Sourcing Officer, at [kasparsL@stoptb.org](mailto:kasparsL@stoptb.org)

**ATTENTION: ITB BIDS SHALL NOT BE SUBMITTED TO THE ABOVE EMAILS BUT TO THE DEDICATED EMAIL ADDRESSES FOR BID SUBMISSION as stated in art 3.2.4 and 3.2.5 of the ITB document**

## SECTION 2: SCOPE OF THE ITB

### 2.1. The GDF/IDA procurement strategy

The GDF/IDA procurement strategy for FLDs and related products has been developed with the following key specific objectives to support the Goal 3 of the Stop TB Partnership of ensuring an un-interrupted 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 the market analysis and discussions with manufacturers, GDF clients, the Global Fund and GDF donors. The principles of the GDF/IDA procurement strategy are:

- a. maintaining a sustainable and predictable supply of the needed FLDs and related products
- b. maintaining sufficient suppliers in the market through sourcing strategy, by understanding and supporting supplier's interest and by encouraging new suppliers to enter in the market
- c. ensuring affordable and competitive pricing through competitive, fair and transparent tenders, supplier engagement strategies and by reducing supplier production costs through improved GDF/IDA forecasts and procurement planning
- d. ensuring reliable supply through improved supplier delivery performance
- e. improving supplier engagement on production capacity by improving demand visibility through accurate GDF/IDA forecasts
- f. enabling supply flexibility through a reduction of supplier production lead times
- g. limitation of risk of expiries and write off by encouraging suppliers to extend product shelf life (36 months or longer)
- h. reducing 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 FLDs and related products against its procurement strategy and had defined different priorities per product. While the affordability and the delivery performance remain a priority for GDF/IDA, the supplier production lead times and delivery lead times, production capacity, the shelf life and storage conditions of product and the number of

countries in which the products are registered are new priorities that will allow GDF/IDA to improve supply flexibility, client's satisfaction and decrease supply chain risks.

GDF/IDA also recognizes that they need to further develop their supplier engagement strategy to improve their partnership and collaborative activities with suppliers for creating additional value for both parties.

### **2.3. Conditions/Eligibility for ITB Participation**

- 2.3.1. This ITB is open to Bidders who have authorization from relevant regulatory authority to manufacture, distribute, and export medicines. Therefore, IDA Foundation and GDF reserve the right, unless this information has already been provided within the 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 GDF/IDA for evaluation and adjudication processes. It is in the interest of the Bidders, if requested, to provide information as complete as possible.
- 2.3.2. Only Bidders with products in compliance with the GDF Quality Assurance Policy are eligible to participate in this ITB as a Bidder (see [http://www.stoptb.org/gdf/drugsupply/quality\\_sourcing\\_process.asp](http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp))
- 2.3.3. A Bid submitted for a product for which the Bidder has not received regulatory approval status in accordance with the GDF Quality Assurance policy, shall not be considered for the ITB evaluation.
- 2.3.4. Bidders whose products shall be prospectively compliant with the GDF Quality Assurance policy in the near future may be conditionally invited to Bid for the product(s) in question by GDF/IDA.
- 2.3.5. 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 the ITB. Only Bidders who provide in writing the relevant confirmation of the compliance of their product(s) to the contacts indicated in art 1.5 and latest 3 hours before the time of the public opening of the financial Bids, will be assessed according to that status.
- 2.3.6. Participation in this ITB is subject to the terms and conditions contained in this ITB document. This ITB shall 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 the GDF/IDA to pay any cost incurred in the preparation and submission of the Bid(s).
- 2.3.7. Bidders shall be responsible for and bear their own costs, expenses, and liabilities arising in connection with the preparation and submission of a response to this ITB, as updated, amended or modified from time to time, and their involvement in the ITB process. In no circumstances whatsoever will GDF/IDA be liable for any such costs incurred by Bidders, whether direct or indirect, irrespective of the outcome of the procurement process, nor if the procurement process is cancelled, altered or postponed for any reason.
- 2.3.8. The Bidders shall not be required to Bid for all products. However, Bidders are encouraged to Bid for as many eligible products as possible.
- 2.3.9. By participating in this process, bidders agree to the legal terms and conditions as stated in this ITB document. There are no other arrangements or understandings between the GDF/IDA and any Bidder with respect to this ITB other than the text contained herein.

