



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 3

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.

A1. This covers process validation reports, protocols, manufacturing processes, flow charts etc. show that the 8.2 physical, microbial properties of the product as well as 8.3 different stages in the manufacturing process were considered, mixing media fill etc. have been considered.

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.

A2. Correct, the WHO PQ and SRA questionnaires require less information. Bidders should put N/A if the required information is not requested in the questionnaire but is on the technical info sheet.

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.

A3. Yes, alternative primary packaging can be submitted with the supporting documentation as stipulated in the questionnaire.

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

A4. In general we consider USP Type I and II glass primary packaging. This is product dependent, also on consideration to the manufacturing processes, i.e sterilisation methods requirements for each type of glass.

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

A5. Poorly soluble products e.g. Azithromycin require dissolution studies to ascertain the bioavailability of the product whether SRA or not.

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.

A6. 5ml or 10ml (if available) as long as the strength of the contents is the same as indicated in the technical specification.

Q7. Annex 9, Bid No. 19. Bupivacaine hydrochloride 0.5%, 20 ml, pack of 10, 20, 50 or 100 vials. Can the bidder offer the product in ampoule instead of the requested packing in vials.

A7. EML's primary container closer for bupivacaine 0.5% is a vial thus request bidders to follow those specifications, only in the absence of vials then we will consider ampoules.

Q8. Annex 9, Bid no 21. Calcium gluconate, 100mg base/ml injection, 10ml, pack of 10, 20 or 50 ampoules. Can the bidder offer the product in LDPE ampoule instead of the requested packing in Type I Ampoule.

A8. No, for Calcium gluconate UNFPA recements the glass primary container.

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

A9. Yes, Clotrimazole 100mg vaginal tablet+applicator packs of 6 is acceptable. Subcategory has been modified for this item to vaginal instead of oral as per Amendment 4.

Q10. Annex 9, Bid no. 63 Ketamine hydrochloride, 50mg base/ml injection in 10ml vial, pack of 1, 5 or 25 vials. The bidder would be grateful to know whether license was required for the supply of the product, in destination countries where the product was supplied under the current LTA.

A10. Import licensing is required for the Ketamine for several countries. The bidder should be in a position to support this when the product is procured from them.

Q11. Annex 9, Bid no. 63 Ketamine hydrochloride, 50mg base/ml injection in 10ml vial, pack of 1, 5 or 25 vials. It is noted that the product can be packed separately, however, could you confirm whether the product can be shipped separately to the destination countries.

A11. Yes, where cost-effective and when the agreement with all parties involved the Ketamine can be shipped separately, but if the bidder tends to supply it for the Lot 4 (kit 11B) it should be included in the kit.

Q12. Annex 9, Bid no 65 Lidocaine hydrochloride 1% injection in 10ml vial, pack of 20 vials. Can the bidder offer the product in a polyethylene ampoule instead of the requested packing in Glass vials.

A12. No, the recommended primary packaging for the lidocaine 10ml is a glass vial.

Q13. Annex 9, Bid no 71 Lidocaine hydrochloride 5% (50mg/ml) injection in 2ml ampoule, pack of 100 ampoules. Can the bidder offer the product in a polyethylene ampoule instead of the requested packing in Glass vials.

A13. No, the recommended primary packaging for the lidocaine 2ml is a glass vial.

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.

A14. Bid Item No. 93 Tetracycline hydrochloride eye ointment 1% in tube was cancelled as per Amendment 2.

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.

A15. Information on UNFPA logo and pantone colours provided in the following link: <https://www.unfpa.org/styleguide/components/palette.htm>. To access the link please use user name: unfpastyle, password: Every1counts!

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.

A16. Please refer to pre-bidding meeting #1 minutes, question 35.

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.

A17. The SRA questionnaire is an abbreviation of the IAFPPQ, with some criteria being waived, please submit supporting documents in accordance with the SRA questionnaire.

Q18. Bid No. 39 Disinfectant tablets for water, 1.67g NaDCC, pack of 10 tablets. Please confirm that alternative pack sizes, e.g. pack of 200 tablets in a jar (bottle) pack, are acceptable. Also if the strength of the product should be “167mg” rather than “1.67g”?

A18. NaDCC, strength is 1.67g and the 10, 100 or 200s pack sizes in a securitainer are permissible.

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?

A19. Comparative dissolution studies using any of the available SRA products is permitted.

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.

A20. We still recommend smaller quantities at this stage to support bulk and patient pack sizes. Please follow the technical requirements.

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

A21. Yes, nifedipine immediate-release tablets are also recommended as per specification.

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.

A22. About item 361, the system is supplied with 2 probes is correct. The printer and trolley are considered as “additional accessories”. In addition to the assembly/user

instruction, accessories/parts list needs to be provided as well. The assembly/user instruction and accessories list have been removed from “Additional accessories” list. We have made the necessary edits to Item 361 in Annex 9 as per Amendment 4.

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.

A23. There is a misspelling in the name of the inventor of the surgical instrument. The correct product description of the device is “Foerster sponge holding forceps”. Items 407 and 408 product descriptions have been corrected as per Amendment 4.

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?

A24. The correct name of item 514 is “Forceps, uterine, tenaculum, Duplay, 248 mm, curved”. UNFPA Item description and detailed technical specifications have been modified in Annex 9 as per Amendment 4.

Q25. Item 515 Forceps, sponge, Foerster, straight, 24 cm. This is for the Foerster forceps, but it is requested in a sterile state? And single use and autoclavable seem contradictory. Which is correct ?

A25. Item 515 is a reusable intended to be sterilised prior to use, autoclavable. Item 515 has been modified in Annex 9 as per Amendment 4.

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.

A26. CE marking or USFDA approval is a prerequisite to supply to UNFPA. CE certificate and US FDA approval 510(k) / PMA clearance are required. Items from non-EU or non-US origin may still be accepted if these had been CE marked or obtained the US FDA approval.

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.

A27. Priority is to have trilingual packaging, where possible to fit all three languages on the artworks, if that is not the case mono and bilingual may suffice with the PIL only being trilingual. Bidders should however note that some countries may strictly want their languages on the artworks.

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.

A28. Detailed Technical Specifications of Bid Item No. 279 have been modified to match kit 6B quantity. In cases where pack size of a kit component does not match required quantity of the product in the kit, bidder must quote for required kit quantity.

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

A29. There are many countries of destination, the bidder is responsible for managing the local permits, registrations, licences, authorizations, and approvals required and/or issued by the National Regulatory Authority of each country. UNFPA will not take responsibility for holding such local permits.

Q30. Annex 9, 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.

A30. MVA kitting services kit will not be considered for the financial evaluation.

Q31. Annex 9, tab 7. In the price request form tab 7, printed materials are included for some kits, however there is no possibility to include the cost, could you please check and advise.

A31. Price of printing materials in tab 7. Price Kits IARH kits can be added in column I. These lines have been unprotected in Annex 9 as per Amendment 4.

Q32. Annex 9, 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 advise.

A32. The cost of reconfiguration is not part of total kit price as it will be only applicable in exceptional cases when reconfiguration of the kit is required. This cost will not be considered for financial evaluation purposes.

Q33. Annex 9, tab 7, bid number 197. For Kit 2A, it is observed that a total price formula seems to be incorrect. The bidder hereby requests UNFPA to recheck the assigned formula and share the revised annex.

A33. Formula has been corrected in Annex 9.

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.

A34. Item 14 in kit 12 - Blood Transfusion has been modified to Bid Item No. 193 in Annex 9 as per Amendment 4.

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.

A35. Please refer to Round 2 of Clarifications, answer 83.

Q36. Annex 9, Bid no 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?

A36. One piece of each size (small, medium and large - 3 pieces) to be packed together and offered as one pack. Please adhere to the technical specifications for item 154, one package includes 3 NASG: one small, one medium and one 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?

A37. It is Nelaton catheter. Device class should be Ila.

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: 1) whether the requested product is for 100 microns. 2) Is the product required to withstand steam sterilization.

A38. Item 340 is a Reusable drawsheet. Specification the thickness should be 100 - 150 microns. It needs to withstand boiling and steam sterilisation, and resists 0.5% chlorine. Detailed Technical Specifications of Item 340 have been modified in Annex 9 as per Amendment 4.

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

A39. The correct risk classification for item 359 is Class IIa. Detailed Technical Specifications of Item 359 have been modified in Annex 9 as per Amendment 4.

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.

A40. The requested standard compliance for IVDs and electrical medical devices are not applicable for item 360. The correct risk classification is IIa "... for Vital physiological processes and parameters include, for example, respiration, heart rate, cerebral functions, blood gases, blood pressure and body temperature, medical devices intended to be used to obtain readings of vital physiological signals as part of routine checkups or self-monitoring are in class IIa". Detailed Technical Specifications of Item 360 have been modified in Annex 9 as per Amendment 4.

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?

A41. The correct risk classification for item 371 is Class Is. Detailed Technical Specifications of Item 371 have been modified in Annex 9 as per Amendment 4.

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?

A42. Secondary pack shall be 100 pcs. Detailed Technical Specifications of Item 444 have been modified in Annex 9 as per Amendment 4.

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.

A43. For item 542, the applicable legislation is IVDD (Directive 2017/745/EC on in vitro Diagnostic Medical Devices) and classified as IVD General.

The requested standard compliance for electrical medical devices (IEC 61010-2-101:2002), IEC 61326-2-6:2005, IEC 62304:2006, IEC 62366:2007) are not applicable for item 542 Syphilis Rapid Test. Detailed Technical Specifications of Item 542 have been modified in Annex 9 as per Amendment 4.

Q44. Is 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?

A44. Yes, CPP is mandatory for all pharmaceuticals, as it informs the legality to sell (import/export) the product. This is a prerequisite to approve a pharmaceutical product.

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?

A45. Megabid includes only ARVs (Dolutegravir, Abacavir/Lamivudine, Tenofovir/Lamivudin/Dolutegravir) that could be ERP-approved. The last ERP recommended products approval list is located [here](#) and will be considered by UNFPA. Please note that the list is continuously being updated.

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

A46. Revision of supporting documents will be reviewed at the technical evaluation stage, after bid opening.

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?

A47. The requested supporting documentation for annex 10 at this stage are for indicative requests in order to ascertain product quality. Requests such as latest COA, stability studies, release specifications etc. implies that the bidder should submit data that is available at the time of bidding, not the actual batch/ product being procured for the customer.

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?

A48. All products that are from an SRA source should be completed on Annex 10 QNR, all other items not from an SRA or WHO PQ source should be completed on Annex 11 QNR, and all supporting documentation per respective QNR should be followed.

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

A49. Yes, certificate of analysis of 3 batches is mandatory, if the COA of the last 3 batches is not available, then the most recent 3 batches will suffice. However if these are deemed outdated such communication will be sent to the bidder via assessment clarification rounds.

Q50. Annex 9, tab Technical Information Medical Devices, Point 1.3. Date of Last inspection manufacturer is requested, could you please elaborate on the requirement?

A50. The date of last inspection / audit by a Notified Body or a regulatory agency. It has been corrected in Annex 9 as per Amendment 4.

Q51. 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?

A51. It is possible to offer one alternative source for items highlighted in red in Lots 1 and 2, by including alternative sources in Annex 9 at the end of the tab 1. Product list - price form and tab 2. Technical Information Pharmaceuticals. For each product, only one price per manufacturing source can be proposed (one source, one price). For Lots 4 and 5, it is possible to propose one alternative source for any kit component included in these lots with a maximum of 5 items per Lot (five alternatives for items in Lot 4 and five alternatives for items Lot 5). Information about which manufacturing source will be used in each kit must be included in tab 1. Product list-price form, Column W - Bidder's comments.

Q52. 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?

A52. The Bidder is requested to provide a secondary source for the range of items highlighted in red in Tab 1 of Annex 9. For the rest of the items, the Bidder can offer 1 (one) alternative per item only if the Bidder bids for Lots 4 and/or 5.

In such cases, in Tab 1 of Annex 9 in the main rows (bid item ## 1-550), the Bidder needs to indicate the item you are quoting for lot 1 or lot 3 as a primary source. Maximum 1 (one) alternative can be added in the additional rows of Tab 1 of Annex 9 (starting from row #573), and in column 23, the Bidder needs to indicate for which Kits' Lot/s (Lots 4 and/or 5) these items are submitted.

In total 5 alternatives are allowed per each of the Kits Lot, except for those items where UNFPA requests a secondary source and which are indicated in red.

The Tabs 7-8 of Annex 9 for Kit's Lot are blocked for changes, so UNFPA will allocate the items to the correct Kit's Lot.

Q53. 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?

A53. The Bidder is requested to provide a secondary source for the range of items highlighted in red in Tab 1 of Annex 9. For the rest of the items, the Bidder can offer 1 (one) alternative per item only if the Bidder Bids for Lots 4 and/or 5.

In such cases, in Tab 1 of Annex 9 in the main rows (bid item ## 1-550), the Bidder needs to indicate the item you are quoting for lot 1 or lot 3 as a primary source. Maximum 1 (one) alternative can be added in the additional rows of Tab 1 of Annex 9 (starting from row #573), and in column 23, the Bidder needs to indicate for which Kits' Lot/s (Lots 4 and/or 5) these items are submitted.

In total 5 alternatives are allowed per each of the Kits Lot, except for those items where UNFPA requests a secondary source and which are indicated in red.

The Tabs 7-8 of Annex 9 for Kit's Lot are blocked for changes, so UNFPA will allocate the items to the correct Kit's Lot.

Q54. 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.

A54. The Guedel airways can be supplied non-sterile. For items 107 and 109, they are requested to be reusable and autoclavable (non-Sterile).

According to the specifications for the Guedel Airways Items 107 (child 7 - 30kg), 108 (neonate <7kg), 109 (adult >30kg) - the airway is "Portable, self-inflating, reusable. The resuscitator is autoclavable between 121°C and 134°C."

Detailed Technical Specifications of Items 107 and 109 have been modified in Annex 9 as per Amendment 4.

Q55. 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.

A55. The requested standards compliance for electrical medical devices (IEC 61010-2-101:2002, IEC 61326-2-6:2005, IEC 62304:2006, IEC 62366:2007) are not applicable for item 550 Pregnancy Test. Detailed Technical Specifications have been modified in Annex 9 as per Amendment 4.

Q56. 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.

A56. The accessories should be included as per indicated in the note (If any Accessories applicable, the requirements must be specified by suppliers whether they are included or not in the package).

Q57. For item 221-223 (Infusion set, sterile, single useI), Infusion sets sterile single use items – could you please clarify if whether vented or non-vented infusion sets are preferred?

A57. Both vented and non-vented will be needed, each type has its specific purpose. Open air inlet for glass bottle or rigid plastic container. Closed air inlet for plastic bag or pouch.

Q58. 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.

A58: The following needle lengths are recommended : 22 mm, 25 - 26 mm and 48mm.

Q59. 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.

A59. Item 184 is requested as non-sterile and single use. The sterilisation requirement is related to the initial sterilization method and is applicable only for items 185, 186 and 187 (sterile). Detailed Technical Specifications of Item 184 have been modified in Annex 9 as per Amendment 4.

Q60. 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.

A60. Both items 157, 158 are not medical devices. The applicable classification is the one specified for item 157, the risk classification corresponds to Class I “Devices intended to be used for a temporary containment or storage function, e.g. cups and spoons specifically intended for administering medicines , empty syringes without needles”.

Detailed Technical Specifications of Item 158 have been modified in Annex 9 as per Amendment 4.

Q61. 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.

A61. The following standards are not applicable for item 344 and have been removed from Detailed Technical Specifications in Annex 9 as per Amendment 4:

IEC 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 61326-2-6:2005 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

IEC 62304:2006 Medical device software - Software life-cycle processes

IEC 62366:2007 Medical devices - Application of usability engineering to medical devices

Q62. Some items are in many packages like items (174, 175, 176) in Annex 9:

- ***Item 174 catheter urinal ch12 sterile P1.***
- ***Item 175 catheter urinal ch12 sterile P10.***

- **Item 176 catheter urinal ch12 sterile P50**

These items we can put price for pcs in item 174 and price for 10 pcs in item 175, but item 176 not available in box of 50pcs. So we will put price for 5 box of 10pcs of the item 174. And when we deliver our item we will deliver 5box of 10pcs.

A62: Please stick to requirements. Box of 50 pieces must be quoted for item 176.

Q63. About two columns (suppliers sales pack size and supplier's sales pack size in number). We can't fill it for each item, but we can provide our samples for it all items when you order.

A63. Columns suppliers sales pack size and supplier's sales pack size in number must be completed. Samples are not required at the bidding stage.

Q64. About column of companies address also we can't write it for all items, but you can see it when we provide our samples, but we can write company address for machines not for disposable items.

A64. Columns of companies address must be completed. Samples are not required at the bidding stage.

Q65. What you mean in column (Bidder's price per UOM for delivery FCA close set port/airport palletized USD).

A65. Unit of measurement (UOM) refers to the one that is in direct contact with the product: tablet, caps, vial, amp, syringe, etc. Secondary packaging is the sale pack, usually cardboard boxes. The column Bidder's Price per UOM for delivery FCA closest port/airport PALLETIZED (USD) is removed with Amendment 4 and thus you need to quote only FCA Bidders Warehouse Price per UOM (tablet, caps, vial, amp, syringe, etc.) (USD).

Q66. We've recently received the WHO- Prequalification of our product Benzathine Benzylpenicillin. This product is identified for this tender and we were wondering if we'll be selected as preference supplier or not.

A66. WHO prequalified products are more often approved on the first round of technical evaluation without clarifications, but the evaluation process is both technical and financial and they will still need to pass financial evaluation.

Q67. During second pre-bid conference, I asked a couple of times about the possibility of offering different packs sizes for the same product (BPG).

I think is important to offer different alternatives as for the IARH-KIT 5 is interesting to offer our pack of 1 vial+ 1 water for injection solvent but for all the market outside these kits, a pack of 50 vials seems more interesting, so it is beyond my understanding that we are not allowed to offer two different packs. Could you please confirm?

Additionally, the language that we've been supplying is English/French. Due to the size of the pack itself, it is not possible to add any further language, however, being a Spanish pharmaceutical company, we could be offering our Spanish pack (1 vial+1ampoule). How should we detail this in the offer?

A67. Please note that for Benzathine benzylpenicillin, pack of 50 is already provided as an option. If pack sizes are specified in one line, you choose only one and submit your proposal only for one size. If it's specified as separate lines, you need to quote for all of them.

Regarding the language, yes it may not be possible to have trilingual on some items due to size, however the PIL should be trilingual. Also please note that some countries may require primary packaging in their language.

Q68. "Minimum of 70% of total list should be compliant, so the bidder could be considered eligible for this Lot", says Lot 1 and 3's requirement.

a. Does this 70% compliance apply to technical compliance only or to overall compliance (technical + supporting documentation such as ISOs, certifications, etc. + other)?.

b. If an item is partially compliant, is it treated as fully non-compliant for the sake of the requirement mentioned above? technical compliance.

c. There is no similar compliance requirement for Lots 4 and 5. The only coverage requirement for Lots 4 and 5 is as follows: "ALL the products in each kit should be offered, and ALL the... Kits should be quoted for". Nothing is mentioned about the compliance of the offered kits / items in the kits. However, these two lots consist of items from Lots 1 and 3 + other items. Hence, if the 70%

compliance requirement is met for both Lots 1 and 3 AND all kits are offered, should this be enough to qualify our kits as compliant?

A68. Answer provided during second pre-bid conference (Q6).

Q69. Q75 from the 2nd round of clarifications concerns "outdated" technical specifications. A75 mentions the following:

"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."

In case we offer an item with superior technical specifications with minimal deviations from the requested specifications as permitted by A75 above, will this item be considered fully compliant or not?

A69: If the technical specification offered for the MDs is equivalent or superior to the one requested in the bidding document, it will be considered as compliant. The superiority or equivalence or the technical specification offered must be documented and demonstrated in the technical proposal for full compliance.

Q70. For bid items no. 182 and 183, from our understanding, P10 and P20 in the short descriptions correspond with packs of 10 and 20. However, in detailed spec-s for both 182 and 183, the following is stated: "II closing clip by 20 pieces". Shouldn't item 182 be stating "II closing clip by 10 pieces"?

A70: Item 182 should be 10 pieces. Detailed Technical Specifications have been modified in Annex 9 as per Amendment 4.

Q71. For bid items no. 182 and 183, what is meant by "II closing clip" in "II closing clip by 20 pieces" in the detailed spec-s? Also, how many closing clips per pack of colostomy bags should be present? 1 clip per 10 pieces for items 182 and 1 clip per 20 pieces for item 183?

A71: The "Clip" in items 182 and 183 is a removable safety clamp. The symbol "II" has been removed from detailed Technical Specifications in Annex 9 as per Amendment 4. The number of clips provided should be the same as the number of bags.

Q72. For bid items no. 182 and 183, will activated carbon adsorption filter be accepted instead of Charcoal granulates filter? According to the manufacturer, activated carbon is better than charcoal granulates.

A72: Activated carbon filter is acceptable. Detailed technical specifications of items 182 and 183 have been modified in Annex 9 as per Amendment 4 to expand the options for filters.

Q73. Sterile MDs tab in Annex 19 doesn't include all the sterile items from the full list of items - is the rest of the items missing or are only these 25 items subject to special packing, storage, and transportation conditions?

A73. These are generic category of Medical Devices that are considered sterile and have special storage, and transportation conditions.

Q74. ISO 14001 is mandatory / has to be obtained at a later stage, according to previous clarifications, for all medical devices. However, item 323, for instance, does not ask for ISO 14001 in its detailed technical specifications on tab 5. Specifications MDs and IVDs of Annex 9. Does it mean that item 323 is exempt from ISO 14001 requirement? If yes, does the same kind of logic apply to all other items whose technical specifications do not mention the need for ISO 14001?

A74. Section 3.7 Environmental Management Systems in Annex 5. Technical Requirements for Medical Devices has been modified to clearly state that ISO 14001 and/or ISO 50001 is not mandatory, but preferable mainly for Class II devices and that manufacturers can also provide (instead of ISO 14001) waste management services contract, a formal plan for the management of waste, procedures for storage and disposal of MDs, procedures on waste management of the company, a declaration of the manufacturer that ensure that the packaging has at least one 25 or 30% recycled content / packing.

Item 323 is exempted from ISO 14001. If the bid item does not explicitly mention in the Technical Specification the request for the ISO 14001, it does not mean that the same kind of approach is applicable for all of the Medical Devices, as ISO 14001 and ISO 5001 are requested in Annex 5 Technical Requirements for Medical Devices, which means it is applicable for all of them.

Q75. Item 323 - the bowl is supposed to be plastic, but the following is requested in the detailed spec-s:

"Must comply with following standards ISO 7153-1:1991 Surgical instruments --Metallic materials --Part 1: Stainless steel".

Should this requirement be excluded from the detailed specs?

A75. Item 323 is Bowl, polypropylene, 6L. The material is polypropylene so reference to ISO 7153-1 has been removed and detailed technical specifications amended in Annex 9 as per Amendment 4.

Q76. Finally, detailed technical specifications of item 323 request CE Certification and ISO 13485. However, this item is below MD Class II which means it does not have CE Certification and ISO 13485. Hence, should these requirements be excluded from the detailed specs? Same question applies to all similar situations.

A76. CE Certification and ISO 13485 have been removed from detailed technical specifications in Annex 9 as per Amendment 4. However ISO 9001 if available will be an advantage.

Q77. It is still unclear what is meant by "1-4 specified above" for the MVA kit:

****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. There are 12 items in the kit, not 4. Or are the following 4 categories meant: silicone, cannulae, dilators, accessory?***

A77. Kit MVA kitting service consists of packing more than one item (from 2 to 4 items out of the 12 items specified in the kit components) into an individual bag as a kit.

Q78. A7 from the 2nd round of clarifications mentions the following:

"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." Do these "brief summary" and exemption rules apply to the MDR CE certification process or do they apply to this tender? In other words, if we have an MDR CE Certificate for an item that does NOT have a long history of use with proved efficiency, 1) do we still have to share its clinical studies with UNFPA, 2) do we still have to share a brief summary of its study outcome with UNFPA, 3) we don't have to share anything since MDR already covers clinical studies?

A78. The brief summary is only applicable for this tender. (1), (2) and (3) Please share only the conclusion of the clinical study outcome with UNFPA.

Q79. In bidding document Section 5.4 Technical Evaluation, it is stated that there is “No need to submit samples at the current stage.”, however in Annex 10 and 11, samples of products are requested in the questionnaire. Can you please confirm if we should provide samples or not? And if yes, where should they be delivered? What is the deadline for samples?

A79. Samples will be requested on items approved at the LTA agreement stage for sustainability reasons.

Q80. For items 38, 55, 56, 57, 90, 91. Is it acceptable for the giving set to be supplied separately from the infusion solution, rather than having both packed in the same secondary packaging.

A80. Yes, the giving sets may be supplied separately from the infusion solutions.

Q81. For item where the yearly requested quantity is extremely small, can an exception be made for the tri-lingual labelling that just English is on the package and a duo/trilingual PIL is provided either digitally or separately in the shipping carton for reference?

A81. Stick to requirements. The preference is trilingual, then bilingual then monolingual. If there are other bidders with multilingual artworks those will be prioritised over the monolingual.

Q82. In annex 9, tab 2 technical Info pharma, for all SRA approved, or WHO PQed product, is it only necessary to complete the columns where the heading is marked in red? Or should all columns still need to be completed regardless of the quality level of the product?

A82. Please complete the form as per the SRA questionnaire requirements, and N/A for spaces where such information is not required from the questionnaire

Q83. Item 41, Dolutegravir, 50mg, pack of 30 dispersible tablets, there is no WHO PQed dispersible option for Dolutegravir 50mg. Could you please confirm if film coated tablets can be accepted instead?

A83. Dolutegravir dispersible is the 10mg strength. For the 50mg strength, the film coated is what is requested.

Q84. Item 39, Disinfectant tablets for water, 1.67g NaDCC, pack of 10 tablets, is not classified as a pharmaceutical as it is used for water purification. Could you please clarify if the standard technical documents for pharmaceuticals still apply for this product? If not, what should we provide instead?

A84. General documentation pertaining to product properties such as: registration/ right to sell, GMP, product specification, stability studies will still be required etc Information pertaining to pharmacological actions such as Bioequivalence etc, are not a requirement.

Q85. Bid item no. 520. The UNFPA item description states: "Electrocardiograph with 12 channels" which would indicate an ECG with 12 channels, however at the same time the detailed specifications state: "Minimum of 3 recording channels" which would also allow a 3 channel ECG, similar to item 517. Please confirm whether for item 520 a 3 channel (or more) suffices or whether you would like to receive an offer for a 12 channel.

A85: For item 520 Electrocardiograph with 12 channels it is requested an Electrocardiograph (ECG) digital monitor and recorder, 12-leads detection, multi-channel recording. For recording and printing it is required to have at least: three (3) or more recording channels simultaneously.

For item 517 ECG Recorder,portable,w/access it is requested an Electrocardiograph (ECG) digital monitor and recorder, 12-leads detection, multi-channel recording, portable. For recording and printing, it is required to have a minimum of 3 recording channels simultaneously.

For both cases item 520 and 517 it is requested to have 12-leads detection and for recording and printing at least 3 recording channels simultaneously, the only difference is that item 517 is a portable ECG. For items 520 and 517, a 3 channel ECG is not acceptable.

Detailed technical specifications have been amended accordingly in Annex 9 as per Amendment 4.

Q86. Bid item no. 119. The specification refers to the IBP functionality, but no consumables are listed. Is this option required? If so, please confirm type and number of consumables to be supplied.

A86: The IBP accessories are optional hence not listed. However the offer might include the accessories / consumables for the initial tests of the device, i.e.. Blood pressure invasive sensor according to the channels included in the offer.

Q87. Pharmaceuticals, SRA v. NON-SRA. Section 1.1 of Annex 3 states the following on eligibility: Only products approved by a Stringent Regulatory Authority (SRA) for sales within the country of the SRA itself, products that are approved by WHO Prequalified (PQ)/ recommended by the Expert Review Panel (ERP) and/or products that are approved by a National Regulatory Agency are eligible for this bid (as defined below by product). The logical interpretation of this section would thus be that non-SRA is allowed for all products (except for the items that fall under the WHO PQ Scheme as is referred to in the following paragraph.

However, in clarifications round 2, as a response to question 3, UNFPA confirms the following: 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.

This would imply that NDRA-approval is not sufficient and all products should be SRA which would thus be in contradiction to Annex3, section 1.1 and the fact that there is an IPPQ (Annex 11) for non-SRA products.

Please urgently provide us with your explicit answer, whereby we would like to mention that if SRA would now become the new standard, an extension of the deadline is unavoidable as for a range of items we, but we assume other participants as well would have to restart sourcing.

A87. The emphasis is on GMP certificates, the product does not have to be from an SRA source, however, the GMP certificate should be from an SRA or inspected by any of the interagency pharmacist group (IAPG) inspectors. That is, the manufacturer of the MNRA should have been GMP inspected by WHO PQ, any of the SRAs or IAPG inspectors.

Q88. Following our review of the further clarifications posted, we had a further follow up query related to Q7 and the answer provided by yourselves (see below). When you refer to evidence of clinical studies, are you referring to evidence of sufficient/adequate clinical data, in line with the MDR requirement?

“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.

A88. Please share only the conclusion of the study. In case the device has had a long history of use with proven efficacy, the clinical study may be exempted.

Q89. Item 222: Infusion set: the set does not specify the needle gauge: please confirm. Please also confirm that this needle size will also have to be delivered with the IV fluids.

A89: The components included in item 222 are: Tubing, Spike or perforator, Air inlet with air filter and protective cap., Drip-counting chamber, Flow regulator, Y-injection site, Luer-lock connection to vascular system. The supply does not include devices intended for invasive use.

Q90. 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?

A90. All products that are from an SRA source should be completed on Annex 10 QNR, all other items not from an SRA or WHO PQ source should be completed on Annex 11 QNR, and all supporting documentation per respective QNR should be followed.

Q91. Misoprostol, 200mcg, pack of 3 or 4 tablets - can we know the blisters and alternatively can we offered Jar pack?

A91. Both pack sizes are required in the kits as dosage of PPH can be 600mcg (pack size 3) or 800mcg, but (pack size 4). However, for medical abortion, we use pack size 4. In essence both pack sizes are needed. A new line has been added to tab 1 and 2 in Annex 9 as per Amendment 4 to allow bidding for both items.

