



Pre-bid meeting #1 (UNFPA/DNK/ITB/23/003)

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

21 March 2023 14:00 CET

via Zoom

Minutes

Present	<ul style="list-style-type: none">● Yana Dovga, Contracting Analyst, Medkit & Pharma Team, UNFPA (Procurement part)● Lorraine Molepo, QA Associate, UNFPA (Technical part)
Other participants from UNFPA	<ul style="list-style-type: none">● Roberto Mena, Procurement Specialist, Head of Strategic Sourcing Team, Supply Chain Management Unit, UNFPA● Linda Serwaa, Head of Quality Assurance team, UNFPA● Maria Ruiz, Contracting Associate, UNFPA● Bagdagul Abdikarimova, Contracting Associate, UNFPA● Denys Shliapkin, Contracting Associate, UNFPA
	<p>The following participants in the call identified themselves:</p> <ul style="list-style-type: none">● Fitsum Asfaw, Wise Team FZC● Andrii Mashyna, Darnitsa Pharmaceutical Company (Ukraine)● Valentyn Olekhnovych-Kadlubyskyi, Darnitsa Pharmaceutical Company (Ukraine)● Sunday Agamah, Emzor Pharmaceuticals Industries Limited, Nigeria● Waqas Akhter, Mediland Pakistan Pvt Ltd● Tariq Mahmood, Mediland Pakistan Pvt Ltd● Arslan Zahid, Mediland Pakistan Pvt Ltd● Elodie Poulsen, Missionpharma

- Bo Birk, Missionpharma
- Lisa Heider, Missionpharma
- Rajesh Ramchandani, Missionpharma
- Agustín Travaini, Missionpharma
- Enrica Cosma, FAZZINI SRL Italy
- Shajan Kurumthodath, Kedrion S.p.A, Italy
- Guido Ranselaar, MEG, The Netherlands
- Astrid de Vries, MEG, The Netherlands
- Ayush Yagnik, Advanced MedTech Solutions Pvt. Limited
- Hardik Khodbhaya, Advanced MedTech Solutions India
- Nitin Ahluwalia, Advanced MedTech Solutions India
- Mark Gilmore, Aero Healthcare
- Reuben Gilmore, Aero Healthcare
- Matthew Gilmore, Aero Healthcare
- Hilco van Beekhuizen, IMRES B.V.
- Deborah Sloof, IMRES B.V.
- Lilian Darko, Durbin Plc
- Twinson, Qingdao LEFF International Tradding Co., Ltd
- Paul Turton, DHL Supply Chain
- Ben Dziczkaniece, Laerdal Medical AS
- Rajendra Prasad, United Poly Engineering Pvt. Ltd. India
- Umesh Adsule, Mylan (Viatris)
- Sachin Wankhede, Ciron Drugs and pharmaceuticals
- Dima Fares, RAMI KABALAN COMPANY
- Louise Macardle, Morningside Pharmaceuticals, UK
- Tom Elliott, Morningside Pharmaceuticals, UK
- Violet Ivanova, Morningside Pharmaceuticals, UK
- Ilir Ibraimi, Via Medica International Healthcare LLC
- Ritesh Nagpal, Eastern Surgical Company, India
- Suby Sanju, IDA Foundation
- Carrie, Well Lead
- Natalia Millán, Reig jofre (Spain)
- Simon Tong, China National Pharmaceutical Foreign Trade Corporation
- Tong Xinmeng, China National Pharmaceutical Foreign Trade Corporation
- Athira, HLL Lifecare Limited, India
- Orhan Tecirli, Ram Dis Ticaret A.S. Turkiye
- Lily Li, AMEX export-Import GMBH