2.3.10. Bidders shall comply with IDA's Code of Conduct for suppliers

## **2.4. Bidder ethics requirement**

2.4.1. GDF/IDA requires that all bidders observe the highest standard of ethics during the entire ITB process, as well as for the duration of any LTA that may be signed as a result of this process.

2.4.2. Therefore, all bidders shall represent and warrant that they:

- (i) have not unduly obtained, or attempted to unduly obtain, any 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 ITB process. For the purposes of this provision, Proscribed Practices are defined as corrupt practice, fraudulent practice, coercive practice, collusive practice, unethical practice and obstruction.

## **2.5. List and Technical Specifications of products**

2.5.1. Bidders are invited to submit Bids for the list and specifications of First line anti-TB medicines and related products presented in ANNEX B – List and Technical specifications of products

2.5.2. The list of products indicated in Annex B will be allocated to selected suppliers based on the outcomes of this ITB

## **2.6. Products quantity estimations**

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

## **2.7. Contracting**

2.7.1. IDA Foundation intends to sign Long-term Agreements (LTAs) on behalf of GDF with awarded suppliers as per the results of the ITB.

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

2.7.3. Any purchases will be made against Purchase Orders issued by IDA Foundation in accordance with the terms and conditions of the LTA(s)

2.7.4. While Bids will be adjudicated on an EXW (EX-Works) basis as stated in art 3.1.6.2, LTAs shall be issued by IDA Foundation with three INCOTERMS (2010): EXW (Ex-Works), FCA (Free Carrier Alongside) and DAP prices (Delivered At Place) for India supplies to Government Medical Store



Depots (GMSD) situated at Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkatta and Guwahati. Detailed GMSD addresses are provided in annex I.

- 2.7.5. LTAs shall be valid for an initial term of 12 months and shall commence on the commencement date and expire at midnight on the expiry date, unless earlier terminated in accordance with the provisions of the LTA. For ERP approved product, the LTA shall be terminated earlier if the ERP approval of product is not renewed or cancelled.
- 2.7.6. After the initial term of 12 months, IDA Foundation shall be entitled to renew the LTA for a further term of up to 12 months and on the same terms and conditions, by giving the supplier written notice of its intention to renew the LTA not less than 60 days prior to the LTA expiry date. GDF/IDA will provide to the supplier the product forecast(s) for the next period. Based on the new forecasts:
- a) The supplier shall notify IDA Foundation in writing within 30 days of receipt of the forecasts the price maintenance or proposed price increases/reductions. In case of a price increase, the supplier shall provide a well-documented justification to GDF/IDA for consideration.
  - b) The IDA Foundation shall notify the supplier in writing within 30 days of receipt of the notice, whether it agrees to the revised prices. In case of any price increase, GDF/IDA shall be entitled to revise existing market share allocation.
  - c) If the parties agree to the revised prices the LTA shall be amended accordingly and if the parties do not agree to the revised prices, the LTA shall be terminated.

## **2.8. Contract management**

During the LTA period

- 2.8.1. GDF/IDA will be monitoring and reporting every three (3) months the performance of the suppliers, focusing on delivery lead time (promised date of delivery versus actual date of delivery) and the compliance to the production lead time stated by suppliers in the Bid. The production lead time is defined as the length of time from the time of issuance of a purchase order accepted by the supplier until the products are available for dispatch at the premises of the supplier (including but not limited to production planning, purchase of API, packaging materials, manufacturing period, batch release etc...). In addition, GDF/IDA will be also monitoring and measuring 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 are used for discussion with suppliers on performance improvement and re-assessment of market share allocation during the LTA period (art 3.8.8) and for the ITB evaluation process (art. 3.7.4)
- 2.8.2. GDF/IDA may issue new Invitations to Bid 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 and additional quality sources 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) Other unforeseen exceptional circumstances at GDF/IDA discretion.
- 2.8.3. GDF/IDA may conduct investigations relating to any aspect of the ITB award at any time during the term of the LTA and for a period of three (3) years following the expiration or prior termination of the LTA. The supplier shall provide its full and timely cooperation with any such inspections, audits or investigations. Such cooperation shall include, but shall not be limited to, the supplier's obligation to make 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 to grant access to the supplier's premises that will be used for the production, testing and packaging of the products and to the suppliers personnel. The supplier shall require its agents, including, but not limited to, the supplier's attorneys, accountants or other advisers, to reasonably cooperate with any inspections, post-payment audits or investigations carried out by GDF/IDA hereunder.

