ITB UKR-HP-2017-18

Procurement of chemotherapeutic agents, radiopharmaceuticals and support drugs for treatment of cancer patients

Dear Bidders, you are kindly asked to pay attention for the following issues while submitting your applications:

1. **Deadline for the submission of Bids – 15 February 2017, 10:00 Kyiv time, inclusive.**
2. **The bids must be submitted0 by mail to: tenders.ua@undp.org**
3. **In case the bid amount exceeds 200,000 USD the participant has to submit the scan copy of the bid security together with the set of documents.**

Questions and answers, including the minutes of the pre-bid conference to the tender ITB UKR-HP-2017-18, held in hotel «Kyiv» on 30 January 2017.

#	Question	Answer
1	In case the supplier wins the tender with the non-registered medications in Ukraine, and faced with problems to register it but not due to his fault. Would UNDP impose any sanctions or liquidate bid security?	Failure to obtain registration and submit in time the required documents to UNDP will serve, at no claim to UNDP, as a ground for contract termination, liquidating Bid or Performance Security amount.
2	What letterhead should be used and who should sign the Certificate of Authorization in case the bidder is not a Manufacturer. Should it be the letterhead signed by the Head Office or local representative/distributor?	The official letterhead signed with the authorized signature and stamped by the Head Office (Manufacturer) should be used.
3	Is it allowed to deliver the part of the requested quantity in a packaging for the Ukrainian market and the other part in original packaging.	It is allowed. It is important that the medications in the original packaging to be the same strength, pharmaceutical presentation, to be produced in the same manufacturing site, that is mentioned in the Certificate of Registration. In case medicines are delivered in original packaging with instructions for the use in the original language, Ukrainian translation of instruction for the use shall be provided in the electronic format at the time of supply. Ukrainian translation of instruction shall correspond to one published in the product's state registration record (State Register of Medicines in Ukraine).
4	If the same medication is registered in Ukraine and other countries under the different product trade	We can accept for consideration the registration/SRA approval issued for the different

	names, is it allowed to deliver supplies in the original packaging under the trade name sold in other countries?	product trade name from the same one in Ukraine. As for supply of the medication with the product trade name different from the one registered in Ukraine, it is necessary to amend registration another product trade name in Ukraine.
5	Since which date the shelf life should be calculated?	The final shelf life should be calculated according to the delivery time, taking into consideration the date of signing the contract, indicated in the tender document.
6	If medication is imported to Ukraine in bulk and is packed in Ukraine to the necessary pharmaceutical presentation, are the GMP certificates necessary for both manufacturing sites or only for one?	The GMP certificates are necessary for both manufacturing sites
7	What is the maximum volume of files could be submitted by email?	5 MB is maximum for one letter. Preferably no more than 10 letters. Only ZIP compressing. For more detailed information, please refer to the p.23 of the "Checklist of the documents required" in the Instruction for bidders in ITB.
8	Will the supply be exempted from VAT, in case it is delivered to Ukraine in bulk, packed in Ukraine and then sold to UNDP?	Goods and raw materials, imported to Ukraine, are imported not for UNDP, but for the local company, therefore there is no exemption from VAT.
9	There is indicated in ITB, that the date of manufacture and the shelf life expiration date must be indicated on the packaging. Is it allowed to indicate the date of manufacture and the general shelf life without expiration date?	It is enough to indicate the date of manufacture and the general shelf life, but the expiration date has to be mentioned in the Analyses Certificate for the respective shipment.
10	If supplies are delivered in the original packaging, is it necessary to label a packaging with a registration number?	No, no need to label with the registration number sticker.
11	You mentioned about the audit reports as for the company's activities. Should the auditor be one of the "BIG-4" companies?	No, not necessary.
13	Financial documents and Statue are in French. Is it necessary to translate them?	The documents have to be submitted either in English, or in Russian or Ukrainian languages. That's why it is preferable to translate them. It is possible to translate the main information.
14	Technical issue. While filing-in the tables with technical description and price proposal, is it possible (allowed) to leave the lines only with the proposed products and hide or delete the other lots.	Yes, you can. You are kindly asked to submit the table with the technical description of the medication both in PDF and Excel.

