ITB UKR/2015/111

Procurement of anti-tuberculosis (TB) medicines

Questions and answers, Round II.

58	Does UNDP require import license to deliver the goods?	Under the given tender, no import license is required.
59	ITB indicates that in case the product is found defective, the supplier must replace it within a month, but this is hardly possible since the goods have to be manufactured and delivered to Ukraine. Please advise.	Should such situation happen, UNDP will negotiate with a contractor the details of replacement and realistic timelines.
60	In case the packing is not in Ukrainian but in English, French, etc., is that allowed?	Under part 6, article 12 of the Law of Ukraine "On medicines" the language of medicines' labeling and instructions for use is determined according to article 26 of the Law of Ukraine "On the basics of state language policy". A similar provision is stipulated in the Technical regulations (section "Information provided by the manufacturer") regarding medical products. Pursuant to part 3, article 26 of the Law of Ukraine "On the basics of state language policy", labelling of medical products and instructions of medical products, procured by specialized organizations, is performed in original language. Under par. 2, p. 3, art.26 of the Law of Ukraine "On the basics of state language policy", labelling of medicines and medical products, subject to be procured according to the procurement procedure conducted by a specialized organization in execution of a procurement agreement between central executive body of Ukraine, that implements the state health care policy, and a respective specialized procuring organization, as well as instructions of use of such medicines and medical products is performed in original language.
61	Do you request to provide translation of instructions for the use of the medicinal product? Hospitals will not accept the instructions without translation.	Pursuant to paragraph 5 of the decree of Cabinet of Ministers № 622 dd. 22.07.2015 "Some aspects of public procurement of medicines and medical products by specialized procuring organizations" the

		Ministry of Health of Ukraine can provide translation of instructions for use of the goods, if necessary.
62	Requirements to shelf life indicate that the date of manufacture and expiry has to be mentioned on packing. The issue is that not all manufacturers indicate manufacture date. Possible variants: Either expiry date only or manufacture and expiry date. Will you accept both variants?	Both variants are acceptable.
63	According to our information the decree on simplified procedure of state registration of medicinal products procured with involvement of the international organizations has not entered into force, is that correct?	The order of the Ministry of Health of Ukraine #721 dd. 03.11.2015 "On approval of the procedure for the expert examination of authenticity of registration materials for a medicinal product submitted for state registration for the purpose of its procurement by a specialized organization" came into effect on 11.12.2015.
64	Who will be responsible for delay with registration if supplier submits all necessary documents in time?	**MOH of Ukraine commits to register new products within the specified timelines or provide timely feedback about any issues regarding the product dossier. If the delay still happens, assuming suppliers acts on "good will", suppliers will not be hold accountable.**
65	Does the regulation on maximum mark up of 10% for public procurement, stipulated in the decree of Cabinet of Ministers № 955 dd. 17 October 2008, apply for **ITB UKR/2015/111**?	Pursuant to the decree of the Cabinet of Ministers of Ukraine #955 dd.17.10.2008, the maximum wholesale and retail margins of not more than 10% of the declared changes in wholesale price including taxes and fees are established for medicines and medical products, which wholesale prices are listed in the registry of wholesale and retail prices of medicines and medical products, that are fully or partially procured from the state or local budgets. Decree of the Cabinet of Ministers of Ukraine #240 dd.02.07.2014 determines exactly what medicines and medical products are subject to declaration of changes in wholesale price. Taking into account the changes introduced to the above-mentioned decree by the decree of the Cabinet of Ministers #449 dd. 04/22/2015, the requirements of the decree of the Cabinet of Ministers # 240 dd. 02.07.2014 shall not apply to medicines and medical products, that are procured by specialized organizations, i.e. such goods are not

		subject to mandatory declaration of changes in wholesale prices. Therefore, the decree of the Cabinet of Ministers № 955 dd. 17.10.2008 does not apply to medicines and medical products, procured by specialized organizations.
66	In case the importation is done by the local distributor, authorized by us, please let us know if it is expected to do the custom clearance by itself before transferring the products to UNDP. We also need to understand whether local distributor will be VAT and import tax exempt as per legislation on procurement via the international organizations.	The operations on delivery of goods purchased through UNDP to the customs territory of Ukraine are exempt from VAT, provided that the supplier will submit to a revenues and duties authority a certificate issued by the Ministry of Health of Ukraine, confirming that the goods are paid based on agreements (contracts) between the Ministry of Health of Ukraine and specialized organization. In order to obtain such a certificate, suppliers shall submit to the Ministry of Health of Ukraine the following documents within no more than five working days following the last calendar day of the reporting (tax) period, when such operations took place: - application for a certificate confirming that the goods are paid under agreements between MoH and the specialized organization; - copies certified in accordance with the legislation: - a contract between the supplier and specialized organization; - a certificate about inclusion of the supplier into EDRPOU[1] (for a permanent representation office); - tax invoices issued by the supplier of goods during the reporting (tax) period without VAT; - copy of the extract from the Register of VAT Payers. The Ministry of Health of Ukraine shall issue a certificate within five working days from the day of receipt of the listed documents.
67	It is clear that UNDP finally wants to purchase registered product. However, the onus of getting registration is left to the manufacturer/bidder as per page 34. UNDP can easily terminate the conditional contract but what will bidder do with the ready products? To submit a dossier in 3 days,	Please be informed that any company should provide the list of previous contracts for similar supplies (p 24). The previous supply history in Ukraine is applicable only to those products, which does not fall under below specified a,b,c,d conditions.

