



Pre-bid meeting #2 (UNFPA/DNK/ITB/23/003)

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

17 May 2023 13:00 CET

via Zoom

Minutes

Present	<ul style="list-style-type: none">● Yana Dovga, Contracting Analyst, Medkit & Pharma Team, UNFPA
Other participants from UNFPA	<ul style="list-style-type: none">● Linda Serwaa, Head of Quality Assurance team, UNFPA● Maria Ruiz, Contracting Associate, Medkit & Pharma Team, UNFPA● Bagdagul Abdikarimova, Contracting Associate, Medkit & Pharma Team, UNFPA● Denys Shliapkin, Contracting Associate, Medkit & Pharma Team, UNFPA● Margareth Charry, Quality Assurance team, UNFPA● Lan Hoon Seow, Quality Assurance team, UNFPA● Olga Maria Pineda Velaquez, Quality Assurance team, UNFPA
	<p>The following participants in the call identified themselves:</p> <ul style="list-style-type: none">● Sabrina Tariq -Morningside Pharmaceuticals Ltd● Mark Gilmore, Aero Healthcare Ltd● Guido Ranselaar, Medical Export Group● Sandra Gerstel, Medical Export Group● Adriaan Grijseels, Medical Export Group● Astrid de Vries, Medical Export Group● Hanson Wu, China Meheco● Elodie Poulsen, Missionpharma● Sophia Zhou, Missionpharma● Lisa Heider, Missionpharma A/S

	<ul style="list-style-type: none"> ● Willem Woudstra, Svizera Europe ● Salah Osman, International SOS ● Orhan Tecirli, Ram Dis Ticaret ● Bouchra Kamil, Fleischhacker ● Juliana Fransisca, Fleischhacker LLP Singapore ● Mireia Vargas, Barna Import Medica ● Margarita Postnikova, AMEX EXPORT IMPORT ● Andrii Mashyna, Darnitsa Pharmaceutical Company (Ukraine) ● Ashish.Kesharwani, Quality ● Amrta Bhat, Sun Pharmaceutical India ● Suby Sanju, IDA Foundation ● Andreas, Remedica Cyprus
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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 conference format and tender's updated timelines. Participants were reminded about the submission procedure. Yana highlighted the importance of usage updated Annex 9 (9a) for submission. Because of forms were updated.

After Yana's presentation, participants were encouraged to ask their questions related to the bidding process/documents.

Questions and answers:

Q1. As per Annexure 9a, in Technical information what exactly do we need to describe in Scope e.g. Production line?

A1. Please specify the capacity of your production line in this section.

Q2. Using Item 371 as an example, we would like to ask a question about alternative offers for items that are present not only in Lots 1 and 3, but also in Lots 4 and 5:

Item 371 is present in both Lots 3 and 4; in Lot 4, it is present in two different kits. Can we offer three different sources for Item 371: one for Lot 3 ("loose" items), another one for Kit 6B in Lot 4, and yet another one for Kit 11B in Lot 4??

A2. 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.

Q3. 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?

A3. Question and answer 75 are related to the medical devices. Please be guided by Amendment No. 3. There is a possible range of variations allowed for medical devices in it.

Q4. Manufacturers also can participate in Lot 1 or only Lot 2?

A4. Manufacturers can submit proposals for Lot 1 in case they are capable of providing proposal for 80% (or more) of the scope.

Q5. For OTC Product Like Povidone-Iodine and Gentian Violet, which Interagency FPPQA should be followed, same as Finished Product?

A5. Yes, correct. For this type of product, you should follow the questionnaire whether the product has the status of SRA-approved or WHO PQ. If not, you should use an extended questionnaire - Annex 11 and if yes, Annex 10.

Q6. Minimum of 70% of the total list should be compliant, so the bidder could be considered eligible for this Lot", says Lot 1 and 3's requirement.

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

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

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?

A6. 70% is related to technically compliant items (not quoted) including all supporting documents. During the technical evaluation, some products could receive the conditional awards with the necessity to provide additional documents at later stages, and conditional approvals will be included to the technically compliant for the purpose of 70% threshold calculation

As for Lots 4 and 5, all items and all kits should be quoted and at least 80% of items should be compliant. For the items that are compliant, the selected Bidders will need to resubmit the bid via further Limited Bid, which will also include the update of IARH kits composition as per the 7th kit edition.

Q7. 80% across all groups? Or per group?

A7. 80% of scope is related to Lots 1 and 3. Submitting proposals for each of these Lots should cover not less than 80% of the list.

Q8. Bid 344 Tile porcelain with Depressions of blood grouping. Is it MDR or IVDR or others please confirm?

A8. IVDR.

