

**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 2**

***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 packs of 7 or 14 tablets?***

A1. No, it is not.

***Q2. Annex 9. Technical Information and Price Bid Form (lots 1\_3\_4\_5). Item #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?***

A2. No, it is not.

***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.***

A3. It should be a GMP certificate from a Stringent Regulatory Authority (SRA) or Inter-Agency site approval. The local GMP certificate from the country of manufacture is not acceptable.

***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.***

A4. As proof of evidence can be presented:

- a) CE Certificate from a recognized Notified Body
- b) US 510(K) approval letter
- c) Any other market clearance from jurisdictions with strong regulatory systems (please refer to the IMDRF Representative Countries and Management Committee, <https://www.imdrf.org/about/management-committee> )

***Q5. Annex 5 - Technical Requirements for Medical Devices. 2.3. Compliance with regulatory requirements. Evidence of a 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 a manufacturing license is not issued by the country of manufacture?***

A5. Medical Devices must be from manufacturers who are legally registered to manufacture the particular device by their national regulatory authority (NRA) and have valid manufacturing licenses; if a manufacturing license is not issued by the NRA from the country of manufacture, a Declaration by the Manufacturer must be presented in the offer and will be evaluated as RELEVANT.

***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"?***

A6. "Objective evidence" means documented proof, which could be a certificate, license, report etc. "Legalized declaration" means a formal letter from the manufacturer which is signed and stamped by an authorized person from the organization.

***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 certificates available.***

A7. Under the new MDR, clinical studies will be a requirement. The manufacturer could provide a brief summary of the study outcome, or in certain cases where the device has had a long history of use with proven efficacy e.g. surgical gloves, clinical studies may be justified to be exempted.

***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 certificates available.***

A8. The requirement is for medical devices above Class I. However, if it is an innovative device, PMS would still be needed. PMS Summary or Conclusion may be given instead.

***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.***

A9. Evidence of clinical studies to all but the class I non-sterile, non-measuring medical devices: e.g. a copy of the study results.

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

A10. There are different types and materials of sutures for specific types of surgeries and wounds. Sutures materials can be absorbable or non-absorbable. The type of needle for suture types has specifications for needle as well, e.g. Type of needle: curved needle, 3/8 circle for suture 3.3/8.30 -36.

***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.***

A11. The maternal health multivitamins are used by UNFPA clients during pre and postnatal. The specifications are not directed specifically for pre or post-natal indication but to cover the whole spectrum as deemed appropriate by the healthcare provider.

***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?***

A12. Bid Item No. 93 Tetracycline hydrochloride eye-ointment 1% in tube of 5g has been marked as cancelled - to be replaced as per Amendment 3. It is not needed to bid for this item.

***Q13. 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?***

A13. It is a thread gauge expressed in the Decimal gauge DEC number. For the DECA abbreviation, please indicate the exact number of the item referred to. ISO 14001 is mandatory for the manufacturers. If ISO 14001 is not available, a signed letter is required from a manufacturer stating that if they are awarded a global LTA with UNFPA, they commit to complete the ISO 14001 certification process before the end of the first year of LTA validity. Manufacturers must have FDA and/or CE certification of compliance.

***Q14. As the Chinese government is not giving out GMPs anymore, what would you like to receive instead?***

A14. For medical devices, ISO 13485 certificate from a recognized notified body and Manufacturing certificate from the Chinese government can be provided in place of the GMP cert. For Pharmaceuticals a GMP certificate from SRA country or IAPG inspectors will suffice.

***Q15. 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?***

A15. These two devices are different. Please do offer for both.

***Q16. 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.***

A16. Item 132: Stove, kerosene, single-burner is exempted from presenting CE mark, a letter from the manufacturer must be presented stating the rationale why the product can't be classified as a medical device and, therefore, cannot be CE marked. The rationale may include the product's intended purpose not meeting the medical device definition according to European Regulation (EU) 2017/745 (MDR) and product claims.

***Q17. Item 350. Pregnancy wheel can not legally be sold as a Medical Device, please confirm if you accept this product without CE mark.***

A17. Item 350: The pregnancy wheel is exempted from presenting CE mark, a letter from the manufacturer must be presented stating the rationale why the product can't be classified as a medical device and, therefore, cannot be CE marked. The rationale may include the product's intended purpose not meeting the medical device definition according to European Regulation (EU) 2017/745 (MDR) and product claims.

***Q18. 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.***

A18. IVDs proposed to UNFPA for procurement and supply must comply with EU Council Directive 98/79/EEC (IVDD) or EU Regulations 2017/746 (IVDR) with a valid EC Certificate and Declaration of Conformity for the CE mark applied.

***Q19. Item 120 mentions plug type and voltage but for 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.***

A19. As both options are listed and pre-qualified by WHO, bidders have the option to propose either one of the options.

Bidders must propose an option that better complies with environmentally sustainable options, it is preferred the Solar Refrigerator/freezer, however, if bidders do not have this option to be offered, and alternative can be proposed to be used with the right voltage in the country of destination and with the plug and socket type that fit the country where it is going to be delivered. The country of destination would be stated in the UNFPA's PO.

For voltage refrigerator / freezer options, Manufacturers are requested to provide proof of ISO 14001 (Environmental Standard) and ISO 50001 (Energy Standard) certification.

***Q20. Item 503 Vacuum extractor, Bird, manual, complete set seems to have the same specifications as item 504. Vacuum extractor, Vacca OmniCup, hand-held, 1 person, reusable. 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.***

A20. Technical Specifications of item 503 have been modified in Annex 9. Technical Information and Price Bid Form as per Amendment 3.

***Q21. 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".***

A21. Please refer to the answer in Q20.

As both options are listed and pre-qualified by WHO, bidders have the option to propose either one of the options.

Bidders must propose an option that better complies with environmental sustainable options, it is preferred the Solar Refrigerator/freezer, however if bidders do not have this option to be offered, and alternative can be proposed to be used with the right voltage in the country of destination and with the plug and socket type that fit the country where it is going to be delivered. The country of destination would be stated in the UNFPA's PO.

For voltage refrigerator / freezer options, Manufacturers are requested to provide proof of ISO 14001 (Environmental Standard) and ISO 50001 (Energy Standard) certification.

***Q22. COLOSTOMYBAG\_10 and COLOSTOMYBAG\_20. Colostomy bag, transparent, drainable, w/filter, shall we know it is one piece or two-piece type? Please provide more details.***

A22. As stated in UNFPA Detailed Technical Specifications (Annex 9) it is required a "one-piece open system".

Please refer to the column G, “UNFPA Detailed Technical Specifications” for more details on the technical specifications.

**Q23. 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.**

A23. The system is typically used across clinical specialities (e.g., general surgery, dermatology, oral surgery, gynaecology, urology, ENT, proctology, and oncology) to remove malignant or abnormal benign tissues.

**Q24. 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?"**

A24. For European Union, certificates are issued by Notified Bodies, templates must vary among them, please refer to [Regulation \(EU\) 2017/745 on medical devices](#) (MDR) and [Regulation \(EU\) 2017/746 on in vitro diagnostic medical devices](#) (IVDR) and rely on the correspondent websites for further information:

[https://health.ec.europa.eu/medical-devices-eudamed/notified-bodies-and-certificates-module\\_en#documents](https://health.ec.europa.eu/medical-devices-eudamed/notified-bodies-and-certificates-module_en#documents)

[https://health.ec.europa.eu/document/download/b8c40a99-9399-4747-8473-c9d30a09ed4f\\_en?filename=md\\_eudamed-certificate-versioning\\_en.pdf](https://health.ec.europa.eu/document/download/b8c40a99-9399-4747-8473-c9d30a09ed4f_en?filename=md_eudamed-certificate-versioning_en.pdf)

For US FDA clearance, a copy of the registration must be presented with the registration number, this will include FDA product code, the FDA Premarket submission number or must be indicated if the device is exempt from the Pre-market submission.

Please rely on the corresponding US FDA website for further information.

<https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#who>

EU - CE certificate from a designated Notified Body

US - 510K) approval letter from US FDA

Other markets - the country's regulatory authority's approval certificate.

***Q25. 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.***

A25. For Medical Devices, in case the manufacturer does not have an in-house testing facility to conduct the necessary tests to verify the compliance/quality status of the device, they may send it to an external laboratory which has the relevant capability and accreditation to perform the tests.

The IVDR requires device manufacturers to conduct clinical performance studies and provide evidence of safety and performance proportionate to a device's assigned risk class. Device manufacturers have to collect and retain post-market performance data as part of the ongoing assessment of potential safety risks.

As an example, please refer to IVDs classified as Class D, rule 1 (IVDR): Devices intended to be used for the detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration.

For further information, please refer to the IVD Regulation for the device in which the Regulation applies:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746>

***Q26. Tender requires "Manufacturer's copy of the latest audit report (audited by a European health product distributor)". Please explain how this audit by an EU distributor could be made for a manufacturer in Asia e.g.***

A26. The audit should be conducted by a designated Notified Body (in NANDO's list), not the EU distributor. The majority of the recognized Notified Bodies have representatives in Asian countries.

***Q27. 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.***

A27. As a rule of thumb, blisters are used for packs of 30s and below (or a blister strip of less than and equal to 10s 15s or 20s). Securitatiners are for bulk products.

**Q28. Can the bidder in general offer ampoules for vials and vials for ampoules for such products?**

A28. Regarding the interchangeability of ampoules to vials, please note that UNFPA relies on the WHO EML guidelines on whether to opt for an ampoule or vial in each case. Please offer as per specification.

**Q29. General Lot 3, Bid nos. 189-195 (Blood bag+CPDA-1 (citrate-phosphate-dextrose-adenine), 250ml, 350ml and 450ml . 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".**

A29. Yes, the "Blood products – Checklist for required documentation Version 1 Dec\_2019" will suffice.

**Q30. General Lot 1 Bid number 99 (Zidovudine, 100mg, pack of 60 or 100 capsules). 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.**

A30. New PEP regimens medicines have been included in the Bid so Item No. 99 Zidovudine, 100mg, pack of 60 or 100 capsules has been removed in Annex 9. Technical Information and Price Bid Form, tab 1, Product list - price form and tab 2. Technical Information Pharmaceuticals as per Amendment 3.

**Q31. 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 characteristics**

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

A31. Yes, please as best as possible submit these for WHO PQ/SRA products too, (although we do acknowledge that there are sometimes challenges in obtaining these from some SRA sources).

***Q32. General Lot 1 Bid no. 53 (Gentian violet crystals USP, 25g, 250ml amber glass bottle). A quote for the product Gentian Violet is requested under the pharmaceutical product category. Could you please specify the Intended use of the product.***

A32. Gentian violet is used during surgical procedures for dyeing organs and sutures. It is in the pharmaceutical category as the specifications require pharmaceutical-grade Gentian violet.

***Q33. Annex 3. Technical Requirements for Pharmaceuticals: point 1.5.2 Marking and labelling for pharmaceutical products, section C. Could you please clarify whether the bidder must submit the SPC (summary of product characteristics), or package insert.***

A33. Whichever is available can be submitted as long as it reflects the FPP being received by the end user.

***Q34. Annex 5 Technical Requirements for Medical Devices and 12 UNFPA QNR for Medical Devices. 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?***

A34. Refer to Q7/A7. Under the new MDR, clinical studies will be a requirement to all MDs but class I non-sterile non-measuring medical devices. The manufacturer could provide a brief summary of the study outcome, or in certain cases where the device has had a long history of use with proven efficacy e.g. surgical gloves, clinical studies may be justified to be exempted.

***Q35. 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?***

A35. For item 293, adhere to the technical requirements detailed in the bidding document “Syringe, two pieces: barrel with Luer Lock nozzle and piston or three pieces barrel with luer nozzle, piston and stopper”.

**Q36. 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?**

A36. We rely on WHO EML for the specification of medicines thus will stick with vitamin K and not the K-1.

**Q37. 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.**

A37. Only 10 ml is considered.

**Q38. 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.**

A38. Only 10 tablets pack is considered.

**Q39. The below document is required for our submission: Letter of Commitment to Compliance to ISO14001?**

A39. ISO 14001 is required for the manufacturer (if available). 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.

**Q40. Page 52, Bidding document, General Documentation to consider when preparing a submission for pharmaceuticals:**

***Here, we need your advice or recommendation. You might know that in Ukraine, the package insert is in the form of Instruction for use, which is a 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 shorter version in the form of PIL?***

A40. Please be guided by WHO guideline about information that should be included. It is required both PIL and PI and these should be included in your submission. Please refer to Annex 6 for guidance.

[WHO Guidelines on packaging for pharmaceutical products, Annex 9, TRS 902, 2002](#)

[ANNOTATED SUMMARY OF PRODUCT \(SmPC\) CHARACTERISTICS TEMPLATE](#)

***Q41. 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 from Ukraine. 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 1 month. In this case UNFPA will reload the goods from passive to active or reefer container?***

A41. SOP Freight Conditions Nov2021 refers to Passive containers only to items that require +2 - + 8 C degree transportation and storage temperature conditions (Oxytocin and IVD products that have keep cool elements). Passive containers for short shipments (up to 3 days transit) are allowed as these items are always packed in Keep Cool Boxes that will ensure up to 120 hours of +2 - + 8 C degree environment. For shipments with transit time longer than 3 days and all other shipments that require +15-+25 C environment, active reefer containers are to be used. Important: goods cannot start their voyage in the passive container and then switch to active. Passive containers can only be used if the entire voyage is less than 3 days. If it is going to be more than 3 days, then active/reefer containers must be used from beginning to end.

Please note that we try to avoid shipping temperature sensitive products requiring +2 - + 8 C range by sea, especially for destinations that require long transit time. The use of sea shipment methods for temperature sensitive products requiring +2 - + 8 C range is chosen only where this is the best option considering all factors.

Transportation mode, Incoterms will be advised by UNFPA for each order and transportation temperature regime will be as per the SOP Freight Conditions Nov2021.

If the order is placed under FCA Incoterm, it will be the freight forwarder who will take care of transportation. If the order is placed with another Incoterm where the transportation is managed by the supplier, UNFPA will pay for the cost (goods order will include the cost of the freight). If the transportation of the items requires reefer container/s, transportation from Ukraine to Poland must also be in reefer containers.

***Q42. The Destinations where exactly the shipment is to be delivered.***

A42. This will be specified in each order, and it can be any country globally.

***Q43. Estimate quantities required for pharmaceutical products so that would help us out in offering the prices accordingly.***

A43. We currently do not have the estimates. Please kindly refer to 01. Annex 1. Past Procurement Statistics to get an idea about the volumes procured for the years 2019-2022. Forecast for 2023 should be available by the end of May 2023.

***Q44. Annex 2: Forecast for 2023 has not been provided. Please advise if this will follow.***

A44. Annex 2: Forecast for 2023 should be available by the end of May 2023.

***Q45. Annex 1. Past Procurement Statistics. Contraceptive Implant Insertion and Removal kit is discontinued as per historical data. Please confirm.***

A45. Annex 1. Past Procurement Statistics does not include the following new medical kits, as they are being newly introduced with this tender:

Intrauterine Devices (IUD) Insertion and Removal kit  
Contraceptive Implant Insertion and Removal kit  
Minilaparotomy Kit

***Q46. 09. Annex 9. Technical Information and Price Bid Form (lots 1\_3\_4\_5).***

***Lot 1: Product 9 (Atropine sulphate 1mg/ml injection in 1ml ampoule, pack or 10, 20, 50 or 100 ampoules) & 11 (Azithromycin Anhydrous, 250mg, pack of 1, 6, 10 or 12 capsules) looks like duplicates. Product 9 is listed as a Parental and Product 11 is listed as an Oral. Please confirm if these are meant to be different products.***

***Lot 1: Product 66 (Lidocaine hydrochloride 1% injection in 20ml vial/ampoule, pack of 1, 10 or 20 vials/ampoules) & 65 (Lidocaine hydrochloride 1% injection in 10ml vial, pack of 20 vials) looks like duplicates. Please confirm.***  
***Lot 4: Product 537 (HIV Blot Elisa Test) & 538 (Anti-HIV 1+2 ELISA Blot) looks like duplicates. Please confirm.***

A46. Lot 1: Product 9 and 11 and 66 and 65 have been corrected in Annex 9. Technical Information and Price Bid Form (Lot 1\_3\_4\_5) RevisedAmend1, which is posted in UNGM. Lot 4: Products 537 and 538. Please refer to full specifications, one detects antibodies, whilst the other detects antigens in the blood.

***Q47. Kindly confirm if you have any historical volumes for the ARV range.***

A47. Megabid includes new ARVs that were not procured in the past.

***Q48. For Paracetamol tablets 500 mg we do not have BE study and to provide Justification on BCS Based Biowaiver -we do not have CDP as well. So kindly let us know can we participate without these documents?***

A48. Paracetamol is a BCS Class I/III highly soluble compound. We need a biowaiver to demonstrate similarity with the innovator product, Panadol. Without this biowaiver, the product will not be approved.

***Q49. For Samples- Kindly let us know if samples require at the time of submitting the quotation. If yes then please let us know.***

***Can we submit samples with dual languages?***

***What should be the minimum Shelf life of Samples?***

***Different pack style than offered pack style***

***Samples of controlled products are also required, example - Ketamine.***

A49. Samples are not required at the time of bid submission. If the samples will be requested at the stage of evaluation, suppliers will be informed of the requirement for the samples when requested.

***Q50. In the case of Venezuela, where would I have to deliver it to evaluate the issue of freight? since you talk about via air and sea.***

A50. Orders for products will come from different countries globally. If UNFPA would like to use the supplier's services to ship the goods, suppliers will be requested to quote for sea or air freight services to the destination country.

***Q51. Can I bid only on the items that we sell?***

A51. You can consolidate products from manufacturers and bid under your offer. You will especially need to do that for lots 1, 3, 4 and 5 in order to achieve the requirement to quote 80% of solicited items for the lots 1 and 3 and 100% for the lots 4 and 5.

***Q52. In the case of the kit, do I have some to offer?***

A52. You are not required to bid for all lots. If you do not have the kitting capacity, you can bid for other lots and not bid for Lot 4 and 5.

***Q53. Can I participate with merchandising items?***

A53. Please participate with the items that are required under the Lots. Do not offer items outside the tender, unless there is an alternative requested.

***Q54. In the documentation reference was made to Annex 2 – Forecast for 2023, to be provided at a later stage. May we kindly enquire when UNFPA expects to share this Annex?***

A54. Annex 2: Forecast for 2023 should be available by the end of May 2023.

***Q55. Please provide PDFs and specifications for printing materials for Implant kits, items 600 & 601. Annex 8. The link to the printing materials is not accessible. Request your kind intervention.***

A55. Printing materials for Implants (Items 600 and 601, Implant Card and Counselling material) are included in Annex 8 - Printing Materials for the Kits. The link has been modified and uploaded in Annex 8 and it is accessible at the moment.

***Q56. We cannot understand the difference between the BPA concept and the LTA, would you be so kind to share a few lines?***

A56. It's a new naming for the same type of contract. This naming just better reflects our modified procedures due to the movement to the new ERP system.

***Q57. Page 53, Bidding document, General Documentation to consider when preparing a submission for pharmaceuticals, namely:***

***-Summary of pharmacology, toxicology and efficacy of the product***

***-Graphic/pictorial representation of summary study results***

***-Copy of the report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, and others if any***

***-Schematic representation of study design, Study protocol summary***

***Please advise these documents are required for the products considered as Well-Established Use? Or not required?***

***OR could these data be provided as a Literature review from open sources?***

A57. Literature review from open resources is not sufficient, bidders are to submit as close to possible the required documents for each respective product.

***Q58. Should we disregard Annex 9 that was sent earlier?***

A58. Yes, please disregard previous Annex 9.

***Q59. Uploading of technical documents- can we do this product by product or all products have to be done at one time?***

A59. You can download your proposal in the way that is more suitable for you, but please ensure that all documents were downloaded before the deadline.

***Q60. Is it compulsory to upload filled in annex 9a (with price offer) prior to uploading the technical documents?***

A60. Please note that Annex 9 and 9a should be submitted by email as per article 26 of Section 3: Data Sheet.

**Q61. Given that the award is by lot, how will individual orders be requested/issued, and what is the expected lead time from order placement to goods availability date (GAD)?**

A61. For each Lot (except Lot 2) we expect to sign 2-4 BPAs. Order will be placed based on a combination of several factors such as price, freight, lead time. As for GAD, you should specify your lead time for each item.

**Q62. Can the infusion solution be in PE bottles instead of bags for item 38 (Dextran 70, 6% in sodium chloride 0.9% in 500ml bottle + Infusion-giving set), 55 (Glucose, solution for infusion, 5% (iso-osmotic), 56, 57 (Hartmann's sol. (Ringer's lactate) intravenous infusion, 76 (Metronidazole, for intravenous infusion, 5mg/ml, 100-ml), 90, 91 (Sodium chloride 0.9% isotonic IV infusion in 1000ml bag + Infusion-giving set), 98 (Water for injection in 10ml)?**

A62. Ideally, we prefer bags, but in the absence of bags, the PE bottles will be considered.

**Q63. Pack size mentioned in above table for Bid item no 78 (Mifepristone 200mg + 4 misoprostol 200mcg tablets (blister)) is Pack of 30s however Sun Pharma offers Pack of 5 which comprises (1 mife+ 4 miso). Remaining all details are the same. Kindly clarify whether we can proceed with a pack of 5s?**

A63. Pack size has been modified in Annex 9. Technical Information and Price Bid Form and Annex 9a. Technical Information and Price Bid Form for Lot 2: Pharmaceuticals as per Amendment 3.

**Q64. As per Invitation To Bid (ITB) document, under Evaluation of Bids in section 5 : Evaluation criteria, we would like to know what is the "weighted score method" that are listed in point d. There are no details of the weighted score method. Kindly confirm how can we determine this score?**

A64. Price calculation will be done applying a percentage calculated based on the structure of the previous spending for such components (and indicated in Annex 9). Technical compliant proposals that will receive the lowest cumulative financial score will be recommended for contract award. For details, please refer to Section 5 of ITB.

**Q65. For bid item no 78 i.e. "Mifepristone 200mg + 4 misoprostol 200mcg tablets (blister), pack of 30 (1mife + 4miso) tablets", kindly confirm if in-country registrations in target countries for UNFPA will help give our product a better score?**

A65. Technical evaluation will be conducted based on the pass/fail principle with no scoring. All items that fully meet the criteria will pass through technical evaluation. As for registration, in some cases, UNFPA may request such registration. It will be negotiated separately. There is a requirement in the bidding documents that you need to provide information about countries where medicine is registered, but we don't ask to proceed with any further registrations on this stage.

**Q66. For Annex 12--Part VII and Annex 14--Part IX, Commitment and authorization, there are two signature places. As we are a wholesaler, I want to ask which place should be signed by the manufacturer, and which by us (wholesaler)?**

A66. As for Annex 12, Section "VII-1 Commitment" should be signed by you as manufacturer and Section "Power of attorney" should be signed by manufacturer or by you (if you'll provide signed Power of attorney separately). Same for Annex 14.

**Q67. For Annex 18. Commitment and authorization letter template, I think this document can be taken as the Power of Attorney, am I right? If I am wrong, could you pls clarify that the Power of Attorney can be drafted in any format at submitter's own discretion?**

A67. Yes, Annex 18. Commitment and authorization letter templates can be taken as Power of Attorney.

**Q68. For Syringes luer sterile single use ( 275 - Syringe, luer, 10 ml, w/21G needle, sterile, single use, P100, 277 - Syringe, luer, 2 ml, w/21G needle, sterile, single use, P100, 283 - Syringe, luer, 5 ml, w/21G needle, sterile, single use, P100, 285 - Syringe, luer, 5ml, with needle, 23G, sterile, single use, P100, 287 - Syringe, luer, 5ml, with needle, 23G, sterile, single use, P1, 289 - Syringe, luer, 5ml, w/23G needle, sterile, single use, P25, 291 - Syringe, luer lock, 20 ml, sterile, single use, P1, 293 - Syringe, luer lock, 20ml, w/o needle, sterile, single use, P100, 297 - Syringe, luer, 10 ml, w/o needle, sterile, single use, P100, 299 - Syringe, luer, 1ml, w/o needle, sterile, single use, P100, 301 - Syringe, luer, 2ml, sterile, single use, P100, 303 - Syringe, luer, 5ml, sterile, single use, P100) – do you require conventional syringes or reuse prevention syringes?**

A68: Both conventional and reuse prevention are acceptable. However, from a technical aspect, reuse prevention is safer and preferred if the cost and availability are the same.

***Q69. Items 157 Safety box, disposal of used syringes & needles, 5L, P1 and 158 Safety box, disposal of used syringes & needles, 5L, P25, the technical specifications are the same. Is there any difference between these items? or is the same item being requested 2 times?***

A69. Technical specifications are the same, the difference is the pack size (pack of 1 for item 157 and pack of 25 for item 158).

***Q70. Items 189, 190, 191, the technical specifications are the same. Is there any difference between these items? or is the same item being requested 3 times? The same situation with 192 and 193; 194 and 195.***

A70. Technical specifications are the same, the difference is in the pack size: item 189 is in pack of 1, item 190 is in pack of 10 and item 191 in packs of 5. The same is applicable to items 192 and 193/194 and 195.

***Q71. For item 222, Infusion set, sterile, single use, P100. Our available package is a pack of 25 pcs. Can we provide 4 packages of 25 instead of 1 pack of 100?***

A71. The secondary package needs to be in pack of 100 as indicated in the ITB.

***Q72. Item 273 Syringe, 0.5ml, with 0.01-ml increments - the above specification requires several 0.01ml graduation lines on the syringe, our syringe has only 2 graduation lines, i.e., the 0 mark and the 0.5ml mark. Kindly verify if this is acceptable.***

A72. It is acceptable.

***Q73. Can 3 parts syringes be offered instead of 2 parts syringes?***

A73. Yes, 3 parts syringes may be offered instead of 2 parts syringes.

***Q74. The requirements for the medical equipment are often pointing to specific models from specific manufacturers, which greatly limits the range of brands we can offer. Can you please indicate what is the tolerance to deviations from the given specifications?***

A74. Only limited deviations are allowed, this is usually in the range of +/- 3 % to max +/- 10%; to be reviewed and considered case by case.

***Q75. Certain specifications are pointing to obsolete technologies, and some are even posing a danger to patients. An example would be with item 393 (Forceps, uterine evacuation, ovum, Bierer, 33cm, jaws 19mm, L): it is risking patient care (say bed doesn't describe trolley with bassinet, etc) and also most importantly, recent medical studies***

***including FDA notices, warning against such portable heating pad uses. Please advise how you wish us to proceed in cases where requirements contradict best practices or fall short of latest knowledge and advancements on the topic.***

A75. The device specifications have been carefully reviewed and developed based on UNFPA and various UN agencies e.g. UNICEF, UNICAT, WHO, ICRC etc current items specifications. We recommend following the requirements as closely as possible. In cases where there might exist variations, this should be minimal and needs to be reviewed case by case.

***Q76. Among the documents for medical devices pictures of primary and secondary packaging are required. Could you please clarify if packaging artwork would be acceptable?***

A76. Yes, as long as the artwork is current and is a controlled document in the manufacturer's ISO 13485 quality management system.

***Q77. For injectable medicines, can you accept pre-filled syringes instead of ampoules or vials?***

A77. Unfortunately, not, only vials or ampoules are allowed at this stage.

***Q78. Shall we pay for softboxes when dispatching IARH Kits from stock?***

A78. Cost of Keep Cold boxes when required for shipment of kits must be included as cost of kitting services as per Annex 7.

***Q79. In the preparation of our bid, we observed a discrepancy in Annex 9 in relation to Lidocaine, item 70 and 71. In the price form and technical information form the strengths do not align.***

A79. Discrepancy in Annex 9. Technical Information and Price Bid Form in relation to Lidocaine, items 70 and 71 has been corrected in Amendment 3.

***Q80. Following up on my previous message, please note that a similar deviation applies for item 90 and 91.***

A80. Discrepancy in Annex 9. Technical Information and Price Bid Form in relation to Sodium chloride 0.9% isotonic IV infusion, items 90 and 91 has been corrected in Amendment 3.

***Q81. Annex 9, Bid no. 346 Haemoglobin photometer handheld w/accessories & 348 Capillary tubes for HemoCue Hb 301, P200. The products under the subject bid numbers are part of RH kit 12 Blood transfusion kit as per Annex 7 but are not highlighted by orange color as for the other components of the RH kit.***

A81. Both items have been highlighted in orange in Annex 9. Technical Information and Price Bid Form, tab 1. Product list - price form as per Amendment 3.

***Q82. Cloud submission: Please note that the storage capacity of the cloud used for document submission is 2GB. Documentation to be collected is heavy and we expect to exceed the 2GB allowed on the Dropbox. Can you increase the capacity, or should we request another link if required?***

A82. Storage capacity of the cloud used for document submission is broader than 2GB. In case you have any issue when uploading documentation above this threshold, contact [contract.pmdk@unfpa.org](mailto:contract.pmdk@unfpa.org).

***Q83. Bid No 239 is marked GREEN, meaning it should be both in IARH kits and other kits. However Item 239 is not in the IARH kit composition, but only in Other kits composition. Kit 7B includes Item 238, which we believe is a mistake since 50 pcs are required in kit 7B. It will make more sense to supply 2 x P25, instead of 50x P1. Can you please confirm that for Item No 8 in kit 7B, you require Bid No 239 instead of 238?***

A83. Item 8 in kit 7B has been modified to Bid Item No. 239 in Annex 9. Technical Information and Price Bid Form, tab 7. Price Kits IARH kits as per Amendment 3. As the item is now part of both IARH kits and Other kits, it remains marked green.

***Q84. Bid Item No. 142 COVERALLS\_L\_50, COVERALLS\_M\_50, COVERALLS\_XL\_50. We understood this item should be a SET of coveralls in size L, M & XL. Our question: is the SET consists of 1 pc of each size L, M & XL, or 50pcs of each size L, M & XL?***

A84: The set is composed by 1 piece of each size L, M and XL.

**Q85. Bid Item No. 526 Autoclave: in the specifications it states: "Capacity 28 L, 75 -200 L,110-880L available". Which capacity is required?**

A85. The internal chamber capacity is 28L. The bidders have the option to propose a different capacity within the available ranges, as long as it complies with the rest of technical specifications: stand alone table top, single door, power requirements 110- 220V / 50Hz-60Hz, etc.

**Q86. Annex 12 & Annex 1.3. It seems the majority of the contents in "Annex 13. Questionnaire for Electrical or Battery Operated Equipment" are identical to that already in the "Annex 12. Questionnaire for Medical Device/Equipment". Only 6 lines concerning lithium batteries in Annex 13 are not in Annex 12. Is it possible for UNFPA to consolidate the both Annexes into one document to avoid the unnecessary double work.**

A86. Please adhere to the requirements. Annex 12 "Questionnaire" has to be completed for Medical Device/Equipment and Annex 13 "Questionnaire" has to be completed for Electrical or Battery Operated Equipment

**Q87. CE certificate in transition period. If a manufacturer's CE certificate under Directive 93/42/EEC is recently expired (end 2022), but the manufacturer has signed an agreement with a notify body (NB) for conformity assessment on MDR(EU) 2017/745, can the products still be accepted by UNFPA for this tender? Due to the current bottleneck situation during MDD/MDR transition, the manufacturer has not or cannot get an extension for the previous CE certificate under Directive 93/42/EEC from their notify body. The new conformity assessment on MDR(EU) 2017/745 will take time. The concerned products belong to Class IIb.**

A87. Refer to the updated notices in relation to the transition to the new medical devices framework:

[https://health.ec.europa.eu/system/files/2023-01/mdr\\_proposal.pdf](https://health.ec.europa.eu/system/files/2023-01/mdr_proposal.pdf)

[https://health.ec.europa.eu/system/files/2023-01/mdr\\_proposal\\_factsheet\\_0.pdf](https://health.ec.europa.eu/system/files/2023-01/mdr_proposal_factsheet_0.pdf)

Article 1 of the Regulation (EU) 2017/745 is amended as follows: 'Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC as from 25 May 2017 that were valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the new dates (refer to the document) set out for the relevant risk class of the devices. Certificates shall be considered to be valid only if before the date of expiry of the certificate, the manufacturer

and a notified body have signed a written agreement in accordance of Annex VII for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device.

Whilst there is current constraint with limited capacity of notified bodies; there are certain conditions for extension to the validity of MDD certificate. The application of the extended transition period is subject to several cumulative conditions as specified by the EU Council notice 2023/0005 (COD) issued on 6.1.2023.

In order to qualify for UNFPA acceptance in this tender, the manufacturer is required to provide a justification letter describing the certification plan with major milestones and dates as agreed with their Notified Body, and detailed explanations how the extension conditions are met per the EU Council notice.

***Q88. Annex 9, bid no. 311. The requested product in the subject tender is Tourniquet, latex rubber, 75cm. Please confirm whether the bidder can instead quote for Tourniquet with closure polycotton, 42x2.5cm, 1 pce as it has better shelf life than the latex rubber product.***

A88. The material can be rubber latex, natural rubber, latex-free or other environmental sustainable option, the bidder have the option to propose the best technical option which complies with the rest of the technical specifications: solid or tubular, autoclavable at 121°C, reusable, non-sterile, length, width, inner and outer diameter. The proposal has to be justified and documented in its compliance with the technical requirements.

***Q89. Annex 9, Bid nos. 567 & 568. Frontal Flashlight & Torch Flashlight: the bidder proposes to quote for the product without batteries as upon award there might be issues while shipping due to IATA regulations. Please confirm, if acceptable.***

A89. Please adhere to the technical specifications for items 567 and 568. If IATA regulations do not allow shipping with batteries, these can be locally acquired by the Supplier at the country of destination.

***Q90. Are the ISO14001 and ISO50001 certifications both absolute requirements – or will you also consider bids from non-certified manufacturers? Are there any alternative standards or requirements you can accept instead? If both are absolute requirements - Do you also accept a letter from the manufacturer also for ISO50001 committing to being certified within 1 year from LTA award? Are these two ISO requirements specific***

***to this tender, or will you also include these requirements in all future tenders for medical devices & anatomical models?***

A90. Refer to Q45/A45 and Q13/A13.

ISO 14001 is required for the manufacturer (if available). Manufacturers are requested to provide proof of ISO 14001 (Environmental Standard) and ISO 50001 (Energy Standard) certification. If ISO 14001 and ISO 5001 are 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 and ISO 5001 certification process before the end of first year of LTA validity.

***Q91. Would you please confirm if ISO9001 certificate is mandatory for medical device manufacturers? Because normally some companies only have ISO13485 certificate, which is derived from ISO9001 system and is as an concrete quality management system specially applicable for medical device industry, while ISO9001 is for general industry.***

***I want to make sure if ISO9001 is the most basic certificate threshold to supply to all organizations under the United Nations, because we have cooperation with WHO and supply medical protective mask to them without ISO9001.***

A91. ISO 9001 is not a mandatory requirement for medical devices manufacturers as long as they have a valid ISO13485 certificate. ISO 9001 is preferable for the supplier.

***Q92. Bid no. 289: In Annex 9. Sheet 1. the item description of the product is “Syringe, luer, 5ml, w/23G needle, sterile, single use, P25”, but in Sheet 5. Specifications it is mentioned “secondary packing: 1 carton of 100 bi-packed syringes with needles”. As this is a kit item, and quantity required is 50 pieces, we assume the correct pack size is P25. Please confirm.***

A92. Adhere to the UNFPA detailed technical specifications requirements in sheet 5 “specifications MDs and IVDs”. The correct pack size is P25.

Technical Specifications of Bid Item No. 289 have been modified in Annex 9. Technical Information and Price Bid Form, tab 5. Specifications MDs and IVDs to correct secondary packaging to “Protective packaging - 1 carton of 25 bi-packed syringes with needles. Labelling same as per primary packaging”.

The following questions were received by UNFPA after April 21st, 2023 and will be addressed on Round 3 of Clarifications to be published in upcoming weeks:

*Q1. Annex 9: Tab 2. Technical Info Pharma. For the information under 8.2 Product related critical quality attributes, Describe & 8.3 Process related critical quality attributes, describe, could you please elaborate on the details requested. The bidder would be grateful if UNFPA could share an example of the information in 8.2 & 8.3 as required in Excel.*

*Q2. Annex 9: Tab 2. Technical Info Pharma. The bidder understands that for WHO prequalified or SRA approved product, the relevant information would be filled in where applicable as per the questionnaire and "Not applicable" would be updated wherever not applicable for e.g. 8.2, 8.3 and so on. Could you please confirm our understanding.*

*Q3. Annex 9, General. Is it permitted for a bidder to quote alternative primary packing material for suspensions i.e quote for HDPE bottle instead of glass bottle or vice versa.*

*Q4. Annex 9, General. For injectables requested in vial or ampoules, is the bidder permitted to select primary packing (USP type I/II/III) of their choice.*

*Q5. Annex 9, Bid no. 14. For the product Azithromycin dihydrate, 200mg base/ 5ml suspension, 15ml bottle: Will UNFPA accept product produced at a SRA approved manufacturing site however without a comparative dissolution profile.*

*Q6. Annex 9, Bid nos. 15 & 16. Benzathine benzylpenicillin, 1.44g (2.4 MIU) & Benzathine benzylpenicillin, 900mg (1.2 MIU) powder for Injection: Please confirm whether the volume of vial needed is 5ml or 16ml.*

*Q7. Annex 9, Bid no.19. Can the bidder offer the product Bupivacaine hydrochloride 0.5% injection in ampoule instead of requested packing in vials.*

*Q8. Annex 9, Bid no 21. Can the bidder offer the product Calcium gluconate 100mg base/ml injection in LDPE ampoule instead of the requested packing in Type I Ampoule.*

*Q9. Annex 9, Bid nos. 34. Clotrimazole 100mg vaginal tablet+applicator - Can the bidder offer the product in a pack of 6 tab blister as available in the UNFPA product catalog.*

*Q10. Annex 9, Bid no. 63. The bidder would be grateful to know whether license was required for the supply of product Ketamine hydrochloride, 50mg base/ml injection in 10ml vial, in destination countries where the product was supplied under the current LTA.*

*Q11. Annex 9, Bid no. 63 . It is noted that the product Ketamine hydrochloride, 50mg base/ml injection in 10ml vial, can be packed separately, however, could you confirm whether the product can be shipped separately to the destination countries.*

*Q12. Annex 9, Bid no 65. Can the bidder offer the product Lidocaine hydrochloride 1% injection in 10ml vials in polyethylene ampoule instead of the requested packing in Glass vials.*

*Q13. Annex 9, Bid no 71. Can the bidder offer the product Lidocaine hydrochloride 5% in 2 ml ampoule in polyethylene ampoule instead of the requested packing in Glass vials.*

*Q14. Annex 9, Bid no. 93. Due to the ongoing quality issues with the product Tetracycline hydrochloride eye ointment 1% in tube, can UNFPA allow the bidder to quote additional source in order to mitigate the risk of delay in supply. If yes, could you please provide an additional line to input the additional bid.*

*Q15. Bid No.565, Lot 4. Shoulder Bag - the link provided in the technical form for UNFPA's color shade of the logo is still not accessible; Error noted is as follows; request your kind support.*

*Q16. Annex 9, Sheet 9, Price DataLogger & ColdBoxes: Could you please confirm the specific requirements UNFPA has on the cool boxes? Parameters such as the cooling agent used, the minimum duration of cooling hours, and the requested size/s of box have a significant impact on their price.*

*Q17. Annex 3, Reference 1.4.12: Patient information leaflets and package inserts: "Validation of manufacturing process should be submitted for all parenteral products, suspensions, low dose products, modified release products Annex 3: WHO Good manufacturing practices: guidelines on validation "*

*As a part of the non-SRA questionnaire (Annex 11) only there is a table given wherein basic info on process validation is accommodated but there is no annexure requirement mentioned for process validation section. Please confirm if this information should also be provided as an annexure to the questionnaire even though this is not mentioned in the questionnaire annex list. Please also confirm that process validation table is applicable to non-SRA products only.*

*Q18. Bid no. 39 (Disinfectant tablets for water, 1.67g NaDCC, pack of 10 tablets):*

*o Please confirm that alternative pack sizes, e.g. pack of 200 tablets in a jar (bottle) pack, are acceptable.*

*o Please confirm if the strength of the product should be "167mg" rather than "1.67g"?*

*Q19. Bid no. 48, 49 (Ferrous salts/Folic Acid coated (60mg/0.4mg), Ferrous salts (60mg)): As there is no international comparator product listed under WHO recommended comparator products, shall we consider that In vitro and/or In vivo study is not applicable for these products?*

*Q20. Bid no. 85 (Paracetamol 500mg): Please confirm that pack of 1000 is acceptable as this is a multiple of the required quantity in the kits.*

*Q21. Bid no. 82 (Nifedipine immediate release): Would immediate release tablets be acceptable instead of capsules?*

*Q22. For the medical equipment it is no/not always clear which accessories are to be included in the standard configuration; these specifications provide a contradictory picture:*

*An example: Item 361 Ultrasound scanner. The specifications first state "System integrates: scanner, 2 probes, trolley & video-printer." Then it states: Supplied with:*

*1 x scanner, ultrasound portable system, main unit with accessories.*

*1 x standard electronic convex sector probe: frequency 3.5MHz, scanning angle 60°, radius 60mm*

*1 x ultrasonic gel 5-litre (supplied as one bottle or multiple).*

*1 x Instructions for assembly, use and maintenance in English, French and Spanish.*

*Here, the trolley and printer are not mentioned.*

*Then later it states: "Additional accessories must be made available at extra costs for orders from UNFPA:*

*1 convex abdominal probe, frequency range: 2.5/3.5/5.0MHz*

*1 convex transvaginal probe, frequency range: 4.5/6.5/8.0MHz*

*2 tubes of ultrasound gel, approx 350ml*

*1 set of spare fuses*

*1 digital B/W video printer with data connecting cable to ultrasound scanner:*

*Thermal printing head*

*1xPlastic protective dustcover*

*1 printer head cleaning sheet*

*1 set of 10 video printer paper rolls, length approx 20m*

*1 matching trolley:*

*1xInstructions for assembly, use & maintenance in English, French & Spanish*

*List of accessories/parts*

*Please confirm which is correct as this impacts both the configuration for the technical proposal and price proposal.*

*Q23. Items 407 and 408 : Forester sponge holding forceps. The name Forester seems like an old existing typing error, where Foerster was meant. Can we change this to Foerster? See also the Martin and/or Aesculap catalogue and the on-line ICRC supply catalogue*

*Q24. Item 514 : the models Schroeder-Braun and Duplay are specified. The reference number of Martin is for the Duplay model, so we assume Schroeder-Braun is not correct ?*

*Q25. Item 515 : this is for the Foerster forceps, but it is requested in a sterile state ? And single use and autoclavable seem contradictory. Which is correct ?*

*Q26. Technical requirements for medical devices – proof that the product has been sold to Europe or the US. In the pre-bid conference, in our recollection it was confirmed that a CE-certificate or USFDA-approval certificate would be sufficient; no proof of actual sales in these regions was required. In the minutes of the pre-bid though under Q8 it was however stated that evidence of supply in these regions had to be provided by means of an invoice.*

*If supply in the EU or US would be indeed a prerequisite, we would like to comment that this is a very sudden, unexpected decision with drastic implications. Please note that this would severely narrow down the scope of items that can be offered by bidders and that if offered this would drive up prices tremendously. Furthermore, this would also imply that all items that we have been supplying over the last 10 years from non-EU or non-US origin would no longer suffice.*

*Q27. For pharma products, in case the bidder has the available packs in bilingual labels, do they have to develop the entire pack in trilingual or the PIL in English/French/Spanish would suffice.*

*Q28. Annex 9, General. It is noticed that pack size requested by UNFPA in detailed technical specification do not always comply as per the kit quantities given. For example Bid no. 279, Syringe feeding catheter tip, 50ml sterile, P1- the required quantity of the product for kit 6B is 10 units whereas in detailed technical specification (tab 5), UNFPA mentions One (1) box of 20 feeding syringes. This is contradictory and such cases are noted for few other bid numbers as well. In such cases, it is ideal for the bidder to quote for a pack size based on the required kit quantity, could you confirm.*

*Q29. Annex 9, General. Could you advice on end destination country registration requirements for Medical devices, does UNFPA takes full responsibility for holding such local permits, registrations, licenses, authorizations, approvals, OR confirms that the supply of the Device is covered by an appropriate exemption or waiver.*

*Q30. Annex9, tab 7. In Annex 9, tab 7, For the MVA kitting service charges: the weighted scoring is not available, further the total kitting cost is not getting captured as there will be a change in quantity of the components. The bidder is asked to include the kitting cost and other ancillary cost, however it is not clear how the evaluation would be performed.*

*Q31. Annex9, tab 7. In the price request form tab 7, for the printed materials are included for some kits, however there is no possibility to include the cost, could you please check and advice.*

*Q32. Annex9, tab 7. In the price request form tab 7, the reconfiguration cost ( column I) is requested, however if inputted these costs do not get added to the total price in column J, please check and advice*

*Q33. Annex 9, tab 7, bid number 197. For Kit 2A, it is observed that total price formula seems to be incorrect for bid no. 197. The bidder hereby requests UNFPA to recheck the assigned formulae of Annex 9 and share the revised annex.*

*Q34. Annex 9, Bid no. 193. Blood bag+CPDA-1 (citrate-phosphate-dextrose-adenine), 350ml is part of RH kit as well as medical supplies lot3 and is requested under 2 different bid nos.192 & 193. However in the tab 7, UNFPA mentions the product and quantity under bid no. 192 and does not include 193. Please advice.*

*Q35. Annex 9, Bid no. 239. UNFPA puts Bid no. 239 Adhesive bandage, wound plaster, waterproof in both RH Kits + Other kits. However we couldn't find it in any of the RH kits. But it could be seen in Other kits (Contraceptive Implant Insertion and Removal kit). So, UNFPA to confirm if it is part of RH kit and if so, to provide the kit name & qty*

*Q36. Annex 9, Bid no 154. For Bid 154\_ Non-pneumatic anti-shock garment, In technical specification of Annex 9, packaging is requested as "Three NASG, one of each size, packaged individually with full instructions in English, French and Spanish", please find questions as follows: -Does this mean one piece of either size (small, medium/large) to be packed together and offered as one pack? Or order will be placed as per individual sizes. -Generally, it is observed that the medium / large garment size accommodates many medium to very large women. Is this acceptable to UNFPA that the bidder quotes alternatively only for the pack as per 2 NASG comprising of small and medium/large?*

*Q37. Annex 9, Bid no 174. UNFPA Short item description is Catheter, urethral, CH12, sterile, P1, whereas Detailed Technical Specifications (Annex 9) specifies Nelaton catheter details. kindly clarify if requirement is of Foley urethral catheter or Nelaton catheter?*

*Additionally, the risk class specified in Annex 9 is Is, kindly confirm or should it be IIA?*

*Q38. Annex 9, Bid no 340. For the product Draw sheet, plastic, 90 x 180cm, reusable, the technical specification as per Annex 9, states a thickness requirement of 10-20 microns, please*

*advice. - whether the requested product is for 100 microns. Kindly confirm. -Is the product required to withstand steam sterilization.*

*Q39. Annex 9, Bid no 359. For Thermometer, clinical, digital 32°C-43°C, P1, risk class specified in Annex 9. technical specification is mentioned as Im, kindly confirm Or should it be IIa?*

*Q40. Annex 9, Bid no. 360. For ARI Timer, safety and product standard requested is as per invitro diagnostic standards while the product is a medical device. The bidder requests UNFPA to check and confirm on the required standards. Additionally, the Risk class mentioned in technical specification is Class II, could you please reconfirm.*

*Q41. Annex 9, Bid no 371. For Clamp, umbilical, 5.2cm, sterile, single use, P1, risk class in Annex 9. technical specification is mentioned as IIa, kindly confirm Or should it be Is?*

*Q42. Annex 9, Bid no 444. Bid no. 444 Needle, scalp vein, butterfly, 25G, sterile, single use,P100, UNFPA Short description specifies pack size as 100pce whereas in UNFPA Detailed Technical Specifications (Annex 9), secondary packaging of 50 pce is required. Could you please confirm the pack size required?*

*Q43. Annex 9, Bid no 542. The product Syphilis Rapid Test, is IVD classified, however technical specification indicates it as "Classified under EU MDR 2017/745 as Class I device" whereas IVDD or IVDR classification should have been requested.*

*Also the list of standards compliance (IEC 61010-2-101:2002, IEC 61326-2-6:2005, IEC 62304:2006, IEC 62366:2007) requested is for electrical medical device whereas Syphilis Rapid Test, is a IVD device. Please rectify.*

*Q44.FOR SUPPLY OF PHARMACEUTICALS, MEDICAL DEVICES AND KITSIs it mandatory to submit a Certificate of Pharmaceutical Product (CPP) for each item against Lot 2 Pharmaceuticals at the time of tender submission, or is this only applicable for WHO pre-qualified/SRA specified items? Do we need to provide a statement if the CPP is not available, if so, could you please provide a template of this statement?*

*Q45. Could you please advise where the list of Expert Review Panel (ERP) recommended products is located, as per Annex 9, section 3.7 of the Technical Info Pharma tab?*

*Q46. If we request the link to upload technical documents to the cloud, at what point will this be reviewed?*

*Q47. Is it mandatory to submit details on Annex 10 as some information can't be confirmed until order confirmation, please advise if we have to add any statement in the field if information is tbc or not available?*

*Q48. Is it mandatory to populate the following fields in annex 9 for Lot 1/2 [CPP, Active Pharmaceutical Ingredient (API) Annex K - P2, Status of Finished Pharmaceutical Product (FPP) Annex Q, Validation of Analytical methods – FPP Annex R – S, Process validation and sterilization methods Annex T – U, Safety & Efficacy and/or Therapeutic Equivalence Annex Z – AD] as some of this information is unavailable until we place orders. Please advise if we have to add any statement in the field if information is tbc or not available?*

*Q49. Is it mandatory to submit a certificate of analysis for the three last batches released, in case of unavailability please confirm?*

*Q50. Please provide artwork for items 590, 591.*

*Q51. Annex 9, tab Technical Information Medical Devices, Point 1.3. Date of Last inspection manufacturer is requested, could you please elaborate on the requirement?*

*Q52. Can you share the weights and dimensions for medical kits used in the past?*

*Q53. On the other hand, as manufacturers, we would like to participate with both the lot 2 and the lot 4. Is there any way we can understand the different prices offered for the same product in the different lots?*

*Q54. If item M is present in 2 or more kits simultaneously (e.g., kits A and B), can we offer item M from manufacturer XYZ for kit A and item M from manufacturer UVW for kit B? In other words, can we have different manufacturers for the same item which is present in several kits at the same time? If it is allowed, how should we reflect this in the template?*

*Q55. Can we offer different manufacturers for the items which are loose and items under the kit? For example, Item X (loose item)- We offer A Manufacturer and Item X (under a kit)-We offer B manufacturer. If it is allowed, how should we reflect this in the template?*

*Q56. Annex 9, Bid No. 107 and 109. The item Resuscitator is requested with Guedel airways as an accessory. The bidder requests confirmation on whether the Guedel airways can be provided as non-Sterile.*

*Q57. Annex 9, Bid No. 550. Pregnancy Test, Strips: Product is IVDD classified, however, in the UNFPA requested technical specifications compliance to standards for medical electrical equipment is requested which seems to be inappropriate. Please clarify.*

*Q58. Annex 9 LOT 4: Bid no. 346 (Haemoglobin photometer handheld w/accessories). 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.*

*Q59. For item 221-223 (Infusion set, sterile, single use), Infusion sets sterile single use items – could you please clarify if whether vented or non-vented infusion sets are preferred?*

*Q60. General Lot 3, Bid nos. 189-195 (Blood bag+CPDA-1 (citrate-phosphate-dextrose-adenine), 250ml, 350ml and 450ml. 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".*

*Q61. Lot 5 Bid No. 261, 262, 263, 264, 265 (Suture, absorbable, DEC 1.5 /2 /3 /3.5 and 4, with needle, fistula repair). The requirement on the Needle length for suture is not clear. Could you please specify.*

*Q62. Annex 9, Bid no. 184. The product Gauze, compress, 10 x 10cm, is requested as non-sterile while bid form specifies a requirement of steam sterilization. Could you please clarify.*

*Q63. 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.*

*Q64. 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.*