	<ul style="list-style-type: none"> ● Danina Takaj, AMEX export-Import GMBH ● Margarita Postnikova, AMEX export-Import GMBH ● Neha Khan, Svizera Europe ● Willem Woudstra, Svizera Europe ● Laura Bleije, Svizera Europe ● Bouchra Kamil, Fleischhacker GmbH & Co. KG ● Zhengye Zhi SHANGHAI MEDICINES & HEALTH PRODUCTS I/E CO., LTD. ● June Nieman, Nova Strategic Alliance ● Anthony Ajose, Northumbria Pharma Ltd. ● Elvia Ramawy, Kalbe International Pte. Ltd. ● Rachel Sinambela, Kalbe International Pte Ltd ● Sandra Lequoy, Didactic ● Andrew McDowell, Durbin plc ● Avik Mukherjee, Durbin PLC ● Randa, Sayun Medical Company ● Giulia Tomelleri, Agmin Italy ● Zoe Chang, Beijing Shenhexin Ltd. ● Seamus McCauly, Innova ● Craig Schreiber, VIA MEDICA INTERNATIONAL HEALTHCARE ● Feroz Khan, VIA MEDICA INTERNATIONAL HEALTHCARE ● Kasia den Dijker, The Medical Export Group BV ● Hanan, Sayun Pharmaceutical and Medical Equipment
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Yana Dovga opened pre-bid meeting and welcomed participants. All participants were requested to indicate their names and the companies they represent. Yana provided information about the administrative part of the bidding process and relevant documents (Megabid Timelines, Structure of Bidding Document, Scope of Megabid, Other important conditions, Submission Requirements, LTA Conditions, and main details regarding Lots). All information provided by Yana is available in the bidding document posted on UNGM.

After Yana's presentation, Lorraine Molepo presented the technical part. Information about questionnaires and common mistakes was provided. The following mistakes were highlighted:

- Incomplete QNR completed
- QNR data not supported by corresponding Annexes
- Incorrect interpretation of an SRA - approved product (SRA - approved product usually confused with an SRA - inspected FPP manufacturing site, results in use of a wrong QNR)

- API and FPP cGMP certificates not included in the submission
- CoAs of the API analysed by both API and FPP manufacturer not provided
- Process validation data not provided and for sterile products media fill studies, sterilisation data also not provided.
- Use of incorrect reference products in BE studies or comparative dissolution studies (a generic product procured in an SRA is not a reference/ innovator product)
- Long-term stability studies should be specific for Zone IV. Studies should be done at the correct time points
- Storage conditions to be included in labels.
- Trilingual product information (labels, PI and PIL)

After presentations, participants were encouraged to ask questions related to the bidding process/documents.

Questions and answers:

Q1. Lots 1 and 3. We want to understand how a manufacturer can quote 80% of the items as they may not be manufacturing all.

A1. This requirement is related to Lots 1 and 3, where Bidders must quote for as many products as possible but not less than 80% of the total list. These lots are more designed for wholesalers.

That's the reason the threshold was included; because the majority of orders should be consolidated by wholesalers. To make sure that the orders can be consolidated and shipped within shorter lead times so to ensure a more optimal and cost-effective supply chain. Also, as for many country offices, it's quite a complicated procedure to get the "green light", to have the products shipped to the country. Requesting many "green lights" will only make the process longer. For medicines, which are very often shipped separately or there is high demand for these medicines, we have Lot 2, which is only for manufacturers.

If you, as a manufacturer, understand that you cannot bid for Lot 1 or Lot 3 we will suggest you find a partnership with one of the wholesalers who might bid for this tender and cooperate with them. So, the wholesaler will represent you, and they will work with you directly and will be consolidating orders for us.

Same logic as with kits. In most cases, countries order a combination of different kits. Shipping these kits separately will make the process longer and not cost-efficient.

Q2. Validity of Performance SECURITY: Is it forty-five days or 30 days?

A2. There are no requirements for performance security in the tender or BPA itself. Performance security may be requested for some particular order of high value or high risk if decided by UNFPA. During BPA implementation, the contractor(s) may be required (case-by-case basis, but not as a default) to submit a Performance Security (PS) within 7 (seven) working days from the receipt of the Purchase Order amounting to 10% of the value of the Purchase Order and shall be valid for thirty (30) days after the date of delivery of the PO.

Q3. As our company is a subsidiary of a group of companies (including the manufacturers), are we allowed to bid for pharmaceuticals from two companies?

A3. If you plan to submit a bid for the same lot/s from two entities that belong to the same group, we advise you to submit a request including information about (of group structure) to us via e-mail so we can advise you better. It is important to make sure that there are no circumstances that could potentially lead to an actual or perceived conflict of interest, collusion, or unfair competition practices.

Q4. May we know why oxytocin must be WHO PQ?

A4. Products that are subject to the WHO- prequalification programmes like hormonal contraceptives and priority maternal health medicines, will need to be supplied from a source that is either WHO-prequalified or SRA approved. Oxytocin belongs to the priority maternal health medicines.

Q5. What are the countries from which the companies can participate?

A5. We don't have any limitations regarding countries, but you should understand that orders will be shipped to multiple countries. If your country has any legal limitations for shipment to certain countries, you should inform us in your bid.