Q9. Regulatory Question: Request to clarify the scenario where the CE Certificate per MDD 93/42/EEC is expired recently and the MDR Application is submitted and still in progress. In such case can we submit the statement/proof of MDR conformity assessment application with the notified certification body as evidence and submit the valid MDR Certificate once available.

A9. Yes, you can. Also, please submit evidence that the manufacturer continues to meet MDR requirements.

Q10. Is it mandatory to submit a certificate of analysis for the three last batches released for MDs, in case of unavailability please confirm?

A10. We're assuming that question is related to medical devices. Yes, it's mandatory. If you can't provide certificates for the last ones, please provide the latest or, at least, last ones for devices within the same family.

Q12. For item 78 in Annexure 9 and 9a, what exact information is required in column AM and AV under scope. Also please confirm as manufacturer do we have to fill both Annexures 9 and 9a or only 9a?

A12. Please note that as stated in the Annex, AM relates to API production and AV to FPP production.

Q13. Where should manufacturers submit the Annex 17- sustainability questionnaire?

A13. This information should be submitted via cloud storage.

Q14. According to the Structure of Submission Folders in the tender document, UNFPA expects e.g. ISO13485 Certificate from the manufacturer should be put under each item Folder. If we (supplier) offer multiple products from the same manufacturer, is it possible to create a manufacturers folder for all the manufacturer-related certificates like ISO 9001, ISO 13485, or MAF ect.?

A14. It's easier to evaluate if all documents related to one medicine are in one folder, but it's not crucial if there will be separate folders for manufacturers. For us, the most important thing is to receive a full package of the documents.

Q15. Please advise is it mandatory to fill all required info on annexes 9 and 9a for Lot 1 & 2 (medicines)?

A15. Yes, all information should be provided. It will be used for technical evaluation. If it's not available due to some reasons, you should provide the relevant statement in the same annex 9/9a.

16. Is annex 9 technical info pharma required to be filled completely for SRA products? e.g. annex K - Active pharmaceutical ingredients

A16. Annex 9 should be filled for all pharmaceutical products. No matter SRA or non-SRA.

Q17. If a product is both SRA approved and WHO PQ approved, how should we fulfill the technical information?

A17. You need to provide the filled in Annex 10 and 9 plus the requested supporting document.

Q18. Is there anywhere we can find an indication of the expected Supply Price from your side?

A18. We can't provide such information. We will analyze the prices submitted through this process, compare with prices in the existing BPAs and with the market to ensure value for money is achieved.

Q19. Many contents in Annex 9 are repeating with that in Annex 12, which should be completed for all medical devices (either consumables, accessories, etc.) listed in Lot 3. Is there any possibility for UNFPA to simplify either Annex 9 or Annex 12 to avoid double work?

A19. Annexes were designed to simplify and speed up the evaluation stage. Unfortunately, we can't revisit them.

Q20. In Annex 1. Past procurement statistics, the total quantities in the file are calculated based on pack of 1, or multiple pack sizes?

A20. It was calculated based on the smallest primary package (pills, ampules, etc.).

Q21. In Annex 9a for lot 2 for manufacturers can we bid for another pack size than the one mentioned in Annex 9a for each product?

A21. We'd prefer to have packs as per options that are specified in the technical specification.

Q22. If multiple pack sizes are requested, should we quote for all? Can we add a new line?

A22. If it's 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.

Q23. But wouldn't it be limiting us the opportunity to quote different pack sizes (if we already have these packs and we've been supplying them for many years already?) I just don't understand the limitation.. (if you're already detailing the different requested pack sizes in the same line).. if we can offer two or three, why shouldn't we do it??

A23. Sizes of packs we have in the requirements are linked to treatment protocols and kits compositions. Thus, having different sizes in the catalogue will not be beneficial.

Q24. For pharmaceutical products, in lot 2 from where we can have an estimate of annual tender volumes?

A24. You can find past procurement in the Annex 1. We expect to have estimates for this year till the end of May. We'll share them as soon as available.

Q25. Will those volumes be published country wise?

A25. We hope we'll be able to share information country wise.

Some questions required additional time to answer. Such questions were collected and are registered below:

Q26. Could the Submission Deadline of 30 June be further Extended?

Q27. Misoprostol, 200mcg, pack of 3 or 4 tablets - can we know the blisters and alternatively can we offered Jar pack?

Q28. 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;.

Q29. 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?

Q30. For CDP, is it mandatory for Comparator to be as per WHO list?

Q31. 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.

Q32. 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

Q33. Some of the suppliers are yet to initiate working on complying to ISO14001 and are a bit hesitant to comply with the time bound (within a year of LTA) requirement by UNFPA as they are not sure they would be able to comply, what would be your advice.

Q34. 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.

Meeting closed