

ITB 51-2017-UNDP-UKR

Procurement of medicines for female infertility treatment by means of assisted reproductive technologies

and

ITB 52-2017-UNDP-UKR-ITB-HP

Procurement of medicines for treatment of patients with multiple sclerosis

and

ITB 54-2017-UNDP-UKR

Procurement of medicines for children with dwarfism of various origins, cerebral palsy, cystic fibrosis, resistant juvenile rheumatoid arthritis and Anti-D immunoglobulin for the prevention of hemolytic disease of the newborn

**Questions and answers on the results of pre-bid conference,
conducted on August 23, 2017 at UNDP office in Kyiv**

Dear participants, please pay your attention once again to the following issues while bids submission:

1. Bids submission deadline for:

ITB 51-2017-UNDP-UKR – September, 6, 2017, 10:00 Kyiv time.

ITB 52-2017-UNDP-UKR-ITB-HP – September, 6, 2017, 10:00 Kyiv time.

ITB 54-2017-UNDP-UKR – September, 8, 2017, 10:00 Kyiv time.

2. Bids submitting – electronic form to e-mail: tenders.ua@undp.org

3. Together with the documents set, the participant must submit electronic scan copy of the Bid security in the amount of 10 000 USD for the Bid on one or several Lots if the Total amount of the Bid is between USD 200,000.00 and USD 399 999,99 or in the amount of 20 000 USD for the Bid on one or several Lots if the Total amount of the Bid is between USD 400,000.00 and USD 599 999,99 or in the amount of 30 000 USD if the Total amount of the Bid is more than USD 600,000.00 (*applicable for ITB 52-2017-UNDP-UKR-ITB-HP and ITB 54-2017-UNDP-UKR*)

#	Question	Answer
1	What is the purpose of Bid Security?	A Bid Security is a guarantee that the winning entity will sign the Contract awarded by the UNDP (details are given in the Form for Bid Security (Section No. 9).
2	What does "other similar certificates" refer to in the List of other documents required for evaluation of Offeror?	It is additional certificates such as ISO, Environmental compliance, etc., they are not subject to evaluation in the context of Bid consideration, but give information about the company.
3	For products that are registered in Ukraine, what is the purpose of providing CoPP?	If the product is registered only in Ukraine, then CoPP is not applicable. For medicines that are

		approved in countries with Stringent Regulatory Authority, it is necessary to provide CoPP.
4	The form of Appendix 3 "Certificate of Authorization to act on behalf of the Manufacturer in case the Bidder is not a Manufacturer" is a mandatory Form for filling in or is it an example?	It is a sample of Form.
5	Is it necessary to fill the following fields: 3.1 Management Structure, 3.2 Staff Time Allocation, 3.3 Qualifications of Key Personnel of the Subsection 3.3: Personnel?	Yes, it should be completed.
6	Is it necessary to provide a certificate of Good Manufacturing Practice (GMP) for all production sites?	Yes, it is necessary to provide GMP for all production sites that are involved in the manufacturing process of product (production, primary / secondary packaging, batch release, quality control).
7	How to indicate correctly the expected delivery date, if not the whole amount of product is planned for delivery in one shipment?	It is necessary to divide dates and proportions / quantities of shipment, for example: 25% - November 1, 75% - December 1.
8	The unit price with EXW delivery terms is specified for UNDP to potentially arrange the delivery?	Yes, UNDP is considering the possibility to arrange the delivery on EXW delivery terms under long-term agreements. The first delivery will be carried out under DAP delivery terms.
9	What should we do if it is not possible to separately indicate the cost of delivery and insurance (DAP, Kyiv)?	You should indicate the cost per unit on EXW delivery terms and indicate in the foot-note that the cost includes insurance and shipping. Nevertheless, it is desirable to specify the price for EXW and the cost of shipping and insurance (DAP, Kiev) separately.
10	Is it necessary to provide the Bid Security and Performance Security at the time of application submission?	At the time of application submission, it is necessary to provide Bid Security (it is mandatory for ITBS 52-2017-UNDP-UKR and 54-2017-UNDP-UKR if the bid value exceeds 200 thousand USD). If the company is awarded a contract, then it is necessary to provide the Performance Security if the value of the contract exceeds 300 thousand USD, or at the discretion of UNDP.
11	Can I submit the same reference letters if we already took part in the tender this year?	Yes, you can.
12	If UNDP already has an experience with the company, is it necessary to provide reference letters?	Yes, it is necessary.
13	Reference Letters are the recipient's feedback, thus, can we request UNDP to provide references?	Yes, please indicate that there was a delivery to UNDP and we will append the supplier's application with company performance evaluation form (an