## SECTION 3: INSTRUCTIONS TO BIDDERS

### 3.1. Preparation of Bids

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

- ✓ Annex A1 - Technical FLD Bid Response Form 2016 (Excel spreadsheet)
- ✓ Annex A2 – Financial FLD Bid Response Form 2016 (Excel spreadsheet)
- ✓ Annex C – Response Form for anti-TB medicines registration
- ✓ Declaration (Section 4 of the ITB document)
- ✓ Annex K: ITB Checklist Form

3.1.2. **Technical Specifications of products offered:** In Annex A1 - Technical FLD Bid Response Form 2016, Bidder is requested to:

- 3.1.2.1. Provide the technical specifications of products offered including INN, dosage, form (ie tablet, capsule...) and specification (ie coated, color, breakable etc..), primary packaging specification (ie Alu/PVC/PVDC film blister, vial, ampule...), secondary packaging size. Where items offered are not exactly in compliance with the technical specifications (Annex B), or wherever alternatives are offered, Bidder shall specify 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 stated in Annex B.
- 3.1.2.2. Provide the information related to the finish products as required.
- 3.1.2.3. Indicate if finished products are produced in countries other than that of the Bidder and if so, to state clearly the country of origin. 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 if finished products are originate from another supplier, and if so, to state which supplier.
- 3.1.2.5. Provide the commercial information as required.
- 3.1.2.6. GDF/IDA will not accept any MOQ for FLDs
- 3.1.2.7. Failure to provide all information requested in Annex A1 - Technical FLD Bid Response Form 2016, may lead to the rejection of the Bid.

3.1.3. **GDF Packaging:** for all information regarding the GDF packaging requirements, Bidder is invited to refer to the Annex J – GDF packaging guidelines and Annex J1 – Artwork sample for India Programme and the art 11 and 12 of the Annex D – IDA model LTA.

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

3.1.5. **Prices and discounts:** In Annex A2 – Financial Bid Response Form 2016, 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 will lead to the rejection of the Bid.

The Bidder shall ensure that the cost of transportation packaging 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 ITB art 2.7.6 and in clause 4 of the model Long-term Agreement (Annex D).
  - 3.1.5.3. Provide staircase pricing according to the required range of quantities of units to be purchased per Purchase Order
  - 3.1.5.4. Advise if additional discounts are applicable for high-volume purchases and if so, to specify them
  - 3.1.5.5. Advise if any other discounts other than those mentioned in art 3.1.5.3 and 3.1.5.4 are applicable and if so, to specify them.
- 3.1.6. **INCOTERMS:**
- 3.1.6.1. Bidder is requested to quote unit prices in accordance with the following delivery INCOTERMS (2010) : EXW (Ex-Works), FCA (Free Carrier Alongside) and DAP<sup>1</sup> prices (Delivered At Place) for India supplies to Government Medical Store Depots (GMSD) situated at Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkatta and Guwahati. Detailed GMSD addresses are provided in the Annex I.
  - 3.1.6.2. The EXW prices will be used to assign the points for the financial Bid evaluation as stated in art 3.7.3.
  - 3.1.6.3. Products for which Bidder does not provide a DAP price for India shall not be considered for India supplies and, therefore, not for the full (India + ROW) market share allocations as awarded.
  - 3.1.6.4. Failure to quote in accordance with the requested INCOTERMS may lead to the rejection of the Bid
- 3.1.7. **With the Annex C - Response form for anti-TB medicines registration**, Bidders shall join a copy of a valid registration certificate for anti-TB medicines stated registered, issued by the relevant regulatory authority of each country. Validity of the registration shall be clearly indicated in the certificate. If the registration certificate is issued in any other language than English, Russian or French, Bidders shall provide a certified translation of the registration certificate in English, otherwise this document will not be considered for evaluation purpose. **Only valid registration certificates will be counted towards the total number of registrations for evaluation purpose.**
- 3.1.8. **Validity of the Bids:** Bids should be valid for a period of not less than 60 days after Bid submission date
- 3.1.9. **Request for information:** Any request for information in relation to this ITB should be sent by email to contacts provided in art 1.5 and by the deadline stated in art 1.4.
- 3.1.10. **Responses to requests for information:** GDF/IDA will sent by email responses to requests for information to all Bidders within up to three (3) working days after the closing date for the request for information, i.e by the deadline stated in art 1.4.