15	About COPP. If COPP is not ready yet at the time of application (it could take one months to receive it from the Manufacture), is it possible to submit a commitment letter for the later submission of COPP?	Yes, please apply with the commitment letter, but make sure to submit COPP as soon as possible.
16	If COPP for the quoted product was issued not in the country of production?	At the date of application please submit COPP you have and request COPP of the production country.
17	Since which date 30 days for the payment of supplies are started to be calculated?	During 30 days after the goods have been delivered provided the written confirmation of supplies acceptance, signed and stamped by UNDP/ MOH, and the hard copy of the supplier's invoice. In case testing is required, the payment will be subject to positive results of such testing. Partial payments could be provided in case of partial deliveries.
18	How long does it take to sign the Act between UNDP and MOH?	Generally, it takes about 7 days. It takes about 2 days to sign the Act between UNDP and DPs MOH "Ukrmedpostach" and "Ukrvaktsyna", and then about 5 days to sign the Act between UNDP and MOH.
19	Regarding the description of 3 top contracts. If the company is multinational and operates all over the world, what contracts should be disclosed?	Please choose and disclose the most representative contracts.
20	Regarding the reference letter. From which entities the reference letters should be provided by: partners (distributors) or medical institutions?	The reference letter from the distributor could be provided in terms of the information about the company and its experience. The reference letter should be provided by the medical institution, duly signed by Chief physician or other authorized person in terms of the product quality criteria.
21	Will UNDP disqualify the bids if there is no significant experience in supplies to the medical institutions, but only small shipments to the pharmacies?	References from the medical institutions is a formal criterion, and the company should demonstrate such shipment experience unless this product has SRA approval. We recommend to submit such a bid, in this case UNDP will conduct the additional verification whether the product meets the standards.
22	In case the bank can't provide the guarantee in the requested form, what actions should be done?	Please submit the drafted guarantee including the bank's remarks in "Track changes" mode, and we will clarify if its possible to include these revisions. Some revisions could be accepted, some – not. You are kindly asked to submit the questions regarding the bank guarantee a couple of days in advance, but not the last day.
23	What actions should be done in case we have the patent for the product.	You submit all available patent certificates and provide the link to the respective source of information.

24	Should the European GMP certificate be confirmed by Ukrainian regulatory authorities?	No, in case GMP Certificate is issued by PICS Authorities.
25	Is it possible to bid only for the part of the lot?	No. Partial bids will be rejected.
26	Why are some of the medications combined in one lot, the other ones not?	This is the requirement provided by MOH to combine injectable medications for oncology with one INN, but different dosage, in one lot with the purpose of supplying different dosages from one Manufacturer caused by the necessity of combination of different dosages of finished drug forms /selection of dosages under prescribed scheme of treatment. There is no such a requirement for onco-hematology from MOH.
27	If the same product is requested according to two sub-programmes: onco and onco hematology, should it be proposed only once? One line in a table?	No, it should be mentioned separately for each of the sub-programmes, 2 lines in a table.
28	What format should be used for the Date of delivery? Should it be the specific date of the month, month or a period (weeks, months) during which the supply will be done.	As is convenient for you, according to your projection at the time of application.
29	If there is any risk that the State Company (warehouse) MOH can't take the delivery due to insufficient storage facilities.	UNDP has 2 signed contracts with such State Companies as "Ukrmedpostach" and "Ukrvaktsyna". Both of them have sufficient storage capacities and there were no cases of non-acceptance due to insufficient storage facilities.
30	Regarding the possible change of the procured quantities +/- 25%. When does UNDP inform about the real quantities to be procured?	At the time of the award, before signing the contract UNDP defines if the provided funds are sufficient to procure the requested quantities. If the provided funds are not sufficient, the quantities possibly will be reduced upon MOH's approval. In case of savings, UNDP requests MOH to confirm procurement of additional supplies and the respective ratio.
31	Is it possible to change the form of contract?	Contract (Purchase Order) is generated by the UNDP system and includes requirements/conditions, that are mentioned in the Invitation to bid.
32	If the company has been awarded for the procurement of 2 medications, one of which has been already registered, and the other one hasn't been yet, how many contracts will be concluded? One or two?	Two contracts will be concluded in order to avoid the registration process' influence on the close of the deal upon performance of the commitment to supply the registered medication. For non-registered medication the conditional contract will be awarded according to ITB.