Q92. Item#20 Bupivacaine - please clarify if the product requested is plain Bupivacaine 0.5% which normally comes in 20ml vials - or if the requested product is

Bupivacaine 0.5% + Dextrose 8% in 4ml amps. Also please re-confirm that requested qty remains 20 amps/vials per kit.

A92. Bid Item No. 20 is Bupivacaine + Glucose. UNFPA item description has been modified in Annex 9 as per Amendment 4.

Q93. ISO 50001 is not generally associated with manufacturers of medical devices & equipment and IVDs. Hence, making having ISO 50001 a mandatory requirement (be it during the submission stage or by the end of first year of the LTA validity) will immediately disqualify the majority of even top-tier high-quality manufacturers from this tender. This will result in offers that are compliant with ISO 50001 requirement but are not fully technically compliant and/or are of low quality. Therefore, can you please reconsider ISO 50001 requirement?

A93. Please refer to A77. Manufacturers are encouraged to work towards ISO 50001, even though presently it is not a compulsory compliance standard for the purpose of this bid exercise. However manufacturers must have ISO13485 certification as the basic requirement.

Q94. For CDP, is it mandatory for Comparator to be as per WHO list?

A94. No, UDFDA and other lists that can be validated may be used.

Q95. Please confirm the requirement of 3 lingual artworks are limited to IFU only or also for primary/secondary? also for SRA products? change in registered SRA artwork (specifically labels primary/secondary) will be difficult.

A95. It is applicable for all the products.

Q96. For product forms in ampules, do you also require 3-language marking? or it's good enough to have only English of the ampule and the rest (secondary package and PIL) in 3 languages? Not always we could put lots of text on the ampules.

A96. It is sufficient to have the 3-language marking on secondary packaging and PIL.

Q97. 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.

A97. The difference between these groups of items is the pack size. Detailed technical specifications of items 189, 190, 191, 192 y 194 have been corrected in Annex 9 as per Amendment 4.

The following questions are under discussion and will be addressed on Round 4 of Clarifications to be published in upcoming weeks:

Q1. Please provide artwork for items 590, 591.

Q2. Can you share the weights and dimensions for medical kits used in the past?

Q3. Annex 7 mentions “Two copies of the packing list in four languages shall be inserted in a self-adhesive plastic pouch firmly attached to the box and easily accessible”. Which 4 languages are meant? English, French, Spanish, and Arabic? Or there’s a typo and 3 languages (English, French, Spanish) are actually required?

Q4. Printing materials. Could you please indicate specifications (e.g. colour vs black & white, double sided printing yes/no, paper size & thickness) and quantities of the individual documentation files to be included as hardcopies in the kits? The Annex 8 only provides a link to the documents but not to the specifications and quantities.

Q5. We truly appreciate UNFPA's strive for thoroughness and evidence for the claims made and we would like to support this as much as possible. However, in all honesty, the number and type of documents requested, are not really in line with the value of the items and the relatively medium to low prospective procurement volume. Whereas for the pharmaceuticals most of the documents requested are related to the IPPQ and thereby quite common, for the medical devices a substantial part of the documents requested are not part of a common product file and apart from taking an enormous amount of time to gather and check the details, is now also leading to substantial push back from vendors. This effect is intensified by the fact that large parts of the information provided in Annex 12, but also Annex 10-11 for pharmaceuticals have to be copied into Annex 9 which is a duplication of efforts. Hereby we would like to kindly ask you to seriously consider narrowing down the type and number of documents to be provided with the bids (for most medical devices > 20).

Q6. Annex 8, the link provides details of the content required to be printed however does not detail the specifications like the paper size, color pantone code and so on. Could you please advice?

Q7. Would you please advise if the following documents should be translated into English, or we could apply with the original language (i.e. Ukrainian):

- 1. Certificate of Incorporation/Business Registration*
- 2. Tax Registration Certificate*
- 3. Copies of the audited financial statements*

Q8. In item number (205) gloves examination latex medium non-sterile in kit 6B.

We put this item price in product list price form in Box of 100pcs and in Kit 6B you order this item in pcs and system don't accept two units for the same item.

How we do? And are quantity for this item are true 300Box of 100pcs?

Q9. In your TAB3 (technical information form for the medical devices) point 5 you mention that we must put manufacture's product code for every item. Are you mean "code word" model number of device or batch no?

Q10. We would like to confirm if we should quote our prices inclusive of Freight charges, custom clearance or only the item price for the time being and later on the freight charges will be added in the Price mentioned in the bid.