## 3.2. Submission of Bids

- 3.2.1. The **Technical Bid** shall contain the following documents:
  - ✓ Annex A1 - Technical FLD Bid Response Form 2016 duly completed (Excel spreadsheet)

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<sup>1</sup> DAP excluded taxes. Please note that when this item is proposed for India, IDA will contact supplier to provide duties & import taxes if applicable

- ✓ Annex A1 - Technical FLD Bid Response Form 2016 in PDF, duly dated, signed and stamped
- ✓ Annex C – Response Form for anti-TB medicines registration duly completed, dated, signed and stamped
- ✓ Copy of valid country registration certificates + Certified translations of the registration certificates as required in art 3.1.7
- ✓ Annex K: ITB Checklist duly completed
- ✓ Annex G: GDF Access to WHO PQ/ERP supplier information

Bidders shall ensure that PDF documents are provided in high resolution easily readable

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

- ✓ Annex A2 - Financial FLD Bid Response Form 2016 (Excel spreadsheet) duly completed
- ✓ Annex A2 - Financial FLD Bid Response Form 2016 in PDF, duly dated, signed and stamped
- ✓ Declaration (Section 4 of the ITB document) duly completed, dated, signed and stamped

Bidders shall ensure that PDF documents are provided in high resolution easily readable

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

3.2.4. The “Technical Bid” shall be sent by email to: [GDFtechnicalBid@idafoundation.org](mailto:GDFtechnicalBid@idafoundation.org) by the deadline of the electronic submission in accordance to art 1.4. The subject of the email shall be “supplier name + ITB-IDA/GDF - FLD/2016/002 – Technical Bid”. The mail shall contain all the documents listed in art 3.2.1 above.

3.2.5. The “Financial Bid” shall be sent in a separate email to [GDFfinancialBid@idafoundation.org](mailto:GDFfinancialBid@idafoundation.org) by the deadline of the electronic submission in accordance to art 1.4. The subject of the email shall be “supplier name + ITB-IDA/GDF - FLD/2016/002 – Financial Bid”. The mail shall contain all the documents listed in art 3.2.2 above.

3.2.6. Non-compliance to the instruction stated in art 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 all Instructions pertaining to the Bid. Failure to do so will be at bidders own risk. Bidders acknowledge that GDF/IDA, its directors, employees and agents make no representations or warranties (expressed or implied) as to the accuracy, currency or completeness of this ITB or any other information provided to the Bidders.

3.3.2. All changes to the Technical and/or Financial Bids must be sent by email to the relevant email address (refer to art 3.2.4 and/or 3.2.5) prior to the deadline for the electronic submission as stated in art 1.4. It must be clearly indicated that it is a modification and supersedes the earlier Bid, or state the changes from the original Bid.

3.3.3. Technical and/or Financial Bids may be withdrawn on written request received from bidders prior to the deadline for the electronic submission as stated in art 1.4. After the deadline, Technical and/or Financial Bids shall remain valid and open for eligibility by GDF/IDA for the entire Bid validity period, as may be extended.