Q6. MegaBid Bidding Document - Section 5: Evaluation criteria.

We understand that each lot will be assessed and evaluated separately. Regarding bidders of Lot 4 - IARH Kits and CC Kits, PEP Kit, we understand that kit bidders must offer all items and all kits in Lot 4. However, please confirm that no preference will be given to kit bidders that bid for all other lots (i.e. Lot 1 - Pharmaceuticals, Lot 3 - MD,

Equipment and IVDs, and Lot 5 - Other Medical Kits) compared to kit bidders that do not bid for all other lots. This question is caused by the fact that in the previous RFP MegaBid from 2017, there was a preference given to kit suppliers that also offered other lots.

A6. We confirm that there are no preferences. Each Lot will be evaluated separately.

Q7. Could you please estimate where all the kits will be delivered and will they be required to be delivered to different cities in different countries ?

A7. We cannot provide this information as this tender is for BPAs with a duration of 3-5 years, and each supply depends on the humanitarian context in the specific countries. To get an understanding of total volumes you can be guided by Annex 1 and Annex 2 (to be shared at a later stage). Geographically, orders for the kits as for other products can be from any country globally.

Q8. MP: 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.

Please note Requirement of "proof of sales in Europe/USA" will have a significant impact in terms of price, lead time, and availability of the Medical Devices and the kits containing those Medical Devices.

A8. To confirm the approval to sell the product in the country, the CE and/or USFDA approval are required. To confirm evidence of sales of product Invoices of Sales should be provided or other relevant evidence of sale.

Q9. Annex 9a. Sheet 1. Product list-price form, column 13

"Multiple Order Quantity (for products ordered in pre-set multiple quantities) (based on Supplier's Sales Pack Size)"

Please comment how we should understand it and share example.

A9. Some suppliers require that certain products be ordered in pre-set multiple quantities. For example, if the multiple quantity is 100, the order must be for 100, 200, 300...If there's an order multiple, then the requestor should respect that and round up to the nearest order multiple.

Q10. Annex 9a. Sheet 1. Product list-price form, column 15

"Bidder's Price per UOM for delivery FCA closest port/airport PALLETIZED (USD) "

In Ukraine at the moment the closest port/airport is located in Poland or Romania. thus, FCA prices could not be calculated without the quantities. Please advise if this data is not obligatory to provide?

A10. FCA Warehouse prices will be used for the commercial and financial evaluation. "Bidder's Price per UOM for delivery FCA closest port/airport PALLETIZED" will be used as information purpose, but not for evaluation. With the war in Ukraine, please provide tentative prices for delivery FCA closest port/airport. If the situation changes, it'll be possible to revisit these prices. Usually, we order under FCA Bidders Warehouse conditions.

Q11. Annex 9a. Sheet 2. Technical Info Pharma

"4.1 Primary packaging label language (English/French, English or French, other - specify)" & "4.3 Secondary packaging label language (bilingual English/French, English, French. Multilingual - English/French/Spanish or other (specify))".

We are confused on these 2 points as they are conflicting with the requirements to Label, PIL/insert and package stated in Annex 6. Technical Requirements for packing, packaging, labelling, namely: English, French and Spanish.

Also, what we have to answer here if current labels and packages in Ukrainian and Russian; but trilingual will be done after contract award?

At the moment of bid submission we could present English version of the PIL/instruction for use.

A11. It's a mistake in the document. Everything should be read as English/French/Spanish. Bilingual options can be submitted, but it will be considered as last option.

The company will be allowed to add required languages after the contract award, but this information should be specified in the bid. In this case, it would be conditional approval. In case of no actions within 6 months, the approval will be recalled and this might lead to the termination of BPA.

Q12. Page 53, Bidding document, General Documentation to consider when preparing a submission for pharmaceuticals:

Are we allowed to present the photos for the product, its primary and secondary packages and labels only in Russian and/or Ukrainian language, exactly those that are registered in Ukraine?

At which moment should be presented the photos/artworks of the packages and labels in trilingual version (English/Spanish/French)?

Are we allowed to present only Russian/Ukrainian version at the moment of bid submission but together with the guarantee letter to prepare it and agree with UNFPA during several months after contract award, and in any case before placement of any purchase order?

A12. Everything should be in English/French/Spanish. Bilingual options can be submitted. Other additional languages are a bonus to the primary required languages.

All documentation that are submitted and not in English should be translated and verified by a certified translator

The company will be allowed to add required languages after the contract award, but this information should be specified in the bid. In this case, it would be conditional approval. In case of no actions, within 6 months, the approval will be recalled and this might lead to the termination of BPA.

