

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 4

Q1. Please provide artwork for items 590, 591.

A1. The stickers include UNFPA logo which consists of two colour palettes. The primary colour palette is UNFPA Orange and UNFPA Blue.



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

A2. IARH kits estimated weights and dimensions:

IARH Kit		Total			Cold chain not required			Cold chain required		
		No. of boxes	Weight of boxes	Volume of boxes	No. of boxes	Weight of boxes	Volume of boxes	No. of boxes	Weight of boxes	Volume of boxes
Kit 0 - Comp. IARH Kit	Administration and Training	1	16,5	0,067						
Kit 1A	Male Condoms	1	6,6	0,032						
	Female Condoms	1	7	0,066						

IARH Kit		Total			Cold chain not required			Cold chain required		
		No. of boxes	Weight of boxes	Volume of boxes	No. of boxes	Weight of boxes	Volume of boxes	No. of boxes	Weight of boxes	Volume of boxes
Kit 2A	Clean Delivery Kits (Individual)	8	13	0,516						
Kit 2B	Clean Delivery Kits (Attendant)	1	16	0,077						
Kit 3	Post-Rape Treatment	1	12,8	0,082						
Kit 4	Oral and Injectable Contraceptives	1	16,6	0,101						
Kit 5	Treatment of STIs	2	49,0	0,230						
Kit 6A	Clinical Delivery Assistance - Midwifery Supplies; Reusable	2	40,0	0,303						
Kit 7A-Comp. IARH Kit	CC Kit 7A - Intrauterine Devices (IUD)	2	23	0,182						
Kit 6B	Clinical Delivery Assistance - Midwifery Supplies; Disposable	17	141,0	0,574	7	140	0,571	10	1	0,003
Kit 7B - Comp. IARH Kit	CC Kit 7B - Contraceptive Implant	1	17	0,122						
Kit 8	Management of Complications of Miscarriage and Abortion	5	88,5	0,449						

IARH Kit		Total			Cold chain not required			Cold chain required		
		No. of boxes	Weight of boxes	Volume of boxes	No. of boxes	Weight of boxes	Volume of boxes	No. of boxes	Weight of boxes	Volume of boxes
Kit 9	Repair of Cervical and Vaginal Tears	2	32,5	0,144						
Kit 10	Assisted Delivery with Vacuum Extraction	1	2,0	0,044						
Kit 11A	Obstetric Surgery and Severe Obstetric Complications; Reusable	1	10,5	0,081						
Kit 11B	Obstetric Surgery and Severe Obstetric Complications; Disposable	44	824,0	2,436	43	822	2,429	1	2	0,007
Kit 12	Blood Transfusion	3	34,0	0,221	2	33	0,202	1	1	0,019
Comp. IARH Kit	CC Kit Non-Pneumatic Anti-Shock Garment	1	5	0,0648						
Comp. IARH Kit	CC Kit Oxytocin	30	3	0,0193						
Comp. IARH Kit	CC Kit Mifepristone	1	5	0,0576						
Comp. IARH Kit	CC Kit Hand-Held Vacuum Assisted Delivery System	1	1	0,0304						

IARH Kit		Total			Cold chain not required			Cold chain required		
		No. of boxes	Weight of boxes	Volume of boxes	No. of boxes	Weight of boxes	Volume of boxes	No. of boxes	Weight of boxes	Volume of boxes
Comp. IARH Kit	CC Kit Chlorhexidine Di-gluconate	1	10	0,0648						
Comp. IARH Kit	CC Kit Misoprostol, 300 tabs	1	10	0,0193						
Comp. IARH Kit	CC Kit Medroxyprogesterone acetate (DMPA-SC)	1	8	0,0648						

Other medical kits estimated dimensions and weight:

Description	Nr of cartons	Length	Width	Height	KG
UNFPA IARH Fistula Repair Kit 1 RESERVED	1	0,4	0,3	0,3	6
UNFPA IARH Fistula Repair Kit 2 RESERVED	1	0,6	0,4	0,27	7
UNFPA IARH Midwifery kit - Equipment	1	0,6	0,4	0,27	19,6
UNFPA IARH Midwifery kit - Renewable	01.Лют	0,6	0,4	0,42	17
	02.Лют	0,6	0,4	0,42	19

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?

A3. English, French, Spanish, and Arabic are required languages.

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./ 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?

A4. Specifications of printing materials have been added to the bid documents as Annex 21 as per Amendment 5.

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).

A5. While we understand your perspective on the number and type of documents requested, we regret to inform you that at this time, we are unable to narrow down the documentation requirements as you have suggested. The current requirements have been carefully designed to ensure transparency, quality, and compliance with international standards.

We recognize that gathering and verifying the requested details for medical devices may require additional effort and time. However, it is crucial for us to have comprehensive information to evaluate the suitability and safety of the products being procured.

Regarding the duplication of efforts between Annexes, this is done to streamline the evaluation process.

We appreciate your understanding in this matter. Our goal is to ensure a fair and transparent procurement process while maintaining the necessary standards for evaluating bids. We encourage you to proceed with the submission of your bid, taking into account the current documentation requirements.

Q6. 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***

A6. While it is preferable to have these documents, you can submit copies in the original languages.

Q7. 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?

A7. Bid Item No. 205 Gloves, examination, latex, medium, non-sterile is included in Kit 6B in packs of 100. 300 units of this product are required in this kit, so it will include 3 packs of 100 pieces.

Q8. 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?

A8. Manufacturer's product code is a unique number issued by manufacturers to identify individual products. Normally, it is a series of numbers and letters.

Q9. 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.

A9. Bids must be quoted based on FCA Warehouse Incoterm.

Q10. We are only able to offer approx. 40 products for Lot 1 for pharmaceuticals products , could you please advise if its mandatory to bid 80 products .I understand we'll not be able to meet the requirement but just need to understand if it lead to disqualification.

A10. While we appreciate your efforts, we regret to inform you that it is mandatory to bid for the full requirement of 70 products as specified in the tender documentation. Failure to meet this requirement may result in disqualification of the bid.

If your company is a manufacturer, we suggest you quote for Lot 2 which does not have such a limit and includes the most demanding products.

Q11. On your Annex 9. Technical Information and Price Bid Form Columns E & F are asking for "Supplier's Sale Pack Size" and "Supplier's Sale Pack Size IN NUMBERS". Please clarify if you are asking for dimensions of the size of the package for shipping purposes or the quantity of Units/Items per "pack" (box, cartons, etc). I understand it is stating that the values should match Colum D, however when we put text in these columns the rest of the excel sheet doesn't recognize the value and so some of the cells become "!REF".

A11. In column E "Supplier's Sale Pack Size" we are asking for the description of the pack, including details of the UOM, and primary and secondary packaging. For example, 15 tablets in the blister, 2 blisters in the carton pack. If column D provides the required pack size or form of primary packaging, the proposed product should match it.

In column F "Pack Size IN NUMBERS", you must include the number of units per pack. You are not allowed to put any text in this column, only numbers. For example, in the case of the example "15 tablets in the blister, 2 blisters in the carton pack", the number "30" should be indicated.

Q12. Item 103, Incubator.

The packaging and labelling requirements state:

**Unit presentation 1 (one) Pump,suction,surgical,2 bottles,w/access
Symbols used according ISO 15223
CE mark and notified body number**

While it seems clear this was incorrectly copied from the line item for the suction pump, please clarify what this line should read if anything different than Unit presentation 1 (one) incubator, infant, automatic.

A12. UNFPA Detailed Technical Specifications of bid item No. 103 Incubator, Infant, automatic have been corrected as per Amendment 5.

Q13. Some of the detailed technical specifications mention the following sentence: "These technical specifications are generic and may vary depending on the selected Vendor". Does it mean that offering products with (slightly) different specifications under these circumstances is acceptable? And how will compliance be assessed in such a case?

A13. For Medical Devices, bidders have the opportunity to propose different technical solutions, as long as the proposals are technically equivalent or superior to the requirements specified in each technical specification, and comply with the Quality Management Standards and regulatory approvals for each product proposed, as well, and also falls under the various requirements as communicated with the Amendment 3: "Please note that limited deviations from medical equipment specifications are allowed in the range from +/- 3 % to max +/- 10%, to be considered on a case by case basis".

Q14. Are there any general requirements regarding shelf-life for non-pharma items? E.g., shelf-life of at least X% at the date of pick-up from the warehouse / delivery to the end destination OR shelf-life of at least Y months / years, etc.

A14: For Medical Devices such as: infusion sets, syringes, tape adhesive, it has been requested in the Technical Specification to add the expiration date and shelf life requirements, for other type of devices (mainly Class II) such as the Electrosurgical unit, it has been specified the warranty period. Please refer to the detail for each item in the column UNFPA Detailed Technical Specification - Annex 9.

Q15. "VII-2 Power of attorney" form in Annex 12 seems to be incomplete. Can you kindly provide an example of how it should look like when filled in? In addition, can you kindly confirm that this form has to be submitted only if we are submitting the power of attorney itself? And that it is not necessary to submit the power of attorney if we are already submitting Letter of Authorization ("VII-1 Commitment")?

A15. Basically what is required in VII-1: The bidder is committing that they will offer

UNFPA a product that was evaluated and approved based on country of origin, strength, indication etc. And in VII-2: The manufacturer is agreeing that the bidder is submitting the QNR to us and they need to attach agreement between the 2 parties (bidder and manufacturer) .VII- 1; commitment is mandatory, VII- 2: POA is only applicable if the QNR is submitted by the bidder and not the manufacturer.

Q16. Does item 323 really have to be classified as MD Class I?

A16: The device is confirmed to be classified under Class I.

Q17. For item 540, the product name is rapid test (colloidal gold), but the accessories required are for Elisa kits . The accessories requested: Coated well, Sample diluent, Conjugate, Conjugate Diluent, Anti-HIV-1 Positive Control, Anti-HIV-2 Positive Control, HIV-1 p24 Positive Control, Negative Control, Substrate Diluent, Substrate Concentrate, Wash Fluid. Could you please check once again the requested specifications and clarify because what is requested in 1 test seems to be 2 different methodologies.

A17. UNFPA Detailed Technical Specifications of bid item No. 540 Incubator, Infant, automatic have been corrected as per Amendment 5.

Q18. "Item #360, Timer, for respiration, ARI": The description references one particular model from one particular manufacturer that can be neither procured under conditions, suitable for the purposes of LTA, nor can it meet the outlined QA requirements. Please advise whether exclusion of this product from the kits that include it would invalidate our proposal for these kits.

A18: For the kits that include this type of device (bid item No. 360), the product has to be included within the kit; exclusion of it might invalidate the proposal.

Bidders can offer alternative technical solutions for this item, as long as the proposal is equivalent or superior in terms of the technical specifications, and it includes all the QMS and regulatory requirements specified in the technical specifications.

Q19. For item 93, Tetracycline hydrochloride eye-ointment 1% in tube of 5g, what will this item be replaced with?

A19. The item was cancelled with Amendment 3.

Q20. For item 80.1 and 80.2, would it be acceptable to submit 1 copy of Annex 10 for both products, or would 2 separate annex 10 be required?

A20. If it is the same product from the same manufacturer, then one submission is ok with all different annexures relevant for each respective pack size, as required by the questionnaire.

Q21. Could you please let us know when the forecast for 2023 will be shared?

A21. It is not finalized yet, and we hope to provide it by mid-July.

Q22. We faced an issue with Annex 11. In many places information could not be texted into the box, there are some mistakes in file structure. Would you please fix it and share the correct file?