### **3.4. Opening and screening of Technical Bids**

3.4.1. After the closing date and time of the electronic submission of the Technical Bids, GDF/IDA will open and screen the Technical Bids to confirm that :

- ✓ All documents requested in art 3.2.1 have been provided,
- ✓ Each document submitted is complete and valid as requested in art 3.1.2; art 3.1.4; and art 3.1.7
- ✓ Each document is dated, signed and stamped as requested.
- ✓ Bidders and products offered are eligible according to art 2.3 and 2.4

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

3.4.3. Bids that are rejected during the preliminary examination will not be considered for further evaluation. Therefore, the corresponding financial Bids will not be opened during the public opening of financial Bids.

### **3.5. Public opening of the Financial Bids**

3.5.1. GDF/IDA will organize a public opening of the Financial Bids for Bidders in IDA Foundation office in Mumbai at the date and time specified in art 1.4. No more than two representatives per Bidder shall attend the public opening of the Financial Bids.

3.5.2. Representatives of UN, NGOs and Donor organizations upon GDF/IDA concurrence may also participate in the Financial Bid opening by sending a request by email to contacts provided in art 1.5. Remote connection via telephone will be ensured by IDA Foundation if requested 3 working days in advance of the date of the public opening of Financial Bids.

3.5.3. Bidders should note that the public opening of Financial Bids is the only time and place where information related to pricing from competitors per product is 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 that do not constitute a material deviation. These are a matter of form and not of substance that can be corrected or waived without being prejudicial to other Bidders.

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

### **3.7. Evaluation of Technical and Financial Bids**

3.7.1. The evaluation and assignment of scores as per evaluation criteria for the Technical and Financial Bids will be carried out by a Bid Evaluation Committee which will comprise of at least 3 members, with at least 1 representative from IDA Foundation and 2 representatives from the GDF and at the scheduled time stated in art 1.4.

3.7.2. Evaluation will be conducted based on the cumulative analysis of the Technical and Financial Bids with a weighting of 60% and 40% respectively for the Technical Bid and the Financial Bid.

3.7.3. The total number of points which a Bidder may obtain for its Bid is as follows:

- ✓ Technical Bid: 60 points
- ✓ Financial Bid: 40 points



3.7.4. Evaluation criteria used to determine the number of points which a Bidder may obtain for its Technical and Financial Bids are as follows:

<b>TECHNICAL EVALUATION CRITERIA (max 60 points)</b>
Supplier performance on delivery lead time *
Shelf life
Storage conditions
Guaranteed production lead time **
Number of country where the product is registered
Production capacity
<b>FINANCIAL EVALUATION CRITERIA (max 40 points)</b>
Price per unit (tablet, vial...) ***
Staircase prices per unit or discounts offered

\* *Historical performance on delivery 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 2015 to 30 September 2016) 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.*

*\*\*The guaranteed production lead time is defined as the length of time from the time of issuance of a purchase order accepted by the supplier until the product is available for dispatch at the premises of the supplier (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 first staircase range of quantities and for the EXW INCOTERMS*

3.7.5. The points allocated per evaluation criteria for the technical evaluation of products are on the GDF/IDA discretion and according to GDF procurement strategy as described in art 2.1.

3.7.6. GDF/IDA will be under no obligation to reveal, or discuss with any Bidder, how technical and financial Bids were assessed or to provide any other information relative to the selection process. Only allocation of points between technical and financial Bids as stated in art 3.7.3 can be communicated to the Bidder upon request. Bidders whose Bids are not selected will be notified in writing of this fact, and shall have no claim whatsoever for any kind of compensation.

