

ITB UKR/2015/122

Procurement of medicines for children with hemophilia A and B or Willebrand disease

Questions and answers including minutes of the pre-bidding conference held at UN Office on
January 08, 2016

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

1. The submission deadline has been extended till Sunday January 24, 2016, 23:59 Kyiv time.
2. The bids are submitted electronically to the following e-mail address: tenders.ua@undp.org

#	Question	Answer
1	<p>According to cl.6 section 3a of «Invitation to Bid ITB/UKR/2015/122. Procurement of medicines for children with hemophilia A and B or Willebrand disease within the National Public Health Programme to the Ministry of Health (MoH) in Ukraine.» 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.</p> <p>However, considering that the total shelf life of the offered product (coagulation factors) is 24 months, duration of quality control of manufactured products by the manufacturer (3 months), manufactured bulk products available for supply from the manufacturers, the time for packing of goods, preparation of documents by the manufacturer, time for transportation of goods to Ukraine and customs clearance of the goods, the required shelf life of minimum 75% (or minimum 18 months) of the total product shelf life significantly restricts the competition, whereas the Ministry of Health of Ukraine has procured these products with a shelf life of minimum 75% of the total product shelf life or <u>15 months shelf life remaining</u> in the past years.</p> <p>Considering the above, in order to improve the competitive environment, please consider the possibility to introduce changes to shelf life requirements and amend them as follows: "products must have a minimum of 75% of the total product shelf life or should have 15 months shelf life remaining at the time of delivery."</p>	<p>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.</p> <p>Bids for the products that do not fulfill the minimum requirements of the shelf life will be disqualified.</p>
2	<p>In the products list (cl. 4) of ITB/UKR/2015/122 «Procurement of medicines for children with hemophilia A and B or Willebrand disease» the total quantity is indicated for the following lots:</p> <p>6. Human coagulation factor VIII and human von Willebrand factor, 500 ME - 2,674,000 (100%)</p> <p>7. Human coagulation factor VIII and human von</p>	<p>Pending clarification from the MoH. Upon receipt of response from the MoH, corresponding information will be provided to the bidders shortly.</p>

Willebrand factor, 1000 ME - 1,260,000 (100%)

At the same time, according to the Decree of the Cabinet of Ministers of Ukraine #787 dd. 08.10.2015 in section VII. "Centralized procurement of medicines for children with hemophilia A and B or Willebrand disease" there is a clear distinction between medicines to be procured for treatment of Willebrand disease 2nd and 3rd type:

Treatment for children with Willebrand disease 2 nd type			
Human coagulation factor VIII and human von Willebrand factor	vials	500 IU	1 944 400
Human coagulation factor VIII and human von Willebrand factor	"-	1000 IU	860 000
Preventive treatment for children with Willebrand disease 3 rd type			
Human coagulation factor VIII and human von Willebrand factor	vials	500 IU	730 481
Human coagulation factor VIII and human von Willebrand factor	"-	1000 IU	400 000

Since different registered in Ukraine medicines have different indications for treatment of 2nd and 3rd types of Willebrand disease, please consider the possibility to introduce changes in these lots, with division of quantities according to the CMU decree #787 dated 08.10.2015.

3	Besides the technical and financial proposals, all other required documents should also be sent electronically in zipped file?	All documents should be submitted electronically in zipped file to the following e-mail address: tenders.ua@undp.org . Submission in hard copies is not required.
4	Should we submit an official letter stating that the company has no litigation history?	It will be enough to list litigation cases in the application or indicate that the company has no litigation history.