A22. Correct file has been included in UNGM as per Amendment 5.

Q23. General, Form E. Section 3: Management structure and Key personnel, sub-heading 3.2 is blank. Could you please advise whether UNFPA desires to include a question.

A23. Please disregard point 3.2. No question to be added.

Q24. Form E:

- SECTION 1: Bidder's qualification, capacity and expertise

"Full organizational structure is shared by another file." Finanacial stability is stated in Form D. Should we double this information here?

A24.1. No need to repeat this information in such a case.

"Relevance of specialized knowledge and experience on similar engagements done in the past." This information is provided in Form D. Should we double it here again?

A24.2. No need to repeat this information in such a case.

“Quality assurance procedures and risk mitigation measures”. To which point this requirement refers? If to the production of pharmaceutical products, we count it will be very many and long documents.

A24.3. You can provide this information in the form of the narrative.

“Organization’s commitment to sustainability.” We share this information in Formal statement on sustainability. Should we double this information here again?

A24.4. No need to repeat this information in such a case.

- ***SECTION 2: Scope of Supply, Technical Specifications, and Related Services***

“A detailed description of how the Bidder will source, stock and deliver the required goods, keeping in mind the appropriateness to local conditions and project environment. Details how the different service elements shall be organized, controlled and delivered.” Please provide examples. Or could we state that everything will be done within GMP ?

A24.5. You can provide this information in the form of the narrative and support it with the relevant certificates.

- ***SECTION 3: Management Structure and Key Personnel***

“Include an organization chart for the management of the project describing the relationship of key positions and designations.[MA1] Provide a spreadsheet to show the activities of each personnel and the time allocated for his/her involvement.” This is the second time when in the same document its required Organization structure, which is required separately. Do we need to triple this information here? How do you imagine this? We have more than 1000 people working on our pharmaceutical plant. Everybody play its role in production of pharmaceuticals. Please provide examples and forms of the spreadsheet.

A24.6. No need to repeat this information in such a case. Organigramme could be presented not per staff

- ***Separately, please advise how to fill in this form. Should we input our answers just below each question?***

A24.7. Yes, that is correct.

Q25. As per Section 3, datasheet, clause 26, 10. instructions for bid submission (page 28), the file format of the documents to be submitted is Word, PDF, Excel or Powerpoint. Please note, however that for various documents only different formats are available and more as per common practice, such as JPEG or PNG. While assuming this is acceptable, we would like to ask you to please confirm.

A25. Yes, JPEG and PNG are acceptable formats.

Q26. Bid no. 20: Product Bupivacaine hydrochloride 0.5%, 4ml, pack of 10 or 20 ampoules is requested in pack of 10 or 20 ampoules. Can the bidder offer the same product in pack of 5 ampoules?

A26. Packs of 5s are allowed but 10s and 20s are preferred. UNFPA Item Description and Packaging modified in tab 1 and 2 as per Amendment 5.

Q27. Bid no. 80,1 & 80,2: In Annex 9_tab 7 price kits IARH kits, Misoprostol 200mcg, tablet is included in several kits. However, we notice different bid numbers are used for the product in tab 7. For example, it appears as bid no. 80 in kit 6B, bid no. 80,2 in kit 8, bid no. 80,1 in kit 11B. According to Amendment 4, bid no. 80,1 & 80,2 both are kit items, will it be possible to let the bidder decide which pack size should be used?

A27. Item No. 5 in Kit 6B and Item No. 1 in CC Kit Misoprotol 300 tabs has been modified to Bid Item No. 80.2. No changes can be made by bidders regarding the pack size of kit components without UNFPA authorization.

Q28. Annex 9, tab 9, ColdBox: In the questions and answers round 3, UNFPA replied to our question regarding the requirements of coolboxes. However, as we can see the answer provided only clarified the specifications of DATALOGGERS. Hence, we are resubmitting the question: 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.