Q13. If I understand correctly, for manufacturers 80% condition will not apply for the Lot #2.

Q13. If manufacturer submits bid for Lot 2, then yes. Each item will be evaluated separately.

Q14. Is the tender include Yemen?

A14. If the question is if items will be shipped to Yemen, it depends on humanitarian situation. Currently we are supplying product there.

Q15. Is ISO 13485 mandatory for distributors of Medical Devices too? We have currently ISO 9001 and are in the process of obtaining ISO 13485. We will only submit products from manufacturers with ISO 13485.

A15. ISO 13485 is mandatory for manufacturers and desirable (not mandatory) for distributors.

Q16. Section 5 Evaluation Criteria

Financial Standing

As we are participating in Lot 3, kindly confirm on the minimum annual sales turnover requirement of USD 12 million.

Is 12 million requirement is total of last 3 years or it is average of last 3 years (i.e. total 36 million).

A16. For all Lots average turnover for 3 years is specified.

Q17. We are LTA holder with other UN organization for Medical supplies requirement in Lot 3, does that give any advantage in Evaluation Criteria?

A17. No, it doesn't give you any advantage at the evaluation stage. All bids will be evaluated equally as per criteria elaborated in the Section 5 of ITB.

Q18. For Lot 2, apart from items in blue which must be WHO PREQ or SRA, can other products be as per country registration requirements?

A18. Yes, for other products the criterion is as following: 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).

Q19. Is the BPA per product or per lot?

A19. For Lots 1,3,4,5, it's per Lot. For Lot 2, it's per item. t.

Q20. Lot 3 - Medical devices. For electrical devices are both Annex 12 and Annex 13 to be filled in?

A20. Yes, both annexes to be filled, including one for compliance to electrical safety.

Q21. Also, for specifications, specifications are complected and not specific. So should we filled the file and provide in same file?

A21. If there are any specific comments, please address them to contract.pmdk@unfpa.org

Q22. Can you please provide with complete specifications in Medical devices for example suture specifications are incomplete as it should be specific to needle types...which is missing

A22. 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.

Q23. For Pharmaceutical - if all information provided in IPPQ or WHO /SRA Questionnaire do we still have to fill Annex 9 (2. Technical Info Pharma). Its duplication of information.

A23. Yes, you should provide these forms filled. It's very important for technical evaluation. Please note, the bid can be rejected if information will be provided not in line with requirements.

Q24. Can the deadline be extended to 4 weeks?

A24. If there is need for extension, please provide reasoning to us through e-mail. We'll analyze and provide feedback.

Q25. Do we need to have a local agent in each country of shipping?

A25. No, there is no need for this.

Q26. There is Requirement of Post market surveillance and Post market study. Can you elaborate on the difference?

A26. Post market surveillance test reports for the past 3 years with detailed assessment of monitoring the product is required for the study. Note that this is applicable to innovative devices and medium to high-risk devices.

Q27. Are both ISO 14001 and ISO 50001 mandatory for Bidder and Manufacturers? Is only ISO 14001 acceptable?

A27. ISO 14001 is obligatory.

Q28. Are suppliers allowed to have multiple FCA Points?

A28. Yes, it's possible. But it should be a reasonable number (not for each product separately). For example, two FCA points are ok. Because shipment from multiple points will be not cost-efficient .

Q29. Page 35 of the Bidding document: "Selected BPA holders may be requested by UNFPA to start registration process in the recipient countries". Please advise how it could be realized in fact? For example, UNFPA will ask BPA holder to start registration in 10 countries. The registration costs might be higher than the contract amount or profit from this deal. And registration time could take from 6 month to 2 years. Or UNFPA

will require only these registrations which are fast-track (within 1-2 months) and free of charge? In this case, we kindly ask to provide information in which cases UNFPA will request to start registrations? Please provide information on the list of countries for each product that requires registrations. At which stage this information could be disclosed? If at the time of signing BPA, and the BPA holder will refuse to sign it because of high cost of registrations, what will be the sanctions from UNFPA?

A29. It's not a requirement for each medicine. In some case, UNFPA may request such a registration. It will be negotiated separately. There is 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.

Q30. Is it possible that the same product from a manufacturer could be quoted by different wholesalers?

A30. Yes, there is no such limitation. Of course, for us, it would be better to have alternative option, but there are no preferences envisioned in the evaluation criteria. Please note that we request secondary sources for some items.