5	Is it acceptable to submit only one letter of recommendation from one client with regard to 3 major contracts in terms of contract value?	<p>Letters of recommendation should be provided from three clients. Three letters will be sufficient if they are relevant to tender subject, supplies should be of the similar nature.</p> <p>These letters are aimed to prove to the UNDP that your company has experience with such supplies.</p>
6	Regarding the cl. 26 Required documents, is it necessary to attach the copies of contracts to the list of similar contracts?	It is enough to list previous contracts for similar supplies, copies of the contracts are not necessary.
7	To whom in UNDP should we address the guarantee letter as indicated on annex 2?	Please indicate the name of Ms. Andra Brige, UNDP Business Development Specialist.
8	In the case of proposal acceptance, what is the term for submission of performance security?	After the contract is awarded to the winner, the supplier should provide performance security as soon as possible, but not later than 30 days from the date of signing the contract.
9	If the goods have already been imported to Ukraine and all import duties and VAT were paid, what will be the mechanism of duties and VAT refund and how should we quote price in the financial proposal in this case? Should we make a remark to a particular lot and specify this information in details?	<p>Reimbursement of taxes is possible in cases stipulated by the current legislation of Ukraine.</p> <p>Ukrainian legislation does not provide mechanisms for VAT and import duties reimbursement in the implementation of centralized procurement involving specialized organizations, as described in the question.</p>
10	Are there any fundamental differences between this tender and previous tender for anti-TB medicines?	There are not fundamental differences, a bid security is not required in this tender, also the evaluation criteria are slightly changed - no WHO and Global Fund prequalification is required, there is no ratio for urgent delivery.
11	If our company operates for only 1.5 years on the market (less than the minimum required experience) and correspond to the rest of tender evaluation criteria, will the application be accepted?	<p>According to the requirements of ITB, minimum no. of years of experience in similar nature and size contracts: 3 years.</p> <p>You can consider the option of bid application in a consortium, member companies of which have the relevant experience. Bids from companies that are registered in the market for less than 3 years, will be disqualified.</p>
12	Participants can submit their proposals in UAH and USD, please clarify how the proposals will be evaluated and in what currency the payments will be effected.	Bidders-residents can submit the financial proposals in UAH, and / or in US dollars. In case of submission of financial proposals in USD, payments will be carried out in UAH according to the official UNDP exchange rate as of the payment date (available at: http://treasury.un.org , usually the exchange rate is updated once a month).

		Non-residents submit applications in US dollars and payments to them will be effected in US dollars
13	This provision is applicable both for residents and non-residents?	Non-residents submit applications in US dollars and payments to them will be effected in US dollars. Payments to residents will be effected in UAH only, regardless of their bid currency.
14	When the results of this tender be announced?	Technically, we have 120 days to evaluate bids, but we will do our best to finalize assessment of the tender as soon as possible.
15	How the UNDP exchange rate is established?	The exchange rate is established by the UN headquarters in New York based on monitoring of the exchange rate dynamics and trends, the updated exchange rate is announced at the end of each month. If the exchange rate varies greatly during a month, update of official exchange rate is possible in the middle of a month. From our experience, the UNDP exchange rate is more in line with the National Bank exchange rate, rather than rates of commercial banks.
16	We have consulted with tax authorities regarding the VAT exemption and we were told that in order that we as distributor are exempt from VAT, the recipient institution to which the goods will be delivered, should provide us with the registration form of participation in the Program project.	Please refer to ITB section with information on VAT exemption, as agreed with MoH.
17	Without MoH coordinating this procedure with Customs and Tax authorities, distributors will not be exempted from VAT, because the resolution is not approved yet.	We expect this resolution to be enacted shortly. 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. Detailed procedure of submission of the required set of documents by supplier is described in the ITB.
18	In the Price Schedule form there is a column "Unit price Include. VAT (if applicable)», in what cases it should be filled or can we leave it blank?	You can leave this column blank and indicate only the unit price excluding VAT. Evaluation of all proposals will be done based on net prices, excluding VAT. Initially, this column was aimed to track the number of suppliers with whom we shall undergo the procedure of VAT exemption.
19	If one of the lots is manufactured by one manufacturer only, will it be procured under the same procedure or under request for proposal?	This situation will be taken into consideration if there is a patent from manufacturer for that certain lot.

	What if only one bid will be submitted for this lot?	If only one bid will be received for such a lot and the bid will meet all administrative and technical specifications, budget and other criteria, the UNDP may award a contract to the supplier.
20	From our experience with previous tender, it is difficult to submit all required information in one 5Mb file.	Submitting all documents in one file is desirable, but not obligatory. It is allowed to submit up to 5 e-mails with the maximum size of one e-mail 5 mb, in this case, please indicate the total number of e-mails/parts.
21	Do we understand correctly that it is not necessary to deliver all quantities by the end of April, meaning, there are no preferences for urgent delivery?	<p>25% quantities must be delivered as early as possible, but not later than 25 April 2016. The bids with later delivery date for this quantity will be disqualified.</p> <p>75% quantities must be delivered not later than 30 June 2016. The bids with later delivery dates will be disqualified.</p> <p>UNDP reserves the right to vary the quantity of the goods by up to a maximum twenty-five per cent (25%) of the total offer, without any change in the unit price or other terms and conditions.</p>
22	Can we combine several languages in the application?	Yes, but it is preferable that application is submitted in English, because the tender evaluation panel will be held in English. If some documents are submitted in language other than Russian, Ukrainian or English, please provide translation of these documents.
23	What document should we submit as a certificate of authorization?	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.
24	Can we submit a letter from the representative of manufacturer? Should the representative's powers be confirmed?	Yes, a document from the manufacturer's representative can be submitted as a certificate of authorization. The representative's powers also should be confirmed with relevant documents.
25	Please clarify whether GMP certificate should be confirmed in Ukraine or we can provide manufacturer GMP certificate.	Yes, please provide manufacturer GMP certificate.
26	According to ITB, latest audited financial statement for the past 2 years should be provided.	The bidders should provide Latest Audited Yearly Financial Statement (Income Statement and Balance Sheet, with the stamp of Statistics department)

