



INVITATION TO BID No. UNFPA/DNK/ITB/23/003

Establishment of Global Blanket Purchase Agreements for Pharmaceuticals, Medical Devices and Kits (MegaBid)

QUESTIONS AND CLARIFICATIONS ROUND 1

Question 1. In reference to the Megabid, where can I find the quantities for Lot No.3 - Medical Devices? as it is not mentioned in any of the bid documents published on UNGM.

Answer 1. The quantities are not there as this tender process is for the establishment of Blanket Purchase Agreements for a period of 3 years (with further possible extension till 5 years).

Q2. Are you able to submit information for only 1 or more product lines? / Are partial bids acceptable?

A2. It will depend on the Lot. This information is included in the bidding document, Section 3: Data Sheet, Article 5 “Submitting bids for parts or sub-parts of the schedule of requirements or Lots” on page 26. Also, the summary is provided below.

Lot description	Expected number of awardees	Eligibility
Lot 1: Pharmaceuticals	2 - 4 bidders	Bidders must quote at least 80% of solicited items. However, Bidders are encouraged to quote for the complete range of the required products.
Lot 2: Pharmaceuticals (only for manufacturers)	up to 3 bidders per item	Partial Bids per item are permitted.
Lot 3: Medical Devices, Equipment and In-Vitro Diagnostics	2 - 4 bidders	Bidders must quote at least 80% of solicited items. However, Bidders are encouraged to quote for the complete range of the required products.
Lot 4: Interagency Reproductive Health Kits (IARH kits) and complementary kits, Emergency PEP Kit for HIV Treatment	2 - 4 bidders	Partial Bids are not permitted.
Lot 5: Other Medical Kits	2 - 4 bidders	Partial Bids are not permitted.

Q3. If you are awarded with BPA as a supplier, will you still have to submit tenders, or would there be direct procurements?

A3. As a result of the tender, Blanket Purchase Agreements will be established. BPAs will allow direct purchasing by placing a purchase order. However, the award of an Order under the BPA might also be subject to secondary competition among the BPA holders when deemed reasonable.

Q4. Clarify the beneficiary countries for the tender.

A4. The list of beneficiary countries may vary. For information about past deliveries, you can refer to the spending analysis published here: [Medical Devices and Kits](#) and [Pharmaceuticals](#).

Q5. To enter the bidding, we can just send you our offer before the deadline via bidtender@unfpa.org or should we register at a certain portal?

A5. Bid should be submitted partially via email and partially using cloud storage space. For cloud storage. Submission of supporting documents required should be done only through a secure and unique link to the cloud storage space provided by UNFPA. Proposers shall request their unique link as soon as possible but not later than 2 (two) weeks before the bid submission deadline to the email address: contract.pmdk@unfpa.org. Please kindly refer to the detailed information on how to submit your bid under Article 10. Instruction for bid submission, Section 3: Data Sheet of the Invitation to Bid document.

Q6. Page 52, Bidding document, General Documentation to consider when preparing a submission for pharmaceuticals: Do we understand correctly that the above documents are not required for the products non-WHO Prequalified/ERP/SRA approved?

A6. Please be guided by Annex 9. Technical Information and Price Bid Form, Tab “Technical Infor Pharmaceuticals” and Annex 3. UNFPA Technical Requirements for Pharmaceuticals and particularly by the respective Questionnaires for the set of documents required to support the submission.

Q7. Page 52, Bidding document, General Documentation to consider when preparing a submission for pharmaceuticals: In Ukraine package insert is in the form of Instruction for use, which is much wider document than PIL, and in fact it is like SmPC. In this case, please advise which option is more preferred? Do we need to translate the existing

Instruction for use in the form approved by the Ukrainian MOH? Or should we develop a shorter version in the form of PIL?

A7. Answered in the pre-bidding meeting #1 minutes.

Q8. Page 53, Bidding document, General Documentation to consider when preparing a submission for pharmaceuticals: Are we allowed to present the photos for the product, its primary and secondary packages and labels only in Russian and/or Ukrainian language, exactly those that are registered in Ukraine?

A8. Answered in the pre-bidding meeting #1 minutes.

Q9. At which moment should be presented the photos/artworks of the packages and labels in trilingual version (English/Spanish/French)? Are we allowed to present only the Russian/Ukrainian version at the moment of bid submission but together with the guarantee letter to prepare it and agree with UNFPA during several months after contract award, and in any case before placement of any purchase order?

A9. Answered in the pre-bidding meeting #1 minutes.

Q10. Annex 9. Technical Information and Price Bid Form (lots 1_3_4_5). Lot #21. Azithromycin, 250mg, pack of 4 or 6 tablets. Is it allowed to offer capsules instead of tablets?

A10. Only tablets are acceptable.

Q11. Kindly please confirm if the required Equipment is for Lebanon or other countries.

A11. Blanket Purchase Agreements will be concluded for products to be delivered globally, including Lebanon.

Q12. I wanted to understand if the below documents:

- ***Interagency Finished Pharmaceutical Product Questionnaire (Version 4 March 2019)***
- ***WHOPQ ERP Approved SRA Questionnaire Pharmaceuticals***

must be submitted by March 31 and all documents should be sent to bidtender@unfpa.org.

A12. Instruction for bid submission can be found in the bidding document, Section 3: Data Sheet, article 10 “Instruction for bid submission” on page 27-28. Please note that only these forms should be submitted by email (bidtender@unfpa.org):

- 1) Form A: Bid Submission
- 2) Form B: Bidder Information
- 3) Form C: Joint Venture/Consortium/Association Information
- 4) Form D: Eligibility and Qualification
- 5) Form E: Technical Bid
- 6) Annex 9. (or 9a for lot 2) Technical Information and Price Bid Form.

Submission of supporting documents should be done only through a secure and unique link to the cloud storage space provided by UNFPA. Proposers shall request their unique link to the email address: contract.pmdk@unfpa.org.

The deadline for bid submission is June 1st 2023 at 2 pm (14:00) CET.

Q13. Annex 11 - Interagency FPP QNR. The Word document is not editable. Please share an editable Word document or editable PDF document.

A13. Annex 11 - Interagency FPP QNR is an editable MS Word document, please download and check again.

Q14. Megabid Bidding Document - Section 5: Evaluation criteria. We understand that each lot will be assessed and evaluated separately. Regarding bidders of Lot 4 - IARH Kits and CC Kits, PEP Kit, we understand that kit bidders must offer all items and all kits in Lot 4. However, please confirm that no preference will be given to kit bidders that bid for all other lots (i.e. Lot 1 - Pharmaceuticals, Lot 3 - MD, Equipment and IVDs, and Lot 5 - Other Medical Kits) compared to kit bidders that do not bid for all other lots. This since in the previous RFP Megabid from 2017, there was a preference given to kit suppliers that also offered other lots.

A14. Answered in the pre-bidding meeting #1 minutes. We confirm that there are no preferences. Each Lot will be evaluated separately.

Q15. Annex 3 - Technical Requirements for Pharmaceutical Products. Appendix 1. Please clarify what the word “(Optional)” means for the following products listed:

Methyldopa 250mg tablet (Optional)

Hydralazine hydrochloride 50mg tablet (Optional)

Hydralazine hydrochloride 25mg tablet (Optional)

Hydralazine hydrochloride 20mg/2ml (Optional)

A15. Please disregard the word “optional”.

Q16. Annex 7 - UNFPA Requirements for Kits Assembly. Page 5: “..stickers are printed on the box as shown below.” Please clarify, to which stickers you are referring to?

A16. Please refer to page 6 of Annex 7 for example.

Q17. Annex 9 - Technical Information and Price Bid Form (lots 1_3_4_5). Tab 7. Prices for the IARH kits. Column I - Cost of reconfiguration/Kit. Please clarify what is this cost referring to and how to fill out?

A17. Reconfiguration means any change to product/s in the already packed kit, for example, to extend the kit's remaining shelf life.

Q18. While going through the Bidding Document, I noticed that clause 4.3 requires us to quote for at least 80% of the items in the total list in Annexure 9. We seek clarification from you that being the primary manufacturer of Surgical Sutures, how can we bid for 80% of the items in the list.

A18. If you, as a manufacturer, cannot bid for 80% of the items under Lot 1 or Lot 3 ,we will suggest you finding a partnership with one of the wholesalers who might bid for this tender and cooperate with them. So the wholesaler will represent your company and they will work with you directly and will be Consolidating orders if BPA is awarded.

Q19. Kindly note that UNFPA/DNK/ITB/23/003 is for multiple destinations and Yemen is one of them, but when observing bidding document the tender is mainly for Denmark. Would you please advise us if it is possible for us to participate in the above tender as we are already registered for UNGM?

A19. Orders will be shipped to multiple countries. Recipient countries are listed in UNGM under the description in the “Countries” tab.

Q20. Please note that there appears to be a possible error in Annex 9 - Technical Information and Price Bid Form (lots 1_3_4_5), Tab 1 - Product list-price form, Column R. For bid no. 48 and 49 the Weighting score seems to be inverted as per the Annex 1 - Past Procurement Statistics.

A20. Change of weighting score of bid items No. 48 Ferrous salts/Folic acid coated (60mg/0.4mg), pack of 100 or 1000 tablets and 49. Ferrous salts (60mg Fe), pack of 50, 100, 250, 500 or 1000 sugar coated tablets in Tab 1. Product list-price form, cells R70 and R71 as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003.

Q21. Firstly, we would like to inquire whether it is possible for us to participate in this tender partially. We are interested in bidding on lot 3 and lot 5, but we are not sure if this is possible under the terms of the tender. We would appreciate any guidance you can provide in this regard.

Additionally, we would like to request clarification on the process for submitting bids. We have reviewed the instructions provided in the tender documents, but we want to ensure that we are fully compliant with all the requirements. Could you please provide us with more information on the submission process and any specific requirements that we should be aware of?

Finally, we noticed that you mentioned that bidders must have at least 80% of the items listed in lot 3 and lot 5. We have most of the items required for lot 3 and lot 5, but we are concerned that we may not meet the required 80 % threshold for participation. Could you please clarify this requirement and let us know if we are eligible to bid on these lots less than the 80 % or?

A21. This information is included in the bidding document, Section 3: Data Sheet, article 5 “Submitting bids for parts or sub-parts of the schedule of requirements or Lots” on page 26. Bidder must bid for at least 80% of the items included in Lot 3, and for all the kits included in Lot 5.

Q22. We are ISO 9001 certified and currently in the process of obtaining the ISO 13485 Certification. We expect to successfully finalize this process in November 2023. Can you please confirm that our current ISO Certification complies with the requirements of above-mentioned tender for distributors, or if the ISO 13485 Certificate is also mandatory for distributors. Please note that in the tender we will only submit products from ISO 13485 certified manufacturers.

A22. Answered in the pre-bidding meeting #1 minutes.

Q23. Annex 9a. Sheet 1. Product list-price form, column 13. "Multiple Order Quantity (for products ordered in pre-set multiple quantities) (based on Supplier's Sales Pack Size)". Please comment on how we should understand it and share example.

A23. Answered in the pre-bidding meeting #1 minutes.

Q24. Annex 9a. Sheet 1. Product list-price form, column 15. "Bidder's Price per UOM for delivery FCA closest port/airport PALLETIZED (USD) " In Ukraine at the moment the closest port/airport is located in Poland or Romania. thus, FCA prices could not be calculated without the quantities. Please advise if this data is not obligatory to provide?

A24. Answered in the pre-bidding meeting #1 minutes.

Q25. Annex 9a. Sheet 2. Technical Info Pharma "4.1 Primary packaging label language (English/French, English or French, other - specify)" & "4.3 Secondary packaging label language (bilingual English/French, English, French. Multilingual - English/French/Spanish or other (specify))". We are confused on these 2 points as they are conflicting with the requirements to Label, PIL/insert and package stated in Annex 6. Technical Requirements for packing, packaging, labelling, namely: English, French and Spanish. Also, what we have to answer here if current labels and packages in Ukrainian and Russian; but trilingual will be done after contract award? At the moment of bid submission, we could present English version of the PIL/instruction for use.

A25. Answered in the pre-bidding meeting #1 minutes.

Q26. Annex 19. Sheet SOP Freight Conditions Nov2021. "Active and Passive Containers" We are not confident that this type of containers is widely available in any country. Please advise who should supply them to the warehouse of the manufacturer? And what is the mechanism of compensation of their costs? Also, in case UNFPA would require the products to be delivered in Warsaw, Poland. We could deliver within 3 days and use passive container by road transport. Then UNFPA will deliver it to the destination country, for example in Africa, by sea which will take 1month. In this case UNFPA will reload the goods from passive to active or reefer container?

A26. Answered in the pre-bidding meeting #1 minutes.

Q27. Annex 9a. Sheet 3. Price DataLogger & ColdBoxes. Could you please share full characteristics and requirements for dataloggers? SINGLE USE OR MULTIPLE USE?

Duration (number of recording days)? Register only temperature or humidity as well? Etc.

A27. Answered in the pre-bidding meeting #1 minutes.

Q28. Page 35 of the Bidding document: "Selected BPA holders may be requested by UNFPA to start registration process in the recipient countries". Please advise how it could be realized in fact? For example, UNFPA will ask BPA holder to start registration in 10 countries. The registration costs might be higher than the contract amount or profit from this deal. And registration time could take from 6 month to 2 years. Or UNFPA will require only these registrations which are fast-track (within 1-2 months) and free of charge? In this case, we kindly ask to provide information in which cases UNFPA will request to start registrations? Please provide information on the list of countries for each product that requires registrations. At which stage this information could be disclosed? If at the time of signing BPA, and the BPA holder will refuse to sign it because of high cost of registrations, what will be the sanctions from UNFPA?

A28. Answered in the pre-bidding meeting #1 minutes.

Q29. We would like to clarify the minimum turnover requirements, specifically for companies bidding across multiple lots. Will a company bidding across all lots have to demonstrate a cumulative turnover i.e. \$32m for all lots? Or can this requirement be covered by having the minimum requirement for the highest lot i.e \$12m for lot 3, if also applying for lot 4?

A29. Answered in the pre-bidding meeting #1 minutes.

Q30. We will be submitting as a consortium; how best administratively can we do this or should keep the main contact as the lead consortium partner?

A30. Please be guided by Section 2. Instruction to bidders, article 20. Joint Venture, Consortium or Association.

Q31: Regarding "Only one bid" (Clause 21, Section 2, page 14):

(1) As a manufacturer of PQed RH products, is it acceptable that if we participate in as a bidder Lot 2 while as the manufacturer of other bidder(s) in lot 1 and/or lot 4

(2) If yes, is it acceptable if we authorize several bidders in lot 1 and/or lot 4?

A31. Yes, one manufacturer can give authorization to one or various wholesalers to include their products in their bid and bid for Lot 2.

Q32: Regarding "Instruction for bid submission" (Article 10, Clause 26, Section 3, p 27) Submission by secured mails: If any documents are required by forms, should it via Cloud storage?

A32. Only these forms should be submitted by email (bidtender@unfpa.org):

- 1) Form A: Bid Submission
- 2) Form B: Bidder Information
- 3) Form C: Joint Venture/Consortium/Association Information
- 4) Form D: Eligibility and Qualification
- 5) Form E: Technical Bid
- 6) Annex 9. (or 9a for lot 2) Technical Information and Price Bid Form

Submission of supporting documents should be done only through a secure and unique link to the cloud storage space provided by UNFPA. Proposers shall request their unique link to the email address: contract.pmdk@unfpa.org.

Q33. Regarding "Instruction for bid submission" (Article 10, Clause 26, Section 3, p 27) Submission manner: Does one drive (mentioned in Page 50) refer to Secure cloud storage space?

A33. Yes, One Drive mentioned on Page 50 refers to Secure cloud storage space to be provided by UNFPA.

Q34. Regarding "Instruction for bid submission" (Article 10, Clause 26, Section 3, p 27). Mandatory subject of the email: according to our understanding, the company name, and email no. X of Y should be filled out. Is it necessary to detail the bid such as "Lot 2" to substitute "Bid", or just remain the wording as "Bid"?

A34. It is not necessary to detail the Lot in the subject of the email. The mandatory subject of email: "UNFPA_DNK_ITB_23_003, Company name, Bid, email no. X of Y" sequentially, and the final "email Y – final".

Q35. Regarding "Instruction for bid submission" (Article 10, Clause 26, Section 3, p 27).

What/who is “c” mentioned in “Bidders not receiving the auto-reply for their first mail should inform c”

A35. contract.pmdk@unfpa.org.

Q36: Regarding “5. Freight” under Section 4 (page 41) Please clarify if the due date (lead time) includes the time to arrange shipping. Because UNFPA sometimes uses designated freight forwarders (FCA), and sometimes uses suppliers’ forwarder(CPT) to ship the goods. But the supplier needs additional time to proceed a series of steps such as customs clearance, transportation to port warehouse, security inspection, etc., which cost at least three days to arrange air shipment and 5 days for sea shipment. It is unreasonable to count this time in the lead time, because if UN appoints the freight forwarder to ship, the supplier can deliver to the freight forwarder on the due date, but the freight forwarder has enough time to arrange the shipment after the due date.

A36. Delivery lead time is defined as the time from supplier’s acknowledgement of UNFPA Order until the goods are ready to be shipped from the point of origin. Lead Time requested in Annex 9. Technical Information and Price Form, tab 1. Product list-price form does not include the time to arrange shipping.

Q37: Regarding “Bid Item Number_Product ID” required for the name of “Folder (level 2)-documents per each product under Folder (Level 1)-pharmaceuticals dossiers” (Section 6, p 51-52)

(1) Does “bid item no.” equal to “Product ID” for medicines? If not, please clarify and tell us where we can find them as we only find the bid item no. of the product in the Form 9a.

(2) Could you give us an example to facilitate our understanding? e.g., “Item 80” used as the level 2 folder name for misoprostol tablets as per the BID ITEM No. stated in Form 9.

A37. Bid Item Number required for the name of Folder Level 2 - document for each product under Folder (Level 1) – pharmaceutical dossiers correspond to “Bid Item Number” in Annex 9. Technical Information and Price Form, tab 2. Technical Information Pharmaceuticals (column A). The example provided for Misoprostol is correct.

Q38. Form E (page 65) Shall we use the given format/structure to prepare the Form E which briefs the required information on the Technical Bid? Or Just add the signature on the given format and provide the supporting documents via Cloud?

A38. Information requested in Form E: Technical Bid can be provided in the same form (by adding the information after each of the points) or in a different document as long as it follows the format stated in the Form. In both cases, Form E should be signed. Any supporting documentation must be provided using cloud storage space.

Q39. Whether one manufacturer can give authorization to another company and can also direct participate in this bid. Please advise.

A39. One manufacturer can give authorization to a wholesaler to include their products in their bid and bid directly in Lot 2.

Q40. Lot 1 contains 100 pharmaceutical molecules, whilst Lot 2 contains 25 molecules. In Lot 2, only manufacturers are permitted to participate and same 25 items are reflecting in Lot 1 as well. The criterion for Lot 1 is that bidders must quote at least 80% of the solicited items, which implies bidders must comply with the coverage of items for 80% of the 75 items for Lot 1 because only manufacturers are allowed to submit offers for 25 items. To be eligible for this lot, bidders must offer at least 60 items in Lot 1. Please clarify if this understanding is correct.

A40. For Lot 1 bidders must quote at least 80% of the solicited items. As there are 100 items in this Lot, the bidder must quote for at least 80 items (80% of 100 items).

Q41. We are the sole authorized distributor for one of the manufacturers for the following products for participating in the UNFPA tender. As your tender conditions state that only manufacturers may participate in these items, please advise how the bidder can offer these products from their manufacturer, as if the bidder (exclusive wholesalers) cannot, the manufacturer may not offer these products directly to UNFPA.

78 Pharmaceuticals Orals Mifepristone 200mg + 4 misoprostol 200mcg tablets (blister), pack of 30 (1mife+4miso) tablets

79 Pharmaceuticals Orals Mifepristone, 200mg, pack of 1, 3, 15, 30 tablets

80 Pharmaceuticals Orals Misoprostol, 200mcg, pack of 3 or 4 tablets

A41. Only manufacturers can bid for Lot 2. The only way to participate in this Lot is the manufacturer bid directly for its products.

Q42. Lot 5 - Other kits: Please clarify if our understanding is correct that bidders should quote for all 5 kits from Lot 5 then they are eligible for Lot 5.

A42. Partial bids are not allowed for Lot 5, so bidders should quote for all 5 kits to be eligible for this Lot.

Q43. For LOT 3 Medical Devices, can a manufacturer participate? If yes, how do we satisfy the minimum 80% items to be quoted from 450 items. We are manufacturers of surgical sutures and interventional cardiology devices. From the discussion yesterday, we understand that this lot is only for distributors. Correct me if my understanding is incorrect.

A43. Manufacturers are allowed to participate in Lot 3, but they must quote at least 80% of solicited items.

Q44. If the above is only for distributors, can you help us with a few names of those who have qualified for this 80% requirement in the previous tenders as we are participating for the first time. Our product quality is equivalent to the market leaders and we don't want to miss this invitation to bid.

A44. Information about the award under the previous solicitation process can be found in UNGM (<https://www.ungm.org/Public/ContractAward/106529>)

Q45. Is the BPA per product or per lot?

A45. Answered in the pre-bidding meeting #1 minutes.

Q46. Lot 2 is for manufacturers: Does the 80% of the total list of products apply here? Must the manufacturer have WHO/SRA certification? or is the country's regulatory approval enough?

A46. For Lot 2: Pharmaceuticals (only for manufacturers) partial bids per item are permitted. Bidders can quote for as many solicited items as desired without minimum product coverage.

Q47. During the bid clarification, we asked for an extension of the deadline, an extension of 4 weeks would be very helpful to do proper bidding for those who bid for many lots.

A47. UNFPA will consider bidders' request to extend the submission deadline. If approved, UNFPA will inform of such an extension through email and in UNGM.

Q48. Is it allowed to provide alternative prices for IARH kits for various FCA locations?

A48. You can provide a set of prices for the alternative FCA location, but the primary FCA location should be clearly identified in your bid.

Q49. Is it allowed to offer secondary sources for other item than the ones indicated by UNFPA?

A49. At this stage, there is no need to do so. If the bidder is awarded LTA and there is a rationale for the inclusion of the secondary source in the course of BPA, this could be done at that time.

Q50. What does 'compliant' mean? 'Lot 1 & 3 >70% compliant'

A50. In Lot 1 and 3, under Lot Coverage section it can be read: "Minimum of 70% of the total list should be compliant, so the bidder could be considered eligible for this Lot." This means that 70% of the total list (70 items for Lot 1 and 299 for Lot 3) should be compliant with technical requirements.

Q51. Does the 'Power of attorney (e.g. in IPPQ)' apply for the manufacturer, the bidder or both? Is "Power of Attorney/Letter of Authorization" required from EACH manufacturer? As per the questionnaires (Annex 10, 12, 14) this document seems to be requested for submission.

A51. If the bidder is not the manufacturer of the item, it must present a certification or authorization of the manufacturer indicating that the bidder is duly authorized to act as an agent on behalf of the manufacturer, or Power of Attorney.

Q52. Kindly indicate if IARH kit 2A should include individual kitting of subkits and stickering/labelling of the individual kits, this is not specified in the Annex 7.

A52. Yes, each kit 2A contains 200 individual clean delivery kits that are packed in separate transparent plastic bags for ease of distribution. Below is a photo illustrating packing of kit 2A as an example. About stickering and labeling, on one side of each bag must appear the name of the kit and contents while the leaflet with instructions is placed on the opposite side of the bag.



Q53. Please indicate if Ketamine and Epinephrine should be packed separately in kit 11B?

A53. Yes, it should be packed separately from the rest of the RH Kit 11B components.

Q54. Page 51 mentions requirement for Corporate Environmental Policy, ISO 14001, ISO 14064 if available. Does 'if available' apply to ISO 14001 and ISO 14064 or only to ISO 14064, which means that ISO 14001 is mandatory for suppliers and manufacturers?

A54. Technical Requirements for Medical Devices and IVDs state: "Manufacturers are requested to provide proof of ISO 14001 (Environmental Standard) and ISO 50001 (Energy Standard) certification. If ISO 14001 is not available, a signed letter is required from a manufacturer stating that if they will be awarded with a global LTA with UNFPA, they commit to complete the ISO 14001 certification process before the end of first year of LTA validity."

Q55. Annex 6 indicates printing on boxes rather than labelling. Annex 7 for kits indicated labelling / stickering is preferred. Is printed boxes allowed for IARH kits and is labelling on regular export cartons allowed?

A55. Yes, as indicated in Annex 7: It is preferred that stickers are printed on the box as shown below.

Q56. Please provide PDF for printing materials for PEP and Fistula kits, items 574, 575, 576, 577.

A56. PEP kit , Item 574 and 577 have been removed from the list of Kits and items that are part of this tender. Printing materials of Fistula Kits have been added to the link in Annex 8: Printing materials for the kits.

Q57. Many Items have either no Item ID OR Item ID have been written as "New". Will UNFPA provide the item ID shortly?

A57. Item IDs are included in Annex 9, tab 5. Specifications Medical Devices & IVDs are for reference purposes only. No other item IDs will be provided. New Item IDs from the new ERP system will be incorporated into the BPA.

Q58. GLOVESSURGICAL8_1. It seems that the size of this item in the Detailed Technical Specifications is 7.5, but the ID reference and UNFPA Item Description show size 8. Please clarify.

A58. UNFPA Detailed Technical Specifications of Bid Item No. 217 Gloves, surgical, size 8, powder-free, sterile, single use have been modified in Tab 5. Specifications Medical Devices, cell G132 to "Size selected: Surgical gloves, size: 8" as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003.

Q59. GLOVESSURGICAL7.5. It seems that the size of this item in the Detailed Technical Specifications is 8, but the ID reference and UNFPA Item Description show size 7.5. Please clarify.

A59. UNFPA Detailed Technical Specifications of Bid Item No. 218 Gloves, surgical, size 7.5, powder-free, sterile, single use have been modified in Tab 5. Specifications Medical Devices, cell G133 to "Size selected: Surgical gloves, size: 7.5" as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003.

Q60. Should "Annex 12. Questionnaire for Medical Devices" be completed for EACH medical item incl consumables under Lot 3? Or only for equipment? Please advise."

A60. Yes, Annex 12 must be completed for all medical devices (either consumables, accessories, etc.) listed in Lot 3.

Q61. We have seen that many required information of the Questionnaires are repeating in the excel sheet ""Annex 9. Technical Information and Price Bid Form (lots 1_3_4_5)"". Please understand that completing both documents (questionnaires & Annex 9) takes time. How could we avoid the unnecessary double work? "

A61. Both documents (questionnaires and Annex 9) must be completed.

Q62. It seems the tender requirements are tremendous, can the submission deadline be extended for e.g. 6-8 weeks?

A62. UNFPA will consider bidders' requests to extend the submission deadline. If approved, UNFPA will inform of such an extension through email and in UNGM.

Q63. What is the target lead time for the kits and the loose items?

A63. There is no target lead time for kits / standalone items, but it is of UNFPA interest to deliver in the shortest time possible.

Q64. Would multiple FCA points be allowed? If yes, how many?

A64. Answered in the pre-bidding meeting #1 minutes.

Q65. Is the unit of measurement for IVD kits tests or kits? If Kits, how many tests per kit is preferred?

A65. Unit of Measure of the IVDs refers to the number of tests (including accessories) per pack.

Q66. For Lot 1 items where a secondary source is encouraged, how should we fill in the required information for the secondary source in Annex 9?

A66. Information about secondary sources can be added in tab 1. Product list-price form, lines 573 and 574 (please add more lines if needed). In regards to Technical Information to be provided in tab 5. Specifications MDs and IVDs, please use the lines at the end of the tab.

Q67. Does the secondary source need to have the same pricing as the primary source?

A67. No, they can have different prices.

Q68. For all items (pharma and non-pharma) where it is not expressly stated that a secondary source is needed, can we propose a secondary source also?

A68. At this stage, there is no need to do so. If the bidder is awarded LTA and there is a rationale for the inclusion of the secondary source in the course of BPA, this could be done at that time.

Q69. For medical devices where there are accessories, how should we express this in annex 9?

A69. Information about medical devices' accessories must be included in tab 5. Specifications MDs and IVDs.

Q70. Could you please help us better understand the set up for the MVA kitting services and the below comment: *Note: Service to pack more than one item (1-4 specified above) into an individual bag as a kit. Requestors have the ability to choose which, and the amount of items to be included in one kit.

A70. Kit MVA kitting service does not include the quantities to be provided of each item. This is because the service consists of packing more than one item (1-4 specified in the kit components) into an individual bag as a kit. UNFPA will decide which items, and the amount of items to be included in one kit.

Q71. For Annex 9--Tab 1. Product List and Price Bid Form, I am not for sure how to fill column M: Multiple Order Quantity (for products ordered in pre-set multiple quantities) (based on Supplier's Sales Pack Size). Hereby I assume an example as following:

Item 215 Gloves, surgical, size 7, powder-free, sterile, single use, P50

• UOM: Piece

- **Column E Supplier's sales pack size: box**
- **Column F Supplier's sales pack size IN NUMBERS: 50**
- **Column L Minimum Order Quantity (based on Supplier's Sales Pack Size): 100**
- **Column M Multiple Order Quantity (for products ordered in pre-set multiple quantities): 5000 (based on Supplier's Sales Pack Size)**

Could please tell me if the above assumed filling is correct or not?

A71. If the Multiple Order Quantity for this product is 5000 (packs of 50 pieces as indicated in columns E and F), UNFPA will consider that your organization can only provide this item in quantities multiple of 5000 packs of 50 (5,000, 10,000, 15,000...). Then Minimum Order Quantity must also be 5,000 packs of 50 pieces.

Q72. In the tender, the bidder is requested to provide secondary sources for 15 items (marked in red), however, only two additional lines are available for the bidder to add this information. We hereby request you to make provision to add additional lines.

A72. Please add lines as needed. It is not limited to only two lines.

Q73. The bidder is requested to submit technical documents as "Bid no_Product ID". Upon checking the respective Annex, we observe that the product ID is not available for the pharmaceutical product category. Could UNFPA please support with the details.

A73. Product ID in the 09. Annex 9. Technical Information and Price Bid Form under the Tab 5. Specifications Medical Devices & IVDS are only given for reference purposes. Product IDs will be assigned to all products at the time of signing BPAs as per the Quantum Item numbers.

Q74. General Annex 9-tab 7. In the price request form column, I – "price per unit (as per primary UOM), as the price is of the lowest unit it is requested to make a provision to accommodate the price up to 4 decimals to avoid display of prices as 0.00

A74. You can use showing up to 4 decimals in this column.

Q75. Annex 8. Annex 8 – Detailed specifications about printing are required such as the size, font, colour, graphics, layout of the printing material for the vendor to

accommodate while calculating the service charges. We hereby request UNFPA to share detailed specifications.

A75. Please refer to Tab 6. Technical Specification Form for Other Items in 09. Annex 9. Technical Information and Price Bid Form.

Q76. Annex 9 Bid no. 312. The components of Kit 11B - mentions bid no. 312 twice with requests of suction tube of different scales. Kindly reconfirm if CH 14 is also required by UNFPA and if so, please advise on the bid no because that would be a different item.

A76. Item No. 32 Tube, suction, CH14, 50 cm long, conical tip, sterile modified in Tab 7. Price Kits IARH kits, Kit 11B - Obstetric surgery and severe obstetric complications: Drugs and Disposable Equipment to Bid Number 313 in cell B426 as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003.

Q77. Annex 9, Bid No. 54. In Annex 9,1st tab : product list-price form, the bidder is requested to bid for Glucose, 10% injection in pack of 20 or 50 ampoules while in the 7th tab : Price kits IARH kits, the requested product is Glucose 5%, isotonic, 1 litre + infusion set, sterile, single use. As both the sheets are interrelated, we hereby suggest making the requisite changes to avoid any discrepancies.

A77. Item No. 11 Glucose 5%, isotonic, 1 litre + infusion set, sterile, single use modified in Tab 7. Price Kits IARH kits, Kit 6B - Clinical Delivery Assistance – Midwifery Supplies: Drugs and Disposable Equipment to Bid Number 55 in cell B192 as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003.

Q78. Tab 1 & Tab 7. In tab 1-product list-price form the product under bid number 78 is a co-blister product of Mifepristone 200mg +4 Misoprostol 200mcg tablets (blister), pack of 30 (1mife+4miso) tablets while in tab 7 Mifepristone 200mg is under bid number 78. Request you to take note of this discrepancy.

A78. Item No. 1 Mifepristone 200mg tablet modified in Tab 7. Price Kits IARH kits, CC Kit Mifepristone to Bid Number 79 in cell B498 as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003

Q79. Annex 9. In the “annex 9 technical information and price bid form (lots 1_3_4_5)” under section 3.5 details related to registration in other countries/licensing status in other countries is asked to be described while in column AB details of countries of

registration is asked, could you specify the details of information expected from the bidders in these 2 columns.

A79. Under section 3.5 details please provide description of the registration/ licensing status in other countries and under column AB just list the countries.

Q80. Bid No.565. Lot 4. Shoulder Bag - the link provided in the technical form for UNFPA's color shade of the logo is not accessible; Error noted is as follows; request your kind support.

A80. You can login with this user name: unfpastyle and password: Every1counts!

Q81. Bid no. 41 Lot 1. Dolutegravir, 50mg, pack of 30 dispersible tablets - Dispersible tablet form is for 10mg strength and not 50mg. Seek clarification from UNFPA to offer 50mg film coated tablet as approved.

A81. UNFPA Item Description of Bid Item No. 41 has been modified in Annex 9. Technical Information and Price Bid Form Tab 1. Product list-price form and Tab 2. Technical Info Pharmaceuticals to "Dolutegravir, 50mg, pack of 30 tablets".

Q82. Bid Number 11. Atropine sulphate 1mg/ml injection in 1ml ampoule, pack or 10, 20, 50 or 100 ampoules. Details of Azithromycin Anhydrous strength 250mg is provided. Different products requested under the same bid number.

A82. Bid Item No. 11, cell C27, modified in Tab 2. Technical Info Pharmaceuticals to "Azithromycin Anhydrous, 250mg, pack of 1, 6, 10 or 12 capsules" as per as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003.

Q83. Bid Number 65. Lidocaine hydrochloride 1% injection in 20ml vial/ampoule, pack of 1, 10 or 20 vials/ampoules. Lidocaine hydrochloride 1% Strength: 10mg/ml in 10ml vial. Different UOM is requested, can the bidder select to quote as per the available pack size.

A83. Bid Item No. 65, cell C81, modified in Tab 2. Technical Info Pharmaceuticals to "Lidocaine hydrochloride 1% injection in 10ml vial, pack of 20 vials" as per as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003.

Q84. Bid numbers 280 & 282. Auto Disabled Syringe, feeding, catheter tip, 50 ml, sterile, P1. Capacity 2ml. Different capacity requested.

A84. Bid Items No. 280 and 282 Auto Disabled Syringe, feeding, catheter tip, 50 ml, sterile, P1 and P50. UNFPA Detailed Technical Specifications have been updated in Tab 5. Specifications Medical Devices as per as per Letter of Amendment No. 1 to UNFPA-DNK-ITB-23-003.

The following questions were received by UNFPA before April 1st, 2023 and will be addressed on Round 2 of Clarifications to be published in upcoming weeks:

Q1. Annex 9. Technical Information and Price Bid Form (lots 1_3_4_5). Lot #62. Ibuprofen, 400mg, pack of 6, 10, 12, 15, 18, 20, 24, 30, 40, 50, 56, 60, 84 or 100. Is it allowed to offer pack of 7 or 14 tablets?

Q2. Annex 9. Technical Information and Price Bid Form (lots 1_3_4_5). Lot #98. Water for injection in 10ml, pack of 20 or 50 plastic ampoules. Is it allowed to offer the same product but in glass ampoules?

Q3. Annex 3 - Technical Requirements for Pharmaceutical Products. 1.4.2. Manufacturing sites. For all pharmaceutical products other than the ones listed in Annex 3 - Appendix 1, please clarify whether they must have a valid GMP certificate from a Stringent Regulatory Authority (SRA) or if a local GMP certificate from the country of manufacture would be sufficient.

Q4. Annex 5 - Technical Requirements for Medical Devices. 1. Introduction and 2.2. Declaration of conformity. "Manufacturer shall provide evidence that the product has been sold to Europe or the U.S." Please define what bidders are expected to share as proof or evidence of sales? This since CE and/or USFDA approval of the products is considered as the allowance to sell the items within the given area.

Q5. Annex 5 - Technical Requirements for Medical Devices. 2.3. Compliance with regulatory requirements. Evidence of valid Manufacturing license from the national regulatory authority is required. Considering that there are countries in which a manufacturing license is not necessarily mandatory, can this be considered as N/A (Not Applicable) if such manufacturing license is not issued by the country of manufacture?

Q6. Annex 5 - Technical Requirements for Medical Devices. 2.3. Compliance with regulatory requirements. "For manufacturers which are supplying CE certificates under the MDD, a legalized declaration letter from the manufacturer that it is working towards compliance to MDR is required. Additionally, the manufacturer shall submit objective evidence to demonstrate compliance to MDR within 1 year after supply awards have been given and signed." Please clarify, what is defined as "objective evidence" and "legalized declaration"?

Q7. Annex 5 - Technical Requirements for Medical Devices. 2.3. Compliance with regulatory requirements. "Manufacturer shall provide evidence of clinical studies to all but class I non-sterile, non-measuring medical devices e.g. a copy of the study results." Clinical studies are an integrated part of CE compliance. Thus, please confirm that it is acceptable that clinical study results are not shared for items having CE certificate available.

Q8. Annex 5 - Technical Requirements for Medical Devices. 2.3. Compliance with regulatory requirements. And 2.4. Quality Management System standards. Post Market Surveillance reports covering the last 3 years are requested. Please confirm that this requirement is only for products above class I. Please confirm that it is acceptable that Post Market Surveillance reports are not shared for items having CE certificate available.

Q9. Annex 4 - Technical Requirements for In-Vitro Diagnostics. 9. Documentation to be submitted with each Offer. 5 Product documentation (n.) Published field testing studies not older than 2 years. Please clarify and elaborate regarding what type of testing studies you are referring to.

Q10. We would like you to clarify on the suture specifications with respect to the suture material and the suture length.

Q11. I would like to know whether the Multivitamin Tablet mentioned in the statistics is the Pre-natal Multiple Micronutrient Supplementation (MMS), UNIMMAP formulation. Our organization is currently in the process of developing MMS Tablets, and we are interested in bidding for the procurement of the Multivitamin Tablet if it is indeed the UNIMMAP formulation. If you could kindly provide clarification on this matter, it would be greatly appreciated.

Q12. I would like to inquire about an alternate bid for the Tetracycline 1% Eye Ointment. Is it possible to bid for an alternative product which contains Oxytetracycline hydrochloride 0.5% and Polymyxin B 10,000 units/g? If so, could you please provide any additional details or requirements for submitting an alternate bid?

Q13. Are dossiers required? If yes, what format?

Q14. Lot 3: Medical devices: in the technical specifications, we have abbreviations like DECA, DEC. Can we have the full meaning? Does 80% of the total list apply here? Must the manufacturers have FDA and CE? Is ISO 14001 enough?

Q15. As the Chinese government is not giving out GMP's anymore, what would you like to receive instead?

Q16. Item 356. Stethoscope, binaural, complete and item 518. Sphygmomanometer, Aneroid, Adult seem like they are the same, can you kindly clarify if they are different, or would you like to receive an offer for both references?

