

ITB UKR/2015/111

Procurement of anti-tuberculosis (TB) medicines

**Questions and answers including minutes of the pre-bidding conference held at UN Office on
December 14, 2015**

Dear Bidders, please pay attention to the following when submitting your bid:

- 1. The submission deadline is December 27, 2015, 23:59 Kyiv time.**
- 2. The bids are submitted electronically to the following e-mail address: tenders.ua@undp.org**
- 3. Please include a scanned copy of bid security (in the form of bank guarantee) when submitting your bid.**
- 4. IMPORTANT AMENDMENT TO THE SOLICITATION DOCUMENT. Lot 14: Presentation of product "Moxifloxacin" has been changed to "tabl., cap., pill". The changes are highlighted in red in the updated solicitation document.**

#	Question	Answer
1	According to cl. 26 (C.15.1) of Instructions to Bidders, the Bidder needs to provide a Valid Certificate of Authorization to act on behalf of the Manufacturer in case the bidder is not a Manufacturer. Please advise which document exactly needs to be provided (for example, a guarantee letter or any other document, please specify).	A valid Certificate of Authorization is an official document on the letterhead of the manufacturer, in which the manufacturer authorizes the Bidder to act on its behalf and to represent its products. The submitted certificate/letter of authorization should be valid at the time of Bid opening and during the entire contract implementation, if selected.
2	According to cl. 5 (C.20), bids can be submitted for separate Lots, in proportions of 25%, 75% and 100 %. Will a bid for 9% of quantity correspond to the requirements of ITB or will it be rejected?	The Bidders can provide the bids for separate lots in proportions of 25%, 75% and 100%. Bids for different proportions will be disqualified.
3	According to cl. 6 Section, products must have a minimum of 75% of the total product shelf life or should have 18 months shelf life remaining at the time of delivery. Will you consider a bid with the products having 12 months of shelf life at the time of delivery or will such bid be rejected?	According to the requirements of ITB, products must have a minimum of 75% of the total product shelf life or should have 18 months shelf life remaining at the time of delivery. Bids for the products that do not fulfill the minimum requirements of the shelf life will be disqualified.
4	Please explain will UNDP consider a bid as corresponding to ITB requirements in the part of product standards, in case the medicine is registered in Ukraine, manufactured at facilities in accordance with the latest Good Manufacturing Practice (GMP) Guidelines established by WHO or PIC/S, but at the same time not prequalified by WHO?	According to the Section 3a, Product Standards, the product(s) will be procured on the condition that they are either: a) Prequalified by WHO, or

		<p>b) Approved by a Stringent National Medicines Regulatory Authority (SRA) of Pharmaceutical Inspection Convention Scheme (PIC/S) countries, or</p> <p>c) Recommended by Expert Review Panel for The Global Fund, or</p> <p>d) Manufactured at sites with a GMP certificate provided by WHO or PIC/S authorities, or</p> <p>e) Registered in Ukraine and the supplier must have successfully completed at least one supply contract for this product in Ukraine within the past three years (since December 2012).</p> <p>Which means that the offered product shall meet at least one of the mentioned quality standards.</p>
5	<p>Please explain the following:</p> <p>Page 51 of ITB/UKR/2015/111 contains the product list. #14 in the table is Moxifloxacin amp., vial, syringe, 400 mg/ 283000</p> <p>The Decree of the Cabinet of Ministers of Ukraine #787 dd. 08.10.2015 states provides the list of products to be procured and it contains the following description:</p> <p>Moxifloxacin/ tablet/capsule/pill/400 mg/ 283214</p> <p>We assume there has been a technical mistake, since this products has never been procured in the form of a solution, only in tablet form. The treatment with this medicine is provided as outpatient treatment during long period of time.</p>	<p>In the requests received by UNDP from MOH in English, the form of presentation of Moxifloxacin was indicated as “ampule, vial, syringe”. After additional clarification MOH has confirmed that required form of presentation for Moxifloxacin is “tablet, capsule, pill, 400 mg”.</p> <p>Corresponding amendments have been made in the ITB (see attached). Amended document is also available at: http://procurement-notices.undp.org/view_notice.cfm?notice_id=27195</p>
6	<p>We have receive your tender notification, and would like to take part as a bidder. But, I have a question: If we don't have any agent in Ukrain, who can register the products on behalf of us, so, in such case, can we get any kind of help from UNDP in getting the product registered in Ukraine?</p> <p>All required documentation and fees will be submitted on time.</p>	<p>Registration of new products should be done through the agent/representative in Ukraine. Unfortunately, UNDP is not in a position to act as a representative of the manufacturer, so directly UNDP cannot help in registration. However, UNDP will facilitate the registration process by providing information support, if needed.</p>
7	<p>According to the Invitation to Bid, Attachment 2 on page 41 contains a Commitment Letter. What are the terms for submission of this letter? Does it have to be presented together with the tender bid or separately?</p>	<p>A Commitment Letter has to be provided together with the bid in case the offered product is not registered in Ukraine at the moment of bid submission.</p>
8	<p>You require to provide a bid security in the form of bank guarantee in USD. Can we prepare it in UAH? What are the conditions of its return?</p>	<p>Bid security can be provided in UAH, according to the official UNDP exchange rate, available at: http://treasury.un.org</p>

		Bid security must be provided electronically, with the rest of the bid. UNDP reserves the right to request the original bid security from the bidder any time until the contract is awarded. Original bid security might be returned to the bidder (if requested) as soon as the contract is awarded and the tender results announced.
9	ITB requires to provide Statement of Satisfactory Performance from the Top 3 Clients – are there any particular requirements to the format and contents of this document? Who can be the client – only medical institutions or not?	The statements have to be provided from previous clients (the entities to which the bidder has previously supplied similar products). It is preferable to indicate time period, scope of cooperation, supply volumes, contracts, etc.
10	Whose name do we indicate in Bidder Information Form, cl. 12 – the person which is entitled to sign the documents or the person which is entitled to sign the bid?	Please indicate the name of the person entitled to sign the documents.
11	Whose name and address in UNDP do we have to indicate in the Bidder information form?	Please indicate the name of Andra Brige, UNDP Business Development Specialist.
12	Regarding quantity mentioned in ‘Section 7 – Price Schedule Form’ quantity is per Tablets / capsules or per pack? Please confirm, because we are not sure this quantity is per pack or per tablets (eg. It is 7445000T or 7445000x10x10T or 74450x10x10T)?	The quantities are indicated in tablets /capsules, etc., not in packs.
13	Also let us know which pack is preferable to you – 2x14T, 1x5T, 1x10T, 10x10T, 100T or 1000T?	The packing is up to the bidder; the only requirement is that unit size for each item is not larger then 1000 pcs per pack.
14	As you stated in Bid, DS 23 – it’s E-mail Bid, so you need Bid Security soft copy only? Or you need original bid security by courier separately	Bid security needs to be submitted electronically, with the rest of the bid.
15	Can we send document through Sendspace or we transfer web site, if email size is more than 5mb?	It is recommended to send documents by email, please divide the whole package of documents into maximum 5 messages, with the volume not more than 5 mb.
16	In ‘3b-Delivery requirements’ Mode of transport preferred by Air & Land only, so you mean you are accepting shipment by Air only from overseas supplier? Or you accept the sea shipment from overseas supplier?	It is up to the bidder to decide which mode of transportation to choose as long as it ensures the delivery within the timeframes required by ITB. Please pay attention that for 25% of the volumes you have to select the most appropriate delivery method. Your bid will be evaluated with the help of multipliers (please see cl. 32 of the Instructions to Bidders).
17	I came to know that registration in Ukraine take 6-7 months time minimum. If this is true, is there any fast track procedure, to ensure timely delivery of the products?	Please check Annex 1 “Brief summary on the simplified procedure of state registration of medicinal products procured with involvement of the international organizations”. According to the Decree

		of the Cabinet of Ministers of Ukraine #376 dd. 26.05. the registration is simplified and is done within short period of time.
18	<p>In the Section 7: Price Schedule Form, Cost Breakdown by Cost Component, there is a table with the following columns:</p> <ul style="list-style-type: none"> - Unit price exclude. VAT - Unit price Include. VAT (if applicable) - Freight Ins <p>In case we offer the price excluding VAT how should we indicate it in the table? Should we indicate the same price in the column "excluding VAT"?</p> <p>What do you mean by the column "Freight, Ins"?</p>	<p>The price must include the delivery and insurance costs.</p> <p>If the product price is excluding VAT, please indicate the same price in the column "Unit price excluding. VAT".</p> <p>In the column "Freight Ins" – please indicate separately the cost of delivery and insurance.</p>
19	What is considered as the delivery date?	The volumes are divided into 25, 75% with different delivery dates. Delivery date is the date when the goods are delivered DAP-Kyiv. It is expected that there will be one delivery address on the DAP-Kyiv terms, the exact location of the warehouse will be communicated to the winner(s).
20	Can we submit the bid for the medicine from different manufacturers?	Yes, but please provide corresponding authorization from each manufacturer.
21	Who will be the contracting party from UNDP side? Can we see the contract draft?	UNDP will place Purchase Order(s) for supply of medicines subject to UNDP General Terms and Conditions which is part of the ITB.
22	Who is responsible for the customs clearance?	UNDP will arrange the customs clearance in case the goods are delivered from a non-resident. All deliveries, imported and local are exempt of VAT.
23	Do we have to provide manufacturer GMP certificate?	Yes, please provide manufacturer GMP certificate, WHO or PIC/S type.
24	In case the bidder has no credit rating, will it be the ground for disqualification?	No, in case the bidder has no credit rating, such bid will not be disqualified. In this case please provide Financial Statement (Income Statement and Balance Sheet) including Auditor's Report for the past 2 years, 2013 and 2014.
25	Is it obligatory to provide ISO certificates?	Preferably, provision of this document is optional, if available.
26	Concerning the delivery on terms DAP-Kyiv, which party will pay for the delivery from the airport to the warehouse after the customs clearance?	The goods have to be delivered to the central warehouse (DAP-Kyiv), the supplier is responsible to pay for the transport costs.
27	Is an alternative bid allowed (two bids for one and the same product)?	No.

28	How long will it take UNDP to arrange customs clearance?	Usually the process of customs clearance takes 1-2 days and UNDP expects to keep this timeframe. However due to new legislation in customs clearance there might be delays with first shipments.
29	Please clarify the issue with pre-shipment inspection. Will UNDP arrange such inspection and how will it influence the delivery time? The same refers to the customs clearance.	In case the delay in delivery is not caused by the supplier, but for example is due to the customs clearance, it will not be the responsibility of the supplier. UNDP reserves the right to arrange pre-shipment inspection if there are concerns related to quality of the products .
30	Will we be able to see the price offers of other bidders, will it be public?	Bids opening is a public procedure. In case you want to take part in it, please register by sending a request to the following e-mail address: procurement.ua@undp.org
31	How will the process of quality control be organized? Do you request analysis certificate or batch certificate issued by relevant laboratory in Ukraine?	In case UNDP has concerns related to the quality of the products, the products might be tested at WHO prequalified LAB. Suppliers must provide A Certificate of Analysis at the time of supply.
32	It is mentioned in the ITB that quality claims can be raised within 30 days, and the supplier must replace the defective goods. From our experience, as soon as the goods are delivered to the warehouse, all risks are transferred to the warehouse and the supplier is no longer responsible for the products. Please advise.	In this clause UNDP refers to the products shipped from a reputable company without obligatory testing, but later on the product turns to be non-compliant to the quality standards.
33	If the product is not registered, which party will arrange the registration? How much time is required for the registration, do we need to have an agent in Ukraine?	<p>Please refer to ITB section describing registration process.</p> <p>Please study the legal requirements before you make your decision to bid. There is a simplified registration procedure for the medicines procured within the programme.</p>
34	What quantity of product will UNDP take for the quality control? How will UNDP pay for these products? In which laboratory will the testing be performed? The manufacturers will not accept any lab, this needs to be agreed with them in advance.	<p>The testing will be conducted based on the WHO specified testing standards</p> <p>Samples would be drawn from the supplied product and tested in a WHO prequalified LAB.</p>
35	In case we have the bid in English and company registration documents in Ukrainian, do we need to translate them?	No, it's not necessary, you can provide the documents in Ukrainian/Russian.
36	Will you accept the bid if we provide it from our global office, but part of the information is from a Ukrainian company?	Yes, in case your bid is provided based on consortium agreement signed between indicated entities. You need to identify the leading party of the consortium and submit the bid on behalf of this company.

37	Can we submit the bid security in UAH? In such case is it allowed to provide prices in USD?	Yes, it is allowed to submit bid security in UAH according to UNDP currency exchange rate. It is also allowed to bid in USD.
38	UNDP currency exchange rate is 10% lower than the exchange rate if the National Bank of Ukraine. If the exchange rate grows, will UNDP compensate the losses?	If exchange rate changes significantly, it can be revised during the month. Nevertheless, the suppliers must foresee possible risks of currency fluctuations when preparing the price offer. UNDP will always use only UNORE official exchange rate, without references to other rates.
39	Will UNDP pay in USD to a non-resident supplier?	Yes.
40	Can you add the obligation to arrange the revision of UNDP exchange rate in case of necessity, to the contract?	No, the exchange rate is established for all UNDP countries worldwide and such obligations cannot be added to the contract.
41	You require to provide the bid security issued by a recognized bank, do you have a list of such banks?	There is no list, but the bank should be not from the suspended vendor list of the UN or other such lists of other UN agencies, not associated with, any company or individual appearing on the 1267/1989 list of the UN Security Council. Please use your common sense when choosing the bank.
42	Please explain the clause about the number of submissions allowed.	It is allowed to submit up to 5 e-mails with the maximum size of one e-mail 5 mb.
43	Do we have to submit the documents in soft or hard copy?	All documents have to be submitted electronically to the indicated e-mail address: tenders.ua@undp.org No hard copies required.
44	DO we need to protect the bid with password?	No, it is not necessary.
45	How should we specify information about litigation during the last 5 years?	It will be enough to list litigation cases.
46	Three reference letters should be provided for each lot or for company in general? Can it be also for medical goods?	Letters of recommendation should be in terms of contract value. Three letters will be sufficient if they are relevant to tender subject, supplies should be of the similar nature. These letters are aimed to prove to the UNDP that your company has experience with such supplies. You can specify both delivery of medicines and medical goods.
47	How should we specify correctly shelf life in the technical part of the bid?	You can specify shelf life in the corresponding column, if exact date is unknown, you can specify month and year
48	If we submit a bid as a manufacturer, but distributors also would like to participate in the tender, can they submit their bids for the same lot?	The bids can be submitted, but if there are suspicions of a collusion between companies, the decision about

		consideration of such bids will be made by the tender evaluation panel and in accordance with UNDP rules.
49	Can UNDP withdraw the placed order?	No, it cannot happen, except in cases of force majeure.
50	Will the protection of personal data be provided according to Ukrainian legislation?	Confidentiality of all received bids is guaranteed on the UNDP's part.
51	Are there temperature requirements?	<p>Shipments of temperature sensitive health products, most particularly medicines and diagnostic products, should be accompanied by dataloggers.</p> <p>The number of dataloggers should be 1 if shipment has 5 or less boxes, 2 if shipment has more than 5 boxes. If products are shipped in containers, each container should have 2 dataloggers.</p> <p>Dataloggers should be activated, set up with adequate alarm levels and placed inside a box with the products. The boxes with dataloggers should be clearly identified with bright color stickers (ideally orange).</p> <p>The minimum technical requirements for dataloggers are as follows:</p> <ul style="list-style-type: none"> ▪ Measures temperature (from -30° to 70°C, with accuracy +/- 0.3°C). ▪ Readings to include time and date ▪ Single or multiple use ▪ Direct USB interface, without need for additional cable ▪ Automatically creates PDF report when connected to computer. ▪ Rapid data download to graph ▪ Alarm levels set up before shipping according to manufacturer's storage requirements ▪ LCD featuring up to 1 decimal point readings ▪ Alarm indication on LCD screen ▪ Sampling rate: at least 1 measure per hour ▪ Push button to activate and stop logging ▪ Easy to understand user's guide & instructions
52	Should we indicate the country of origin or the country of manufacture in the table on page 51?	Please provide as detailed info as possible, better to specify both if different.
53	When performance security should be issued?	The supplier should provide performance security after contract award to the winner.
54	Will the estimated budget of procurement be announced?	The estimated budget of procurement will not be disclosed, however, the bids will be announced at the public bid opening.

55	Our company follows very strict rules of engaging third parties and would require UNDP project staff organizing tender on behalf of the MOH of Ukraine to fill in our anti-corruption questionnaire and to take part in on-line training. These steps need to be fulfilled before contract is signed. Please let me know UNDP position on this matter.	UNDP has “Zero tolerance” policy and “Ethics” trainings, mandatory for all staff members. Therefore there is no need for proposed arrangement.
56	On page 13, point 27. Confidentiality. Please explain whether the price of the winning bid will be made public by your Agency and/or whether you are mandated to transfer this data to MOH of Ukraine. Will the announcement be INN based or there will be a trade name listed?	Following the best practices of the public procurement, as per its policy UNDP will publish the winning bidder (including lot), and total contract amount at UNDP website.
57	Page 18, Cross Ref C.20 – Condition for submitting alternative bid: We have product registered in Ukraine in a pack of 5 and in Portugal in a pack of 1000. As you know that we are not fully sure how fast track registration will work, we would like to quote for both the packs. Since “alternative bid “ is prohibited, kindly inform how can we submit two prices for the same product. Or there is possibility that submission of alternate bid will be considered.	Submission of alternative bids is not allowed, therefore your company should decide which product to offer.