

PRE-BID MEETING CONFERENCE: -

Ref # UNDP-ITB-2021-004 – Supply of Medicines, Medical Equipment and Protective items.

09th March, 15.00 Nur-Sultan time zone.

UNDP representatives:

1. Ali Saeed, procurement Associate a.i
2. Zulfiya Suleimenova, Procurement specialist
3. Kamila Gaitova, project Manager
4. Konstantin Sokulskiy, GLD Head

Participants:

20 people from different international companies (the list of companies confirmed their participation is attached).

Questions raised during the meeting:

1. **Question #1:** As per RFP Page 24/45 Clause 7 " Each primary package shall contain a sticker in Kazakh and Russian languages with instructions for the use of the product(s)". Kindly advise if it will be acceptable to add a leaflet in the Kit box having instructions for use for each component of the Kit in Kazakh and Russian Language. Having a sticker on each primary pack is not feasible, especially in case of Pharmaceuticals it will require regulatory approvals which is a long process and hence will delay the delivery process.

Answer: Yes exactly, adding a sticker is considered a relabelling which is a GMP activity. Adding a leaflet/explanatory note in the kit is possible but this should be (ideally defined,) agreed and approved by KAZ MoH if it does not come as an exhaustive leaflet translation from the manufacturer.

2. **Question #2:** As per technical specifications, we are required to submit ISO9001 for the Masks whereas the ISO standard applicable for masks is 13485, kindly confirm that ISO 13485 will be acceptable.

Answer: Yes the ISO13485 + Declaration of Conformity are the required document to be submitted..

3. **Question #3:** As per section 5b, customs if needed shall be cleared by Bidder. If we read this point in conjunction with section 5a part 4, we understand that UNDP will help us get the necessary import permits and exemptions, its only the administrative part of the customs clearance which will be in our scope, please confirm.

Answer: UNDP will help get the necessary import permits and exemptions from Government Providing necessary documents. The administrative part of the customs clearance and inland transportation will be in the bidder's scope as DAP Delivery Terms.

4. **Question #4:** For the artwork to be pasted on the Kit packs, will UNDP provide a high-resolution file for us to use.

Answer: Yes, UNDP will provide the high resolution file of Art-Work for Packs/Boxes

5. **Question #5:** “For the Thermometer line as per ITB, the compliance against European standard EN 12470-3:2000+A1:2009 is required whereas the said EN standard is obsolete and the current standard for thermometers is ISO 80601-2-56:2017. Kindly confirm that the thermometer complying with the current standard ISO 80601-2-56:2017 are acceptable”

Answer: For the Thermometer line as per ITB, the compliance against standard ISO 80601-2-56:2017 is acceptable.

6. **Question #6:** If the company applies for Lot 1 and Lot 3 shall the bid security be 15,000 USD?

Answer: Yes, Lot 1 (10,000 USD), Lot 3 (5,000 USD), cumulatively the required Bid security shall be 15,000 USD.

7. **Question #7:** In the tender document, Kazakhstan is mentioned as a country of destination. Can any other countries apply?

Answer: Kazakhstan is delivery destination for these Goods. This is an open international bidding process in which any bidder outside Kazakhstan may apply

8. **Question #8:** Is it possible to change 80% ethanol to 75% ethanol of hand sanitizer?

Answer: Not allowed.

9. **Question #9:** Do international companies need to quote VAT?

Answer: No, VAT is applicable for local companies only because UNDP Kazakhstan obtain the VAT reimbursement from Government on quarterly basis. The International Bidders should quote without VAT.

10. **Question #10:** In Certificates and Licenses there are SRA and CPP required? Are they both mandatory or one of them is suffice?

Answer: Bidder may submit one of these documents. Either SRA or CPP or equivalent.

11. **Question #11:** Will UNDP be able to facilitate an appointment of local representative?

Answer: UNDP either will not appoint local representative nor facilitate the appointment. UNDP just will award the contract to a successful Bidder who is supposed to arrange delivery to UNDP Warehouse.

12. **Question #12:** If the company cannot use MSDS can the SDS be used instead?

Answer: The older MSDS formats could vary from source to source within a country depending on national requirements; however, the newer SDS format is internationally standardized and acceptable under this ITB.

13. **Question #13:** There is a minimum turnover requirement for each Lot. If we apply for Lot 1 and Lot 3 does it mean the minimum turnover must be increased?

Answer: Yes, the bidder must meet cumulative turnover requirement for Lot 1 and Lot 3. .

14. **Question #14:** Regarding thermometer shall it be IR or normal thermometer?

Answer: It shall be normal thermometer; no IR is required.

15. **Question #15:** Minimum 3 contracts/Purchase Orders (of Value USD 500,000 each or equivalent) for supply of similar nature and complexity in the last 5 years. Is it applicable to provide confirmation from same client in a same year to reach 500,000 USD?

Answer: Yes, bidder may submit those contracts/POs from same clients if they meet the \$ 500,000/- each. However, Bidder must provide Satisfactory Performance Certificates from three different clients for the reference checks.

16. **Question #16:** Three former similar contracts are required for each Lot. If the company applies for two Lots does it mean it has to provide 6 contracts?

Answer: No, 3 contracts remains but their value shall meet cumulative threshold of these two Lots.

17. **Question #17:** By similar experience what do you mean? Does it mean the company has to provide only contracts for thermometers or it can be related contracts, for example, laboratory equipment?

Answer: It can be any related medical equipment. Medical/ Laboratory equipment is acceptable.

18. **Question 18:** About the bid security , due to the bank inter applying process , we may receive the bid security document from our bank on 26-March , that is to say , we could not contain our copy of scanned bid security with the bid in the bidding system before the bid deadline. And the original document of the bid security need another 15 days to be sent to your Nur Sultan office by DHL which is about to arrive on 4-April. So is this will lead to disqualification of our bid ? We need to confirm this to decide whether we should go on this tender.

Answer: We are working with strict timeline. Keeping in view that 19th March 2021 is Friday and weekend ahead, UNDP may accept the original bid security to reach our office on **Monday 22nd March 2021**. However, UNDP will be unable to accept the bids without security, and 4th April date is quite late and will result into disqualification of the bid.

19. **Question 19:** About previous experience , we found that it is required to submit“Statement of Satisfactory Performance from the Top 3 – Clients in the past 5 years. Copies of 3 contracts/Purchase Orders” Does that mean we need to submit both the reference letters of Satisfactory Performance from the clients, and copies of contract as well ? And if our client is UN organization , we may not get the reference from them right now since we have not tried to ask the UN organization to write a reference letter before. Can we just provide the UN contract document and the UN contact person to you without reference letters of Satisfactory Performance ?

Answer: About previous experience, Bidder may submit copied of Contracts with UN Organizations clearly mention the Value/Type of Goods/contact details/email of UN Agency, UNDP will reach out and carry the performance reference checks from those UN organizations. For E-tendering bid submission, supplier may provide 3 Satisfactory Performance Certificates of their clients other than UN.

20. **Question 20:** confirmation about the bid security, if original of the Bid Security delivered to your address later than 19th is acceptable for you? because the estimated date of issuing the bid security from the bank is about 18th March, and it will need about 7 days express delivery date. Kindly note the bank issuing the security form usually need more than two weeks.

Answer: Since it is Friday on 19th March and keeping in view of Weekend ahead, we may allow bid security to reach till **Monday 22nd March 2021** COB. However, Bidder must upload scanned copy of Bid Security with E-tendering submission by 19th March 2021.

21. **Question 21:** In the FORM G, at first line UNDP Representative Account, which information should be filled? We cannot find the account contact information in the data sheet.

Answer: Yes, indeed there is no information there. Please use account information from the table below. The revised FORM G is uploaded with E-Tendering System.

USD account: KZ2483201D0500006013

KZT account: KZ2483201T0500006005

Kamila Gaitova

Zulfiya Suleimenova

Ali Saeed

Clarifications Received Before Pre-Bid Meeting

1. **Question #1:** For lot 1, what form of hand sanitizers is acceptable: liquid or gel?

Answer: Both forms are acceptable.

2. **Question #2:** For lot 2, Is standard ISO13485 also acceptable instead of ISO9001?

Answer: Yes, Certified quality management system for medical devices (e.g. ISO 13485) as Quality Management System from the manufacturer, for the PPE types is acceptable.

3. **Question #3:** Is it possible to waiver the bid security due to the high rates for logistic and other obstacles? Is advance payment acceptable?

Answer: UNDP cannot waive a Bid Security and Advance payments are not allowed. These tender terms are applicable to all the bidders who are interested to participate in bidding process.

4. **Question #4:** Is it possible to provide packing of 1000 tablets in HDPE bottle for ibuprofen 400 mg?

Answer: UNDP cannot allow packing of 1000 tablets in HDPE bottle, because this will be challenging to sort and pack the items further, as the requirement says 20 tablets per 1 kit.

5. **Question #5:** If a Bidder applies for several Lots in Options 2, is it necessary to submit company documents separately for each lot?

Answer: No, only one document submission.

6. **Question #6:** Is direct submission of tender **outside** of Kazakhstan possible or the company has to submit through a local representative?

Answer: Direct submission of tender **outside** of Kazakhstan is acceptable if it is satisfying with the ITB requirements.

7. **Question #7:** Is it a strong requirement to submit Bid through the local representative? If so, will submission of Manufacturer's Authorisation Form be sufficient?

Answer: It is not a strong requirement, direct submission of tender outside Kazakhstan is possible if it is satisfying with the ITB requirements. If Bidder is submitting a Bid on behalf of an entity located outside the country (which is possible), then Official appointment as local representative is required, a Manufacturer's Authorisation Form will be sufficient.

8. **Question #8:** If a Bidder applies only for Lots 1-3 (or one of them), does the company need to provide - Good Distribution Practice (GDP) and Medicines Regulatory Authority (SRA) (GDP/SRA are usually used for medicine)? Are there any other **local** (in Kazakhstan) **registration** documents required?

Answer: Not required as Good Distribution Practice (GDP) and Medicines Regulatory Authority (SRA) applies only for medicines. No other local registration documents required.

9. **Question #9:** The financial documents for 2020 will be available later this year. Could a Bidder provide the latest Audited Financial Statements for *year 2018 and 2019* (in Chinese)? Is English version for the Income Statement and Balance Sheet (the whole auditory report is very long) sufficient for your examination? And do you accept our translation or only Translation Company's documents?

Answer: In case there is no audited report for 2019-2020 available, it is possible to provide any document confirming company's financial stability (for example, Income Statement and Balance Sheet), but for 2017-18 and 2018-19 – audited reports are obligatory. The notarized English translation must be provided.

10. **Question #10:** In the selection of providers, does UNDP have preference for *local* provider or company with a local representative? Does UNDP have preference for a Bidder that applies for several items in Option2?

Answer: No preferences between national and international Bidders. UNDP will award a contract to the lowest-priced technically responsive bid under Option 1 which shall be the default option as it is a preference of UNDP to have the goods packed in kits by the bidder. However, UNDP reserves the right to award a contract based on Option 2 if:

- No responsive bids have been received for Option 1 or
- Price difference between the lowest-priced technically responsive bid under Option 1 exceeds 10% of total price of the lowest priced technically responsive bids for individual lots in the OPTION 2.

11. **Question #11:** Do products registered in China meet UNDP requirement? If don't, which country or certification institution will be acceptable?

Answer: The medicines (items 4 and 5) should be registered and marketed in one of the SRA (a stringent regulatory authority) countries at least. The List of Stringent Regulatory Authorities (SRAs) can be found on <https://www.who.int/medicines/regulation/sras/en/>. The other items must comply with the ITB requirements.

12. **Question #12:** Should all products be packed in paper box or plastic one? Are there any other requirements besides “duly sealed and protected from spoiling”?

Answer: Each kit should be packed in a separate carton box suitable for storing and transporting medicines and medical supplies. As for the rest packaging it is on Bidders discretion, but packaging must preserve quality, safety and stability of the product it contains. The entire package must be duly sealed and protected from spoiling.

13. **Question #13:** Should the instruction for use be in original language? Or it should be translated into Russian?

Answer: The instruction for use provided in the original language must be translated into Russian and Kazakh languages.

14. **Question #14:** After awarding the contract, the order should be issued with 145000 in one tranche, or in several tranches?

Answer: After contract award the PO for full quantity 145,000 will be issued.

15. **Question #15:** What information about local representative is required?

Answer: The requirements in ITB are equal for both international and national companies/local representatives.

16. **Question #16:** Does UNDP accepts two packages of 50 pc for masks instead of one package of 100 pc?

Answer: UNDP accepts 2 packs of masks per 50 pc, but in the price proposal the unit price must be given for 100 pc.

Kamila Gaitova

Zulfiya Suleimenova

Ali Saeed