[1] EDRPOU stands for a Unified State Register of Enterprises and Organizations of Ukraine.

	after award of contract, will mean that we start working on making dossiers now (as they require translation into Ukrainian) and keep them ready for filing. However, page 28, actually puts a registered product at a disadvantage, as you want that product to have previous supply history in Ukraine. Can this be changed to companies just having registration without any supply history?	1. The product(s) will be procured on the condition that they are either: a) Prequalified by WHO, or b) Approved by a Stringent National Medicines Regulatory Authority (SRA) of Pharmaceutical Inspection Convention Scheme (PIC/S) countries, or c) Recommended by Expert Review Panel for The Global Fund, or d) Manufactured at sites with a GMP certificate provided by WHO or PIC/S authorities, or ***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).*** Products falling under E) category would be acceptable only if the supplier will demonstrate successful previous supply and positive feedback about utilization by MOH. This condition could not be waived.
68	Ukraine MoH normally gives artwork approval at the end of registration process. How can we get approved artwork for non-registered products? Will UNDP approve artworks?	According to law on simplified registration newly registered products could be imported in original packing. Therefore suppliers will not be requested to repack the products.
69	Your quality criteria allows you to buy product WHOPQ or SRA approved product, irrespective of registration. Why not make WHOPQ/SRA a prerequisite? This will weed out many companies, atleast for 16 of the 19 line items but ensure you quality of delivered product.	Bidders are kindly requested to follow the quality criteria indicated in ITB under the given bidding process. The quality criteria for future tenders might change.
70	Sodium aminosalicylate powder/enteric coated granules. The specs are not clear. Can you clarify which product you need and what dosage will you accept?	According to the product list, the product is required in the form of powder/ enteric granules, the dosage is 1 000 mg.
71	In clause 15.2 page number 8, Technical Specification and Implementation plan: we would be providing documents as specified in Data sheet page number 21, 26 (C.15.1). Please let us know which other documents are required, if any?	All documents to be submitted by the bidders are listed in the Data Sheet, C.15.1.

72	Also as per Clause 26 (page no. 21) of Data Sheet; C.15.1 Documents which we have to provide has to be "Certified True Copy". Please let us know in this if we can notarize our documents from a Lawyer and send black & white copy of those notarized documents. Request you to allow us to send black and white copies as colored scanned documents will increase the size of each page thus would be difficult for us to adhere the "5 MB" size of the file which we have to submit in our BID.	There is no need to notarize the documents. You can confirm that the documents are "true copy" with your company stamp and signature. Black and white copies are also allowed.
73	Language of the documents: Please confirm that we can send all our bidding documents ONLY in ENGLISH language	As indicated in the ITB, the bids can be provided in one of the following languages: English, Ukrainian or Russian.
74	What do we need to indicate in the Bidder Information Form, cl. 14?	Please choose the statement that refers to your particular company, either a Joint Venture, Government corporation, etc.
75	Regarding the lots which are not marked with the "star" (*), is it allowed to quote only 25%, 75% or only 100%?	You can quote 25/75 % or 100% for all lots. The marked "*" lots are the products, which are needed at the country immediately. For further details please refer to ITB page 25 "Criteria for the Award and Evaluation of Bid.
76	Regarding the bid security, do we need to issue one document for all lots or a separate document for a separate lot? For example 3 lots = 3 bid securities?	Bid security in the amount of 10,000 USD is required per each lot. Except for Lot 4, Bid security is waived for Lot 4. If the company chooses to submit bids for more Lots, the Bid security amount should be respectively multiplied to the number of Lots (e.g. 30,000 USD for 3 lots). However bidders quoting prices for more than 5 (five) lots should only provide Bid security in the amount of 50,000 USD.
77	If our company is awarded the contract for several lots, will you sign one contract for all lots or separate contracts?	If a company will be awarded the contract for several lots, one (all inclusive) contract (Purchase order) will be signed.