3.7.7. 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 which will comprise of at least 2 members, with a least 1 representative from IDA Foundation and 1 representative from GDF and at the scheduled time stated in art 1.4. Additional independent participants to the adjudication process may be invited under strict confidentiality framework with GDF/IDA and as an observer.
- 3.8.2. The Bid Adjudication Committee will take its final decision on the basis of the Bid evaluation outcomes presented by the Bid Evaluation Committee. The Bid Adjudication Committee will operate by consensus.
- 3.8.3. While IDA/GDF shall make multiple awards for maintaining enough suppliers in the market for 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. The market share allocation is indicative, based on a primary/secondary/tertiary and auxiliary supplier status as per the outcomes of the ITB and implemented per product based on anticipated total quantity to be purchased over the contract period as follows:
- a) 100% for primary/sole supplier
  - b) 55%/45% for primary/secondary suppliers
  - c) 50%/30%/20% for primary/secondary/tertiary suppliers
  - d) 0% for auxiliary suppliers.
- 3.8.5. For sole supplier, GDF/IDA reserve the right to negotiate the terms of the agreement including price.
- 3.8.6. While auxiliary suppliers will sign LTAs without market share allocation, they may receive purchase orders based on specific country requests.
- 3.8.7. GDF/IDA principles for market share allocation are as follows :
- a) If there is no product WHO PQ/SRA approved, and there are product(s) ERP approved, ERP approved product(s) will be considered for market share allocation
  - b) When there are at least 2 products WHO PQ/SRA approved, product(s) ERP approved will not be considered for market share allocations, except if the production capacity of the WHO PQ/SRA approved products is assessed as not sufficient to cover the estimated quantities in the necessary timeframe
  - c) For other cases, including but not limited to the case when only 1 product WHO PQ/SRA approved is available, and there are product(s) ERP approved, the market share allocation between WHO PQ/SRA and ERP approved products will be at sole discretion of the Bid Adjudication Committee.
  - d) When a product has been offered in a different pack size than requested, the supplier may be awarded with an auxiliary supplier status without market share allocation but the supplier may receive purchase orders based on specific country requests.
- 3.8.8. IDA Foundation shall award LTA based on the market share allocation resulting of the outcomes of the ITB. However, GDF/IDA reserves the right to adjust or cancel the market share allocation awarded to suppliers over the period of the validity of the LTA and/or suspend or terminate the LTA and reallocate quantities to other contracted suppliers and at its sole discretion for any of the following reasons:
- a) 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) On the occurrence of any unforeseen event, which the GDF/IDA determines and establishes a tangible risk that the supply or price continuity cannot be maintained;
- d) Supplier's failure to meet performance standards (including but not limited to compliance with actual lead time, responsiveness, production capacity, importation requirements, registration status, etc...). Supplier performance will be assessed quarterly by IDA. In case of underperformance of a new supplier, GDF/IDA may issue an order for only limited quantity until satisfactory performance is established
- e) A change in the WHO recommended treatment regimens whose enactment will materially impact the demand profile for supplied products within 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. Prior to the expiration of the period of Bid validity and at the scheduled time stated in art 1.4, IDA Foundation will notify all Bidders in writing about the outcomes of the ITB. 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 GDF/IDA contacts indicated in art 1.5. IDA Foundation will respond in writing within 5 working days to the unsuccessful Bidder.

### **3.10. Complaints related to the ITB**

3.10.1. In case a formal complaint with regard to the outcomes of the Bidding process is lodged by a Bidder, a dedicated Review Committee will be set up and will comprise of independent representatives of both GDF and IDA Foundation, different from the members of the Bid Evaluation or Adjudication Committees, and may include representatives of other agencies or external independent experts as required. Complaints made through any third parties will not be considered.

3.10.2. Complaints will need to be filed to GDF/IDA at the contacts stated in art 1.5 within maximum 5 working days after the outcomes of the Bidding have been communicated to Bidders. After this period, no complaints will be reviewed.

3.10.3. The recommendation made by the Review Committee regarding the complaint in question shall be final and the award, if necessary, will be modified accordingly.

### **3.11. Bidder warranties**

3.11.1. The awarded 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 to ensure integrity of the product and fully correspond to the valid regulatory approvals;
- d) It has not and shall not enter into any agreement or arrangement that restrains or restricts the GDF/IDA 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. GDF/IDA may provide assistance upon request.
- g) Successful Bidders shall register their products in the countries for which they have received orders and where the registration is mandatory.
- h) Bidder confirms by offering a Bid that all First line TB medicines and related products offered is identical in all aspects of manufacturing and quality to that approved by 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, packing, 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-FLD/2016/002** 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:

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Postal Address:

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Telephone:

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Email:

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Validity of Bid (not less than 60 days from the deadline for the electronic submission of Bids):

\_\_\_\_\_ days

Name of authorized representative:

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Title:

Date:

Signature/Stamp: