ITB No. UNFPA/DNK/RFP/19/024
QUESTIONS AND CLARIFICATIONS

1. Is there an estimative price for total supply?
   There is no estimate price for total supply. This RFP is aimed to award a non-exclusive Long Term Agreement, not a fixed contract, please refer to Section 31 of the RFP document.

2. If contract signed, would the delivery be made to one location and then you handle dispatching to the list of countries? Or it is up to supplier to send to each country (and if so, is there a plan and quantity quotas for each country?)
   For freight: please refer to section 41.2.3 of the RFP document for details. The UNFPA procurement plan is available publicly: web. This plan is just an estimated forecast (subject to changes) and shall not be interpreted as a firm order to your company.

   For UNICEF procurement the delivery terms (INCOTERMS 2020) are:
   FCA - FCA specified airport/seaport or
   DAP - Delivered at Place to UNICEF Warehouse SD Copenhagen, Denmark

3. Page 37 of 61, Section II – Annex A: Spend Analysis: is the amount in USD for year 2018 for the item we will offer (the Mg Sulphate injection 500mg/ml in 10ml ampoule), concerning the total amount UNFPA has spent in year 2018 to purchase the product?
   The spend analysis is applicable for both UNFPA and UNICEF.

4. We don't have SRA or WHO-PQ at the moment for the products we are interested to bid and under planning. Can we bid without SRA or WHO-PQ approval? However, our plant is EU audited, approved and has EU-GMP Certificate.

   The product will need to be SRA approved and registered for use in the SRA country. Alternatively, the bidder should be in a process of applying to the UNFPA/DNK/EOI/20/011 call for ERP opinion (sited in this bid) to be eligible for this bid.

5. What form must be submitted Annexes from the SECTION VI? Can they be submitted on our company letterhead?
   Please refer to Section VI: Bid and Returnable Forms of the Request for Proposal document, page 46. They can be submitted on your company letterhead.

6. There is an information in UNFPA Questionnaire for Pharmaceutical Products, that it is necessary to send a product sample. Please indicate the address and contact person for receiving these samples.

   Sample shipping are currently on hold due to COVID-19, shipping dates will be communicated in due course.

7. According to the information in SECTION 2, paragraph 2 «Eligibility requirements», participants whose products are prequalified by WHO may not participate in the ERP. I ask You to confirm or deny this information.
   Yes, if the product is already WHO Prequalified there is no need to receive further opinion from ERP.

8. Page 14, clause 16.2.3. Balance sheet and financial statement of last three years refers to year 2016-2018, or year 2017-2019?
   2017-2019

9. Page 15, clause 19.1 and 19.2. Does Two-envelope system submission and Alternative method mean that we should submit the bidding documents through hardcopy such as flash disk, CD by courier? If so, please indicate the receipt information. Please confirm if sending by email is the only way to submit the electronic bidding documents or we should both send hardcopy by courier and by email.
   Only electronic Bids submitted via email are permitted. Please refer to section 20 of the RFP document, where the electronic submissions of technical, alternative and financial bids are explained.

10. Page 29, clause 46.1.1. GS1 tracing, please confirm whether it requires bar code or QR code, and whether it requires each pack has one unique code or each kind of drug has one unique code?
    GS1 tracing it is not a requirement of this RFP but we would appreciate to hear from bidders that have adopted or are planning to introduce the GS1 standard. Please refer to section 47 of the RFP document. Should you wish to follow through with the coding, it is advisable that each product/ drug has its own unique code.

11. Page33, clause 7. As all our products are stored under 30℃ and there is no special transportation requirement, we assume they are not temperature sensitive pharmaceuticals. In this case, do we need to provide the information about data logger? In addition, shall we fill out "Not Applicable" for the information of data logger in the forms (Product and price form, Technical information form)? Is it acceptable?
    It is mandatory that all pharmaceuticals under UNFPA/UNICEF LTAs regardless of temperature sensitivity be transported with data loggers. Data loggers will need to be procured and price should be provided in Price Form.

12. Page 42, Clause 8 financial stability, 2.7. Table of Financial ratio: should be provided information for year 2016-2018 or year 2017-2019?
    2017-2019

13. Page 50, Performance statement form. Do the information and certificates of last three year refer to year 2016-2018, or year 2017-2019? As a supplier of UNFPA, could UNFPA provide a performance evaluation certificate to us as evidence? If not, shall we provide UNFPA PO only and UNFPA can check our performance from the system?
    2017-2019

14. Technical information form

(1) Should it be submitted in pdf or excel?

Technical Information Form shall be submitted in Excel format.

(2) In addition to a summarized technical form covering all interested bidding items under the folder "Bidding Forms", should we prepare a separate form for each item (only information on one item will be filled out) and incorporate it under the separate product/item folder?

Technical Information Form shall be submitted as part of the Technical Bid in a separate folder with all bidding forms as stated in Section I: Instruction to Bidders, D. Submission of Bids, 21. Bid structure and naming convention. It is not necessary to submit a separate form for each item.