		internal document for the supplier which completed the contract).
14	In the event that another counterparty supplied the drug, is it possible to give references from UNDP on this drug?	The references for drugs are provided from medical institutions, if there is no approval of stringent regulatory authorities, without binding to the counterparty.
15	If the drug is approved under the one name in European countries, and in Ukraine it is registered under a different name.	This is acceptable.
16	With reference to the Question 15. If they are different manufacturers with different names?	We will compare it according to the COPP, in which the production sites are indicated. The COPP should be provided for the product that will be supplied to UNDP.
17	The question regarding the situation, if the drug is not approved by countries of stringent regulatory authorities, and was not supplied to Ukraine and a letter will be provided that the drug will be registered.	We cannot accept the goods if it is not approved in the countries of stringent regulatory authorities and it is not registered in Ukraine.
18	If the drug is not approved in the countries of stringent regulatory authorities, but the production site (that is not in the countries of PIC /s) is certified and it has a GMP certificate issued by the PIC/s authorities, the drug is not registered in Ukraine and there will be a letter that the drug will be registered.	We cannot accept the goods if it is not approved in the countries of stringent regulatory authorities and it is not registered in Ukraine.
19	Did UNDP have an experience in registering of goods in Ukraine after winning a tender (over the last 2 years) if the goods were not registered in the SRA country and the goods were not registered in Ukraine?	Yes, we had, but the goods were pre-qualified by WHO.
20	Should the Section 4 of the bid application be submitted?	Yes, it should.
21	The question related to the price, if the package implies 2 vials, and an odd number of bottles is required, the price will vary accordingly (3 decimal places).	We ask you to apply and quote the price for the vial, at the time of signing the contract we will be able to round up the number to the smaller side. Please write all the decimal places.
22	What is the guarantee of signing 3-year contracts?	We plan to conclude long-term agreements for this year and with the possibility of its extension for the next year.
23	Conclusion of long-term agreements will be only in regard to monopoly positions?	No, not always. Long-term agreements will be concluded at the discretion of UNDP, taking into account the following factors: reliability of the Supplier, price level, purchase volume, etc.
24	Are there any criteria for what drugs will long-term agreements be concluded?	Long-term agreements will be concluded at the discretion of UNDP, taking into account the

		following factors: reliability of the Supplier, price level, purchase volume, etc.
25	What are the terms for making decisions on concluding long-term agreements?	The decision will be made as a result of the tender evaluation.
26	The price will be fixed for all 3 years?	Yes, a long-term agreement will be negotiated between the supplier and UNDP.
27	Question on the delivery terms (4 months after the contract signing), UNDP expects delivery in the 1st quarter of next year?	Within 4 months after signing of contracts.
28	How does UNDP expect deliveries this and next year (what amount in 2017, and what amount in 2018)?	UNDP expects to receive the maximum possible number of drugs in 2017.
29	What determines the delivery time - 4 months?	Necessity to deliver medicines in the shortest possible terms.
30	For the past year, the lots were not purchased in full, part of the lots were held under a separate procedure within the program, it will be the same this year?	All procedures within the same program are synchronized. Reduction of drugs will be in case of budget deficit, after approval from the MOH.
31	Long-term agreements will be concluded on the supply of all non-alternative drugs?	If possible, yes. Long-term agreements will be concluded at the discretion of UNDP considering the following factors: reliability of the supplier, price level, volume of goods, etc.
32	Delivery of all other drugs will be carried out through a tender?	If a long-term agreement is not signed, then the further procurement will take place through a tender procedure.
33	Can I specify two options for the cost of the drug in case of placing the PO (according to the bidding document) and in case of concluding a long-term agreement?	Yes, please offer 2 options in the technical part (financial proposal).
34	Have you corrected the error in the amount of Adalimumab in the ITB 54-2017-UNDP-UKR?	Yes.
35	If the delivery of goods will be done from a manufacturer to the distributor for UNDP, will the import VAT be applied?	The details are described in Appendix No. 1 to the tender document (Annex 1)
36	Is it possible to submit 2 (two) options from different manufacturers within the same INN?	Yes.
37	Will other dosages be taken in the application, differ from those requested?	No.
38	How long does it take to award a contract after the bids opening?	According to the tender documents, UNDP has the right to evaluate the tender within 120 days, but we try to conduct all procedures within 1-2 months depending on the complexity of the procurement.

39	Is company registration documents legalization (legal assurance) required?	Not necessary. Companies that are applying must submit Form No. 5 and a financial proposal with the applicant's stamp.
40	Do I need to provide a letter that the drug, which is registered in countries with stringent regulatory authorities, is being re-registered in Ukraine?	Yes, please provide a letter.