

ITB UKR-HP-2016-09

Procurement of Anti-D immunoglobulin for the prevention of hemolytic disease of the newborn.

Dear participants, we draw your attention to the following when submitting the Bids:

- 1. The deadline for Bid submission is January, 23, 2017, by 10:00 a.m. Kyiv time;**
- 2. Bids should be submitted in electronic form to the e-mail address - tenders.ua@undp.org only.**

Questions and Answers including the minutes of the meeting with potential Bidders within the framework of tender ITB UKR-HP-2016-09 conducted in the UNDP's office on January, 12, 2017.

#	Question	Answer
1	What should be indicated in the "Reference" column in the Table of the Section 4 "Criteria for award and checklist of documents required" next to the columns for answers "Yes" or "No"?	Since each Bid includes significant quantity of documents you are asked to refer to the number of section/page, where the requested documents are enclosed.
2	You ask to describe the general approach and org structure of project management, the time schedule and measures taken by each employee, qualification of each employee in the sub-section 3.3. What should we indicate here?	It is a standard text of solicitation document. In this definite case you should indicate general information on org structure and on 1 key employee responsible for communication with UNDP on tender issues and further contract coordination.
3	If the contract is signed between UNDP and Head Office (Head Quarter) of the company, should we indicate contact info on key employee in HO or in the Representative Office of company in Kyiv?	You can indicate contact info on two key employees – on the side of HO and on the side of Rep Office in Ukraine.
4	Could we submit the Bank's guarantee in UAH?	Preferably in USD but in UAH it is also possible. Amount in UAH should be calculated by UNO exchange rate on the date of tender announcement (http://treasury.un.org).
5	Could you specify which currency exchange rate to be used – the one of National Bank of Ukraine or UNDP?	We use the operational currency exchange rate of UNO (http://treasury.un.org)
6	The solicitation document envisages 2 options of Product Standards: 1 (A+C) and 2 (B+C). Which variant should we select if our product is SRA approved – (A) and is registered in Ukraine – (B)? Is the experience of this product supply in Ukraine is necessary? Обязателен ли для данного продукта опыт поставок в Украине?	You provide all the necessary documents and we define by which option your product corresponds to the Product Standards. The experience of supply of this product in/to Ukraine is not necessary in case the criteria A+C is met.
7	Do you provide the sample of Authorization letter from manufacturer?	Authorization letter from manufacturer can be in free form.

8	<p>You request the proof of positive results of activity (reference letters), confirming the experience of work under similar contracts (<i>see Section 4 ITB "Compliance of Bidder with Qualifications Requirements"</i>)</p> <p>Do you need the experience confirmation on supply of only medicine quoted in this tender or the experience on the supply of other medicines is also acceptable? Medicines should be supplied only in/to Ukraine, in definite organizations or you also consider the experience of supply in other countries, to different counterparties?</p>	<p>The matter is about the checking of the experience of company's work in medicines supply, therefore we ask for confirmation of supply of any medicine in similar volumes in/to Ukraine or other countries, to any medical entities/organizations/counterparties.</p>
9	<p>Should the company have the minimum 3 years of experience of work in supply of definite medicine within the framework of criteria "Minimum 3 years of experience in similar nature and minimum 2 similar contracts fulfilled over the past 3 years?"</p>	<p>Company should demonstrate the experience of work with similar products.</p>
10	<p>If the company lacks several months of experience of work since the new company was established, the employees were transferred and so on, how can we proof our experience?</p>	<p>The company should provide the documents confirming its right of inheritance or other documents confirming the link between previous and new company.</p> <p>The company can also participate in consortium (refer to item #19 of Section 2 "Instruction to Bidders")</p>
11	<p>Terms of delivery - DAP-Kyiv, Central warehouse of MOH – is it the only one term of delivery?</p> <p>Can the representatives of Central warehouse of MOH customs clear and accept the goods placed in the "consignment stock"?</p>	<p>UNDP declares the common conditions for all the Bidders – it's DAP-Kyiv, Ukraine, (central warehouse of State enterprise), that would not be changed.</p> <p>If your Terms of delivery will correspond to DAP-Kyiv, Ukraine (Central warehouse of State enterprise) UNDP will be able to accept these goods.</p>
12	<p>Could we supply medicines in original package?</p>	<p>Yes, you could.</p> <p>At the same time the Labelling of primary package at the moment of supply must correspond to the one in the product's state registration record (State Register of Medicines in Ukraine). In case of any deviations found, the supplier must provide additional documentation to enable receipt of goods.</p> <p>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.</p>
13	<p>You request all the information regarding any past and current litigation during the last five (5) years, in which the Bidder is involved. It's quite a long period of time during which a big quantity of litigations could take place, especially in case of global corporation.</p>	<p>You should provide information (not the copies of documents) on the most relevant cases (that linked to the manufacturing or supply of medicines).</p>