	Please clarify, does it mean one report for 2 years period?	including Auditor's Report for any two full years in the period from 2013 to 2015.
27	<p>How much time will the simplified registration take?</p> <p>In case the tender winner will have no valid registration of medicine in Ukraine, registration procedure may delay the delivery of the goods. This discriminates other bidders who offer already registered medicines.</p>	<p>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.</p> <p>UNDP will consider penalties provision for the delay in delivery on a case by case basis, depending on the reasons and timing of delays.</p>
28	In the list of Required documents there is Instruction for medical use in accordance with the legislation of Ukraine. If we submit an application under Option 2 (medicine is not registered in Ukraine yet), then before passing MoH examination, we can not provide instructions approved in Ukraine.	In this case, you can provide in the application the original instruction for medical use.
29	Is the CMU Resolution no. 1071 with the list of medicines to be procured for state budget funds applicable to UNDP? Does UNDP have a right to buy medicines that are registered under simplified procedure, but not included in the above-mentioned list (where drugs are listed by brand name, not INN)?	<p>UNDP is not guided by the Ukrainian law and carries out procurement according to the list of medicines to be procured pursuant to the Agreement with the Ministry of Health of Ukraine. The agreement was drawn up based on the Decree of the Cabinet of Ministers of Ukraine #787 «The list of medicines and medical products subject to be procured pursuant to the procurement agreements with specialized organizations, conducting public procurement».</p> <p>UNDP carries out procurement of medicines only by INN.</p>
30	Can we register the medicines under simplified procedure only according to MHU Resolution №721 or according to MHU Resolution №460 as well?	Participants may register the medicines according to chosen procedure, it is important for UNDP that medicines should be registered in Ukraine at the time of delivery one way or another.
31	<p>Please clarify regarding requested shelf life, the products must have a minimum of 18 months shelf life remaining at the time of bid submission or at the time of delivery?</p> <p>We have medicines on stock in Ukraine with a shelf life of less than 18 months, that can be delivered the next day after signing the contract. Would you accept a guarantee letter stating that if</p>	<p>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.</p> <p>In case of partial shipment, it is acceptable that each part of the delivered goods corresponds to the required shelf life. In case of delivery of the total quantity of the goods, it is not acceptable if only a part</p>

	the medicine is not used before the expiration date, we undertake to pick it back?	of total quantity will correspond to the required shelf life. Guarantee letters regarding the shelf life will not be taken into account. Bids for the products that do not fulfill the minimum requirements of the shelf life will be disqualified.
32	What should be provided as the registration documents of the Ministry of Health?	Certificate of medicine registration in Ukraine.
33	Please clarify this paragraph “Based on the urgency for the specific product(s) UNDP reserves the right to award the contract in 25% and 75% proportions to different companies.” If there are no preferences for urgent delivery, how the applications will be evaluated?	The Bidders can provide the bids for separate lots in proportions of 25%, 75% and 100% depending on the possibility to fulfil the required delivery time for each part. The decision on contract award for 25% and 75% of one lot to different companies will be made based on the lowest price and fulfilment of the required delivery time for 25% and 75% respectively, provided that the application meets all other technical criteria.
34	Experience of similar contracts should be indicated for deliveries to public institutions only?	You have to prove to the UNDP that your company has experience with such supplies, not necessarily delivered to public institutions.
35	We deliver the goods to the customs and UNDP will make the customs clearance?	UNDP will make the customs clearance of the goods.
36	How will the information with tender results be published? If the lot is awarded with a breakdown in 25% / 75% of the total quantity, the prices for the 25% / 75% will be published separately?	The bids will be announced at the public bid opening. Information on contract award is published at UNDP website only for contracts exceeding 100 000 USD. As for contracts under 100 000 USD, the name of the winner company for each lot will be disseminated. Information about the winner and the date of awarded contract for 100% or 25% and 75% will be disseminated among the bidders via e-mail.
37	The payment for partial shipments will be done in one month after the delivery of each part?	As a general rule, UNDP makes payments within 30 days from the date of each delivery.
38	Please clarify what is required as Bidder’s Authorized Representative Information? About how many representatives should we provide information?	Please provide contact information of a person, who will be a focal point for us and can provide clarifications on the submitted bid upon our request.
39	How will the contract be awarded in case of bid from a joint-venture/ consortium?	UNDP will sign a contract only with the lead entity identified to represent the joint venture and communicate with UNDP. In the case the bid is submitted from a joint-venture/ consortium, the participants have to submit an agreement among the legal entities, completed forms