(3) Should the Column "Final Risk category" be filled out by UNFPA?

Yes, it is to be filled by UNFPA.

15. Product and price form, column J. Column J: Please explain the meaning of "Multiple Order Quantity".

Multiple Order Quantity refers to Minimum Order Multiple. I.e. if the Multiple Order Quantity is 50, that means that the order quantity can only be in multiple of 50 packs, such as 100, 150, 200, etc.

16. In the case that there is no alternative bid, is it necessary for us to enter (primary bid) in the subject line when sending the bidding documents by mails?

Yes.

17. Point No: 11: Bid timelines, Page No:2, "On 26th June 2020, Time: 18:00, Submission of completed bid confirmation form", it means we have to submit only Annexure A- i.e. Bid confirmation form only to email i.e. maruiz@unfpa.org ?

Yes.

18. What are the documents required for each steps of the Bid timeline, please explain and provide details? Also, kindly inform us what are the technical bid documentation and financial bid documentation needed from our end to submit, we are afraid that we may Miss some documents, so please provide in details compete sequence?

Information on documents to be submitted is included in Section I: Instruction to Bidders, D. Submission of Bids, 16. Technical Bid and 17. Financial Bid. Section VI – Annex G: Checklist of Bid Forms is also provided to be used while preparing the Bid to ensure that the Bid contains all required information.

19. We would like to know remaining all forms i.e. Annexure B, C, D and page No: 36 contains Forms and Questionnaire: i) Technical information form ii) Product Price Form iii) WHO PQ, ERP, SRA Questionnaire, we have to submit before deadline 6th July 2020, to email id Bidtender@unfpa.org ? Please advise and explain.

Completed Bid Confirmation Form must be submitted no later than 26 June 2020 at email maruiz@unfpa.org. Rest of documentation must be submitted in accordance to clause 20

Submission of electronic Bids before the deadline on 6th July 2020 to the bid secure email address.

20. Page No- 2, Point No:11, "Date: 7th July 2020, Technical Bid opening", what is Technical Bid opening and what we have to do?
Technical Bid Opening is the stage in the bidding process where the received technical bid emails are opened and examined by the bid opening panel. No action is required from the bidders.

21. What is the Minimum and Maximum Order Quantity of Oxytocin Injection from UNFPA & UNICEF?
Minimum and Maximum Order Quantity information must be provided by the bidder. It is the minimum or maximum order size that the supplier is willing to accept.

22. When the result of this tender is going to be declared i.e. date, and how we will come to know about the results?
UNFPA aims for this RFP to be finalized by end of 2020. The result will be posted in the United Nations Global Marketplace (UNGM) and a non-award letter is sent to the bidders who were not successful on this bid.

23. What is the link between this RFP and EOI UNFPA/DNK/EOI/20/011? Is participation in the EOI a prerequisite to participate in RFP UNFPA/DNK/19/024?
The purpose of the EOI was to invite Reproductive Health Medicines manufacturers to submit product documentation for WHO Expert Review Panel (ERP) evaluation and increase the base of manufacturers that received a positive opinion from the ERP and meet eligibility requirement of RFP UNFPA/DNK/19/024. Participation in the EOI is not a pre-requisite to participate in this bid process. Products that are WHO Prequalified and SRA don't need to participate in the EOI call, the EOI call is specifically for potential manufacturers whose products are eligible for RFP UNFPA/DNK/19/024 but are not SRA or WHO Prequalified.

For details/updates regarding Expression of Interest for Product Evaluation by the WHO Expert Review Panel ERP please refer to this link:

https://www.ungm.org/Public/Notice/108756.

24. In the current UNFPA LTA's all items are already covered: what is the value of these LTA's with this tender being floated? / What will the existing LTA for these items be used for and when will the LTA's resulting from this RFP be used?

This RFP is a joint solicitation with UNICEF, which aims to expand the product and supplier base and to award a Long Term Agreement from UNICEF and UNFPA separately. Strategic decisions and negotiations may be done for the UNFPA existing LTAs for the same product, supplier and manufacturing source.

25. On the TXA a specific request was already floated by UNFPA in relation to the LTA's this year. To our knowledge this request is still under evaluation; what are the implications of the RFP on this exercise?

    Please refer to the response in No. 24 above.

26. In Sections II, 7 is written that "All orders of product/s that require active temperature monitoring shall include at least one data logger. UNFPA approved data loggers are based on WHO prequalified data loggers. I would like to ask if UNFPA accept tempmate S1data loggers for deliveries as it was used before for UNFPA shipment deliveries from our company? Do you accept tempmate S1data loggers for RFP UNFPA/DNK/RFP/19/024 deliveries or it is obligatory to use WHO prequalified data logger?
    QA Bidders are encouraged to use WHO Prequalified data loggers. If this is not possible, supplier may use the ones approved by the supplier.