Q17. Item 132. Stove, kerosene, single-burner, pressure-type can not legally be sold as a Medical Device, please confirm if you accept this product without CE mark

Q18. Item 350. Pregnancy wheel can not legally be sold as a Medical Device, please confirm if you accept this product without CE mark

Q19. For the products that fall under IVDs you request a CE under MDR but the products fall under IVDD/IVDR. Kindly clarify if the products can be certified under IVDD/IVDR

Q20. Item 120 mentions plug type and voltage but at environmental requirements it mentions a Solar Refrigerator/freezer. Both types are listed in the WHO PQ site. Please clarify the type of refrigerator/freezer you would like to receive an offer for.

Q21. Item 503 seems to have the same specifications as item 504. The specifications seem to align with item 504 and not with 503. Please confirm if the specifications are correct for item 503 and 504 and share the correct specifications for item 503 if these are incorrect.

Q22. Please provide artwork for items 590, 591.

Q23. REFRIGERATORC. Is this an ice-lined vaccine refrigerator/freezer or a solar direct drive type? In the specification sheet, at the beginning it mentions voltage while at the end it mentions solar".

Q24. COLOSTOMYBAG_10. Colostomy bag, transparent, drainable, w/filter, shall we know it is one piece or two-piece type? Please provide more details.

Q25. COLOSTOMYBAG_20. Colostomy bag, transparent, drainable, w/filter, shall we know it is one piece or two-piece type? Please provide more details.

Q26. CRYOSURGICALUNIT. Which specific use is intended for this device? As the mandatory Cryo probes that should be included are dependent on the major purpose of use. Please advise.

Q27. Tender requires "Evidence that product has been sold to Europe or U.S. or other large market areas with strong regulatory systems". How should the document look like?"

Q28. Tender requires "Copy of third party laboratory test reports, if available (Laboratory name and ISO 17025 accreditation status), if applicable". For which product this requirement applies? Please specify.

Q29. Tender requires "Manufacturer's copy of the latest audit report (audited by an European health product distributor)". Please explain how this audit by an EU distributor could be made for a manufacturer in Asia e.g.

Q30. For many items especially for the pharmaceutical product category, product packaging specifications mention the requirements of products to be packed in blisters as well as jars. Does this mean that the bidder has the option to quote either in jar or blister pack.

Q31. Can the bidder in general offer ampoules for vials and vials for ampoules for such products.

Q32. General Lot 3, Bid nos. 189-195. The bidder is requested to fill in questionnaire for blood products; however, we observe that the questionnaire is not included in the bid document. Could you please advise whether the bidder could use the questionnaire "Blood products – Checklist for required documentation Version 1 Dec_2019".

Q33. General Lot 1 Bid number 99. As per the market information, the manufacturing of the product Zidovudine 100mg, pack of 60 or 100 capsules has been discontinued by the WHO PQ and generic suppliers since few years. Could UNFPA consider an option of replacing Zidovudine with a suitable alternative molecule.

Q34. Please specify whether the below mentioned additional information requested in pharmaceutical requirement (Annex 3) is also applicable to WHO/SRA product.

Additional information requested-

-3 API COAs of supplier and manufacturer

-Summary of product characteristic

-Validation of manufacturing process should be submitted for all parenteral products, suspensions, low dose products, modified release products."

Q35. General Lot 1 Bid no. 53. A quote for the product Gentian Violet is requested under the pharmaceutical product category. Could you please specify the Intended use of the product.

Q36. Annex 3: point 1.5.2 section C. Could you please clarify whether the bidder must submit the SPC (summary of product characteristics), or package insert.

Q37. Annex 5 and 12. Evidence of clinical studies to all but class I non-sterile, non-measuring medical devices: e.g., a copy of study results. Is it required for all risk class medical device products?

Q38. Annex 9, Point 1.3. Date of Last inspection manufacturer is requested, could you please elaborate on the requirement?

Q39. Annex 9, Bid No 293. Syringe, Luer lock, 20 ml, sterile, single use P100 – we observe that for the other range of syringes requested in the bid luer slip is acceptable, we would like to quote the requested product also in luer slip, Could you please advise whether this is acceptable?

Q40. Annex 9, Bid No 97. Requested product in Kit 11B is Vitamin K-1 (Phytomenadione) 1mg/ml, 1ml vial, we would like to propose an alternative concentration Vitamin K-1

1mg/0.5ml, 1ml injection which is been manufactured at an SRA approved manufacturing site. Could you please advise whether the alternative suggested is acceptable?

Q41. Lot 4 and 5: Bid Number 157 and 158. The product BOX.SAFETY_1 and BOX.SAFETY_25, seems to be technically the same product however it is classified as Class I and not a medical device. Could you please clarify.

Q42. Lot 4: Kit 11B Bid no. 18. Product Bupivacaine hydrochloride (as anhydrous) 0.5%, Intrathecal inject., 5g/min, is requested in 10 ml ampoule, can the bidder offer the same product in 20 ml ampoule.

Q43. Lot 5 Bid No. 261, 262, 263, 264, 265. The requirement on the Needle length for suture is not clear. Could you please specify.

Q44. Annex 9 LOT 4: Bid no. 346. Technical specification excel sheet says," Haemoglobin photometer handheld w/accessories" in column D while in column E it says" accessories: None" Could you please clarify whether the product is required with/without Accessories.

Q45. Annex 9, Bid no. 344. For the product Tile, porcelain with depressions for blood grouping, which is a part of RH kit 12, few documents or certifications requested by UNFPA in technical specifications tab 5 seem to be irrelevant as the requested product

Q46. Bid no. 39 Lot 1. Disinfectant tablets for water, 1.67g NaDCC, pack of 10 tablets - Seek clarification from UNFPA for 200 pack acceptance economic pack.

Q47. The below document is required for our submission: Letter of Commitment to compliance to ISO14001?