Q&A IDA/GDF - SLD/2020/002 - 30 September 2020

Q1A: With all due respect, I would like to ask if there is any possibility of extending the deadline for another week since longest holiday is coming up in Korea from 30th of September to 4th of October.

Q1B: Section 1.4: Electronic submission of Technical & Financial bids. Timeline given is very short. Total of 7 working days for FLD Tender and 9 working days for SLD Tender. Can the Bid submission be extended? Especially the submissions of registration data/proofs/translations.

A1: The deadline for submission of Technical and Financial Bids cannot be extended. Bidders are requested to submit Technical and Financial Bids as per the deadline stated in the ITB document for the tender n° ITB-GDF/IDA - SLD/2020/002 published on 22 September 2020

Q2: Section 2.1.3.d: "To ensure reliable supply through improved supplier performance. In this regard GDF uses a set of Key Performance Indicators (KPIs) and information which cover supplier's timely readiness of products (guaranteed supplier's lead time), supplier's responsiveness, collaboration and communication with GDF/IDA."

What are the parameters to evaluate responsiveness, collaboration and communication? We have not received any evaluation of our performance on these parameters so far.

A2: For the last contract management period, GDF/IDA have collected information on supplier's responsiveness, collaboration and communication during the management of supply issues with the supplier. Based on this information, GDF/IDA will issue an overall satisfaction score per supplier that will be used as evaluation criterion.

Q3: Section 2.1.3.f: "To enable supply flexibility through a reduction in supplier delivery lead times. Suppliers are encouraged to implement different approaches to decrease their delivery lead times such as buffer stock, consignment stock, increased production capacity, multiple sources of API..."

Can we expect GDF/IDA to share quantities for maintaining buffer stock? Also, Will GDF/IDA pay to the supplier for maintaining buffer stock?

A3: As per its procurement strategy, GDF/IDA will continue to improve its partnership and collaborative activities with suppliers with the aim to reach the common goal of timely access to quality-assured TB medicines. Therefore, any new approach to decrease supplier delivery lead time will be discussed between both parties in a win-win spirit.

Q4: Section 2.2.1:" the number of countries in which the FPP is registered have also emerged as priorities."

Can GDF share with suppliers country wise / product wise forecast or past supply volumes to strategize country registrations?

A4: Please refer to Annex L: List of priority countries for registration. GDF can only share information about the countries where supply/importation of TB medicines is possible only for products registered (mandatory requirement), or where it is strongly recommended (preferred requirement). GDF also encourage the Bidders to consult TB-related data by country, available on the StopTB website at the following link

http://www.stoptb.org/resources/cd/MappingTool_Main.html.

Q5: Section 2.2.5: "Of the 123 countries ordering TB medicines via GDF in 2019, only 22 countries represent 80% of the total value of SLDs and/or FLDs delivered (class A countries)."

Can GDF share the list of Class A countries?

A5: Please consult TB-related data by country, available on the StopTB website at the following link <u>http://www.stoptb.org/resources/cd/MappingTool_Main.html</u>.

Q6: Section 2.3.1: "......Given that manufacturers of listed products may apply for a waiver of the annual fees, GDF will not consider WHO PQP fees to be an additional cost burden for manufacturers. "

Can GDF influence WHO for an annual maintenance fee waiver for low volume products, which have sales less than \$2.5 mn?

A6: WHO PQP has accepted a fee waiver system for many TB products to ensure long-term price security. The list of products eligible for fee waivers has been published at <u>https://extranet.who.int/prequal/content/prequalification-procedures-and-fees-0</u> Manufacturers are encouraged to contact WHO PQP directly.

Q7: Section 2.9.2.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"

Floating a new tender will be unjustified for the eligible bidder at the time of ITB. Suggest keeping some allocation % for the newcomer instead of retendering?

A7: As per GDF/IDA key procurement principles and to ensure effective competition, GDF/IDA may issue new ITB for a product that had only one eligible Bidder at the time of the ITB, but additional quality sources have become available during the LTA period.