		UNDP reserves the right on post-qualification checking, i.e. confirmation of accuracy, correctness and authenticity of information provided by Bidder.
14	The Latest Expected date for commencement of Contract is indicated as February, 23. Is it a date when the contract should be signed or the negotiations on contract should be started?	It is an approximate date when we expect the contract is signed.
15	Inspection of goods before/after shipment. Did you perform such inspections during previous supplies? How was it organized in practice?	<p>Upon receipt of an incoming batch, UNDP follow a thorough quality control procedure, which includes review of Certificates of Analysis (CoA) for each batch of finished product to be supplied, Registration Certificate with issued by the Ministry of Health of Ukraine, inspection against UNDP specifications, labelling and packaging.</p> <p>UNDP reserves the right to have at any time the items inspected, tested for quality assurance and rejected if found not in compliance with the requested specifications.</p> <p>During previous supplies UNDP inspected goods several times before shipment.</p> <p>Details are indicated in Section 3 "Schedule of Requirements and Technical Specifications".</p>
16	Does public opening envisage the opening of Bids in the presence of representatives of companies that participated in tender or in the presence of all the people who want to be there?	<p>The Bidders have to inform UNDP on their intention to participate in the procedure of Bids opening. During the opening the prices of all the Bids are announced and the protocol of opening is prepared.</p> <p>Only the representatives of companies which submitted their Bids would be allowed to participate in the opening procedure.</p>
17	The Bid shall include details of the Bidder's internal technical and quality assurance review mechanisms, all the appropriate quality certificates, export licenses and <u>other documents</u> . Should we obligatorily include the quite volume Standard Operational Procedures?	Not obligatory. Their listing is sufficient.
18	Who applies for the Certificate from MOH on VAT exemption for supplier- non-resident?	The representatives of Central warehouse of MOH apply for the Certificate from MOH on VAT exemption for supplier-non-resident <u>for each shipment</u> based on appropriate letter from UNDP and documents from supplier.
19	On which language the supplier-non-residents should prepare the Certificates of Analysis?	The Certificates of Analysis should preferably be bilingual: English-Ukrainian or English-Russian. In case it is impossible to provide bilingual Certificates, you are requested to provide also the translation validated by manufacturer.

<p>20</p>	<p>How could we confirm the experience of successful supply of medicine in/to Ukraine within the framework of criteria “Product is registered in Ukraine and Bidder successfully executed at least one contract for the supply of quoted medicine to/in Ukraine within the past three years (from December 2013)»?</p> <p>If a company has no experience in supply of the quoted product but has experience in supply of other medicines under the Programme, would it be taken into consideration?</p> <p>If Bidder had no experience of supply of quoted medicine in/to Ukraine but other suppliers supplied it, would it be taken into account?</p>	<p>The experience of successful supply of the product should be confirmed by at least one contract and/or confirmation from recipient on supply of quoted medicine in similar volume in/to Ukraine during the last 3 years (where “recipient” is medical entity), if there is no approval by Stringent Regulatory Authority (SRA).</p> <p>In case the Bidder has no the experience of supply of the requested medicine, it should provide the info on the supply of this medicine by other companies or manufacturer.</p>
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