A28. UNFPA has not prescribed specifications for cold boxes, IF the cold boxes duration of action is 120hrs, and can maintain 2-8 (cold temperatures throughout the

duration of action). Sizes will also depend on the consignment, we kindly request bidders to propose different sizes as this will also support different size consignments.

Q29. Bid no. 289: According to Amendment 3, the secondary packing of the product in the tab 5 specifications MDs and IVDs have been changed to "1 carton of 25 bi-packed syringes with needles". As of now, it still shows "1 carton of 100 bi-packed".

A29. UNFPA Detailed Technical Specifications of bid item No. 289 Syringe, luer, 5ml, w/23G needle, sterile, single use, P25 have been corrected as per Amendment 5.

Q30. Can you please confirm the strength of item 53 Gentian violet crystals USP, 25g, 250ml amber glass bottle, is indeed 25g not 2.5g?

Q30. This item is cancelled as per Amendment 5.

Q31. Kindly confirm that if CE certificate is expired, and a manufacturer is in the process of attaining one, the letter from a Notified Body will be enough to prove quality status. Can the new CE certificate be shared once it is received at a later stage?

A31: It is required to add to the offer Compliance to EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR) with a valid EC Certificate and Declaration of Conformity for the CE mark is applicable.

In this case, a letter from a Notified Body to prove quality can be added to the offer and for manufacturers which are supplying CE certificates under the MDD, a legalized declaration letter from the manufacturer that it is working towards compliance with MDR is required as well.

Additionally, the manufacturer shall submit objective evidence to demonstrate compliance with MDR within 1 year after supply awards have been given and signed. UNFPA reserves the right to change the probationary period of one year to an appropriate length of time which could be shorter than one year.

Q32. Item 314 Bag, urine, collecting, 2 litres, P1 - in the item description it is mentioned "pack of 10", please kindly confirm to what UoM we need to refer.

A32. Adhere to the UNFPA detailed technical specification for Medical Devices and IVDs - Annex 9: Packaging and labelling: "Ten (10) urine bags in a plastic bag Symbols used according ISO 15223". UNFPA Item Description modified to "Bag, urine, collecting, 2 litres, P10" as per Amendment 5.

Q33.189-is package of 1, 190 -package of 10 and 191- package of 5. Our manufacturer provides this item in Package of 1. Due to the vast number of items and time limitation, it is difficult to check with all the manufacturers at this stage whether they can customize the packaging according to the tender requests. Can we provide the prices like following: For example

Line 189- We provide P1 price

Line 190-We provide Price per 1 unit* 10

Line 191-We provide Price per 1 unit* 5

Same situation with item 192 and 193; and 194 and 195

A33. Please stick to requirements.

Q34. UNFPA requests to add datalogger to products such as diagnostic test kits, male/female condoms, lubricants, IUDs, clean delivery kits, etc. At the same time, it is proposed as general cargo in transport mode. The bidder would like to know whether the datalogger is a necessity especially for air shipments as some international air companies do not prefer to include dataloggers for general cargo.

A34. The inclusion of data loggers in shipments that go in general cargo is necessary in case of temperature extremes which may have an effect on the products and/or the sterile packaging in which they are kept. We are aware of carriers refusing to accept data loggers in general cargo and we are working on a long term resolution of this situation. However in the meantime this will be dealt with on a case by case basis.

Q35. Can we submit more than one pack sizes per item.

A35. Only if this in case of two separate items.

Q36. Item 522 - Automated external defibrillator system

The following accessories are requested however these are not part of an AED, but more of a semi-automatic defibrillator with AED function:

- ***Defibrillator with AED and External Pacemaker - 01 Adult with Built in***
- ***Patient cables - 01***
- ***ECG Rolls - 50***
- ***Adult SpO2 reusable Sensor - 01***
- ***Adult NIBP Cuff and Hose - 01***
- ***88 etCO2 Tubing (box of 20) - 01 box***

A36. UNFPA Detailed Technical Specifications of bid item No. 522 Automated external defibrillator system have been corrected as per Amendment 5.