Q8: Section 3.1.7: "Registration of supplier's TB medicines in countries."

How do we need to share the supporting of the product registrations in various countries, in product folders country-wise OR in a Country named folder with all the registration certificates?

A8: Please provide requested supporting documents about product registration by product in dedicated folder (for more information, refer to article 3.1.7.3 and 3.1.7.4)

Q9: Can we submit the registration status of the products in the countries not captured in Annex L – List of priority countries?

A9: Yes. Please also provide the country registration status by product offered for countries not captured in Annex L – List of priority countries. Please also refer to article 3.1.7.1 that states: "Products whose registration is confirmed by supporting documents (the more the countries a product is registered in, the higher the number of points given)"

Q10: Section 3.7.3: "The total maximum number of points Bidders may receive for their Bid is as follows: $\sqrt{}$ Technical Bid: 40 points".

Could you please share a breakup of 40 points among the below mentioned technical evaluation criteria?

A10: The technical score assigned by product offered during the Technical evaluation will be done based on the evaluation criteria listed in article 3.7.4 of the ITB document and in line with the scope of the ITB (section 2 of the ITB document).

Q11: Section 3.8.8: "The supplier's inability to deliver against agreed lead times for any reason, including a force majeure event".

Considering the current COVID pandemic, this clause "including a force Majeure event" should not be considered for Bid Adjudication or Market share allocation decision.

A11: Article 3.8.8 is not linked to Bid Adjudication and Market share allocation decision during ITB evaluation process, but to the market share allocation review during the LTA period (contract management) in case of any events as stipulated in 3.8.8 a) to h). Please also refer to the article 2.9.1 of the ITB document.

Q12: There is no information for the payment term for the bid or the future orders, could you pls specify.

A12: There is no payment requested for the Bid submission. For the payment terms for future orders, please refer to the page 2 and section 13 of the Annex D - IDA model long-term agreement.

Q13: For the product of Amikacin 500mg in WHO-RECOMMENDED GROUP C MEDICINES, could you pls advise if it is Amikacin 500mg/2ml

A13: Yes, it is Amikacin solution for injections, 500mg/2ml

Q14: I am wondering if it is required for a product to have been registered in all those countries or to one of them?

A14: Bidder can offer a product that is not registered in countries where registration is a mandatory requirement, but during the evaluation process Bidder will get less points. Please refer to article 3.1.7 of the ITB document for more details.

Q15: What territory is the destination of Meropenem 1G and Amikacin 500mg

A15: GDF/IDA supply TB medicines to more than 140 countries. GDF/IDA do not have yet the information about which countries will purchase Meropenem 1G and Amikacin 500mg for the next LTA period.

Q16: In Annex H there are no estimate quantities but in Annex A1(row 47) have 100.000. Could you confirm if we should consider that quantity is 100.000amp?

A16: The number provided in row 47 of the Annex A1 indicates the quantity of product per order that defines a "regular" quantity (quantity below this number) or a "high" quantity (quantity above this number) for which Bidder is requested to provide a guaranteed delivery lead time. For more details, please refer to article 3.7.4 of the ITB document.

Q17: In the begin of Annex A1 have the phrase" Please do not make any change to this file except as stated in rows 20 and 37. Any manipulation of this file may invalidate your submission". We should to fill only row 20 and 37 or we have to fill all rows about the product(WFI 10ml ampoule)?

A17: Bidders are requested to provide in Annex A1 all information requested for each product offered BUT are not allowed to change the format of the table, except for rows 20 and 37 for which the Bidder is authorized to add rows if needed.

Q18: As we do not have estimated quantities, can we only present prices for complete batch size?

A18: Bidders are requested to provide the price for each product in USD of the packaging offered as requested in Annex A2 and indicate the minimum order quantity (MOQ) in basic units as requested in Annex A1.