		for each company-participant of the joint-venture/consortium. More detailed information on submission of the bid in a consortium is stated in clause 19 of ITB.
40	Should we specify contracts for similar medicines as a list of previous contracts for similar supply?	Yes, bidders should specify information on minimum 2 similar contracts for the last 3 years in terms of supply of similar products (medicines for treatment of hemophilia A and B or Willebrand disease).
41	Bidders should give information about the freight forwarder. Does it mean the freight forwarder that will transport the goods from the manufacturer to the customs territory of Ukraine or also from the customs point to the destination warehouse?	Please specify the name of freight forwarder that will arrange all transportation, or please specify information about the company's own vehicle fleet for transportation.
42	Please clarify about minimum 3 references for key personnel.	It is enough to list referees (including employers) whom we can contact for recommendations about the key personnel.
43	If insurance will be paid by the manufacturer, not the distributor, is it necessary to indicate the insurance cost?	The delivery cost should be quoted on DAP Kiev terms, according to which the insurance cost is covered by the supplier. It is enough to specify joint freight and insurance cost, it is not necessary to specify the insurance cost separately.
44	Please clarify the unit measure. 500 IU makes 1 package, in this case the price should be quoted per 1 vial/package or per 1 IU? The total required quantities of medicines are given in IU or in vials?	Pending clarification from the MoH. Upon receipt of response from the MoH, corresponding information will be provided to the bidders shortly.
45	One of the technical requirements of ITB is "Digital Certification/Signature: [if needed]", is it necessary?	It is not necessary.
46	In ITB the opening of envelopes is mentioned. Does it mean the opening of e-mails with applications?	Yes.
47	If we deliver the goods to the customs territory of Ukraine and the UNDP will make the customs clearance of the goods, how will VAT be charged during the customs clearance?	According to procedures on VAT exemption for supplies of goods, that are described in ITB. After UNDP makes the customs clearance, the supplier shall deliver the goods to the destination warehouse, specified by UNDP.
48	Where and by whom the data loggers will be stopped - at customs point, or for example, at destination warehouse (Ukrvacina)? We have doubts that there are devices for reading the data-loggers at Ukrvacina.	Data-loggers recording will be stopped in the place where the ownership for the goods is transferred from the supplier to the buyer. The address of the warehouse, where the goods will be received, is not yet defined and will be communicated to the winner. We will ensure that

		necessary devices for reading data-loggers records are available at the destination warehouse.
49	If the goods have already been imported to Ukraine and we stopped dataloggers at receipt in our warehouse, will we need to set up and activate the dataloggers prior to shipment to the defined warehouse? The ITB describes the process of dataloggers set up before the goods are imported.	Data loggers will be checked at the final place of destination.
50	Please clarify the delivery terms: shall we arrange further transportation after the goods are delivered on DAP-Kiev terms?	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).
51	<p>We have a question on accounting documents in case of supply from Ukrainian distributor: if the customs declaration will be issued for UNDP, how we shall record the receipt of the goods to our credit for further sale of the goods to UNDP? If the distributor makes the customs clearance, it will not be exempt from VAT.</p> <p>Please clarify what bylaws or internal regulations of the Customs Service that regulate the procedure for VAT exemption, which can be referred to during the customs clearance of goods by distributors?</p>	<p>UNDP will buy the goods from resident suppliers on the territory of Ukraine, after the customs clearance of the goods is already arranged by the supplier.</p> <p>The CMU Resolution № 1153 dated December 2, 2015 "On approval of procedure for the importation, delivery and target use of medicines, medical products are exempt from the value added tax" provides the procedure for confirmation of the exemption from VAT for operations of import / supply of medicines and medical products. (http://www.kmu.gov.ua/control/uk/cardnpd?docid=248750453).</p> <p>In addition, the exemption from VAT for the mentioned operations until 31.03.2019 is provided for in para. 38 of subsection 2 of section XX "Transitional Provisions" of the Tax Code of Ukraine.</p>
52	Regarding deliveries from nonresident, the ownership for the goods is transferred at customs, when the consignment note and tax invoice will be signed?	Ownership of the goods is transferred from the supplier to the UNDP upon signing the acceptance and delivery certificate, after the incoming goods inspection is conducted at the destination warehouse. The tax invoices are issued by the resident supplier.