27. Section V: Supplier qualification requirements. Point 9. Experience and Technical Capacity: b. List of similar contracts executed for other clients, including contract details - please inform what kind of information we should provide?
    Contract details may include at least project name and country of assignment, client and reference contact details, contract value, period of activity and status, and types of activities undertaken.
    g, h, I. Is it enough with statements approving our compliance with the requirements?
    Declaration of compliance with requirement will be accepted for section I. For section G documentary evidence in support that the Bidder is in the continuous business of manufacturing/supplying and providing after sale services for goods similar to those offered during the last 3 years prior to bid opening date must be submitted. For section H bidders must provide a brief write-up, backed up with adequate data, explaining available capacity and experience in the manufacture and supply of the required products within the specified time of completion after meeting all their current commitments.

28. Could you list the target destination countries both for UNFPA as well as for UNICEF specifically for this project?
    Destination countries are listed in the following link:
    http://unstats.un.org/unsd/methods/m49/m49regin.htm#developed
    UNICEF works with governments and partners in need to deliver essential products across the globe.

29. At least for one of the products our organization has already a valid LTA in place with UNFPA. Will this LTA be considered with possibility to sign the same product also with UNICEF or the full set of technical and commercial documents need to be (re)submitted specifically for this new tender?

    Existing UNFPA LTA suppliers who wishes to bid for this RFP shall submit bids. The existing LTAs with UNFPA for some of the listed products in this bid are non-sharable with other UN agencies. This bid aims to establish LTA separately by UNFPA and UNICEF.

30. Based on article 2.1 for agents/resellers a notarized letter of authority to be submitted. Is there a preferred template for this?

    There is no template for notarized letter of authority.

31. We wish to participate on the Pre-bid webinar. Is there any registration required or can we directly connect using the connection details from UNGM?
    Registration is not required to attend Pre-bid webinar. Connection details have been included in UNGM. Presentation, and recording will also be shared in UNGM after the Pre-bid webinar session.

32. In Technical Bid form:
    (1) What would be Manufacturing Product Code? We have our internal manufacturing code (basically a number created for SAP)
    Manufacturing Product Code is the internal reference that the manufacturer has assigned to this item.
    (2) What is Product Warranty Month, is it same as shelf life month. If not, then what is the difference between shelf life and warranty month?
    Product warranty month does not have to be completed by the bidder and has been removed from the form.

    (3) What should be marketing authorization Name. Is it brand name registered in countries? If yes, there might be multiple brand names registered in different countries. Which brand name we should consider?
    Market authorization name is the brand name of the original country of export.

    (4) And what should be the Manufacturing Authorization number. (Is it same as the Product registration number to be marketed into the respective country. If yes, then there might be multiple brand names registered in different countries. Which brand name we should consider?
    Market authorization number is the product registration number of the original country of export.

33. What is meaning of Business Authority and Legal authority which is mentioned in Bid Submission Form (Annex B). For this particular bid, we will give power of attorney to one of the employee of the company who will be authorized to sign and submit this bid including necessary documents. Considering this, if this bid Submission form is by this employee only as a legal authority, whether this will suffice the requirement?
    Submission Form may be signed only by the Business Authority if the bid is accompanied by a duly notarized letter / power of attorney from the company authorizing the designated employee to sign the offer on its behalf.

34. Is mixing of 2 batches allowed in one pallet to ensure proper stacking?
    Please refer to WHO good distribution practices for pharmaceutical products guidance of transporting pharmaceutical products.

35. Can you provide estimated volume for Tranexamic acid 100 mg/ml - in 10 ml ampoule?
    Tranexamic acid 100 mg/ml - in 10 ml ampoule is a new product so there is no procurement for this item in previous years.

36. In case the bidder is not the manufacturer, the financial information to be provided only for bidder or also for manufacturer?
    Only bidder's Financial Information has to be provided.

37. Are the volumes supplied for 2019 by UNFPA available?

Product Name	Total 2019	
	Spend (USD)	Quantity
Magnesium sulphate, injection 500 mg/ml, in 10 ml ampoule	$ 1.238.095,85	96.208
Magnesium sulphate, injection 500 mg/ml, in 2 ml ampoule	$ 387.634,36	61.471
Misoprostol, 200 microgram tablet	$ 880.799,64	1.249.202
Oxytocin, injection 10 IU, 1-ml	$ 1.917.506,30	704.620

38. I started to fulfill Technical Information Form but I´m allowed to insert data in columns L–– W. When filling the technical form, we are not allowed to insert data in columns L to W …. data only for pharma appears - please advise.
    Technical Information Form has been modified to allow bidder to include information in columns from L to W.

39. Regarding item #10: Antifibrinolytics - Tranexamic acid 100 mg/ml - in 10 ml ampoule (pack of 5 ampoules). We have the exact same strength requested but only have the pack of 10 ampoules (no pack of 5 ampoules). Can we still bid or the pack of 5 ampoules is a mandatory condition?
    Bids of 5 ampules packs will be accepted for item 10 Tranexamic acid 100 mg/ml. Please notify on the offer if you are offering a different pack size.