Q31. Page 52, Bidding document, General Documentation to consider when preparing a submission for pharmaceuticals: 6. recent as well as historical/acceptance letters issued by PQP/SRA in relation to the specific product dossier

7. Copy of relevant WHO prequalification acceptance letter signed by your company

8. WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product

Do we understand correct that the above documents are not required for the products non-WHO Prequalified/ERP/SRA approved?

A31. Yes, your understanding is correct.

Some questions were required additional time for answer. Such a questions were collected.

Questions and answers:

Q32. As a medical company we have number of items, so it is possible to participate with our items for lot 3?

A32. Please consider the 80% requirement for Lot 1: Pharmaceuticals and Lot 3: Medical Devices, Equipment and In-Vitro Diagnostics.

Q33. There's clarification needed in written statement, how it read as forty-five (30-days)

A33. There are no requirements for performance security in the tender or BPA itself. Performance security may be requested for some particular order of high value or high risk, if decided by UNFPA. During BPA implementation, the contractor(s) may be required (case-by-case basis, but not as a default) to submit a Performance Security (PS) within 7 (seven) working days from the receipt of the Purchase Order amounting to 10% of the value of the Purchase Order and shall be valid **for thirty (30) days** after the date of delivery of the PO.

Q34. For lot 3, what is the full meaning of DECA, DEC, Spool?

A34. For Lot 3, Medical devices, these terms are used as description for the products. As example: Suture, absorbable, DEC 3 (2-0), 1/2, 30mm, round, sterile, P36. Here, DEC 3 describes the characteristics in the sutures as coating, elasticity, diameter, ductility, among others.

Q35. Could you please share full characteristics and requirements for dataloggers? SINGLE USE OR MULTIPLE USE? Duration (number of recording days)? Register only temperature or humidity as well? Etc.

A35. WHO prequalified data loggers are used. Alternatively, the data logger must bear the CE mark

The following minimum parameters are recommended:

- a) Range: -30 °C to +70 °C (narrower ranges may be suitable for products that require cold storage condition and are transported in cold condition)
- b) Resolution: 0.1 °C
- c) Accuracy: ± 0.5 °C
- d) Levels of alarms: 2

- e) Battery life: minimum 1 year from the time of activation
- f) Data readout requirements: Interface with USB port, General purpose PC with Windows operating system
- g) Data read out capabilities: Report in PDF format, Charts of temperature profiling, calculation of Average and Mean Kinetic Temperature, Incidents and time duration of outside the set range with alarms
- h) Validity of calibration: minimum one year, traceable to National Standards
- i) Validity of usage of data logger: minimum 1 year from the time of usage
- j) Validity of Prequalification status: Valid at the time of start of the usage
- k) Data points: Minimum of 8000 time points readings
- l) Programmability: Programmable by user for temperature alarms, time intervals and expected time duration.
- m) Usability: UNFPA recommends one-time use.
- n) Disposition after use: The manufacturers' recommendation regarding the disposal of data loggers after use should be followed without conflict to the national regulations on disposal of electronic wastes.
- o) All data loggers to be included in consignments that are transported by air have to comply with the IATA Dangerous Goods Regulations.
- p) Other restricted materials: The product and its constituent components, including batteries, must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE)

Q36. In Annex 9 Technical 1.3 Date OF LAST INSPECTION MANUFACTURER is requested. It is not clear exactly what information is required.

A36. This refers to the date the site was last inspected for current Good Manufacturing Practices.

Q37. Are any of these items intended to be supplied for the Global Fund?

A37. Generally no, but in case Global Fund requests, the products could be supplied to Global Fund.

Q38. Annex 9. Technical Information and Price Bid Form (lots 1_3_4_5). Lot #21. Azithromycin, 250mg, pack of 4 or 6 tablets.

Is it allowed to offer capsules instead of tablets?

A38. No.

Q39. Annex 9. Technical Information and Price Bid Form (lots 1_3_4_5). Lot #62. Ibuprofen, 400mg, pack of 6, 10, 12, 15, 18, 20, 24, 30, 40, 50, 56, 60, 84 or 100.

Is it allowed to offer pack of 7 or 14 tablets?

A39. If the pack complies with the established requirements, yes.

Q40. Annex 9. Technical Information and Price Bid Form (lots 1_3_4_5). Lot #98. Water for injection in 10ml, pack of 20 or 50 plastic ampoules.

Is it allowed to offer the same product but in glass ampoules?

A40. No.

Meeting closed