Questions and answers on the results of pre-bid conference,
conducted on March 22, 2018 at UNDP office in Kyiv
Вопросы и ответы по результатам пред-тендерной конференции, состоявшейся
22 марта 2018 года в офисе ПРООН в Киеве

Procurement of anti-hepatitis C medicines/Закупка медикаментов для лечения гепатита С (REF: 94-2017-UNDP-UKR-HP)

Deadline for the Bids submission on ITB 94-2017-UNDP-UKR – April 02, 2018, 9:00 Kyiv time./
Окончательный срок подачи заявок по тендеру ПУТ 94-2017-UNDP-UKR – 02 апреля 2018 года, 9:00 по Киевскому времен.

Bids submission – electronic on https://etendering.partneragencies.org **/ Подача заявок – электронная, через систему** https://etendering.partneragencies.org

No.	Вопрос / Question	Ответ / Answer
1.	If we do not have GMP certificate issued by PIC/s or WHOPIR and do not have WHO prequalification, will our Bid be accepted?	There should be GMP certificate issued by a country member of PICs or WHO Public Inspection Report (WHOPIR). This is a must requirement under all quality criteria options.
2.	According to the Option 4 is it necessary to provide Letter on Acceptance for Assessment for FPP pre-qualification by WHO. Does it mean that you will evaluate either the bids that are WHO-pre-qualified or in the process of WHO-prequalification?	No, submitting of this letter is not mandatory. In such a case you must submit filled-in Interagency finished product questionnaire attached as Annex #5 to ITB with copies of requested documents and/OR ICH Common Technical Document (CTD)* for the product/s quoted.
3.	Option 4 is applicable for products which neither SRA registered nor WHO pre-qualified nor GF approved products?	Yes, as there are not that many products that are SRA registered or WHO-prequalified (this mostly links to the originators), UNDP introduced this option in order to widen the pool of participants.
4.	FOR LOTS ##1-4 only. If product is selected under Option #4, how such products can be registered in Ukraine then (as per the Decree of the MOH #721 same pubic assessment report (PAR) and dossier should be submitted as in the origin country and if the product is registered in India and there is no PAR) In case of the standard registration it might take 6 months or. How fast this could be done?	UNDP is aware of this, for some cases fast-track registration won't be applicable, therefore products should go through the standard procedure. Considering urgent need of the patients in these medicines, patients' organizations and UNDP will collaborate with the MOH in order to facilitate the process. As well it will very much depend on the company and its interaction with State Expert Centre (prompt responses to clarification, submitting of all required documents, etc.).
5.	FOR LOTS ##1-4 only. If the product is not registered timely due to external reasons, will the Performance Security be cashed up?	Each case will be assessed separately whether to cash Performance Security or not based on assessment of the reasons for delay and information provided by the company and State Expert Centre
6.	FOR LOTS ##5-6 only.	By the time of supply, the products must be either registered with the Ministry of Health of the Republic

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	Question re registration in Kazakhstan. Does it required to get medicine registered prior delivery?	of Kazakhstan confirming their legal use in Kazakhstan or one-time import permit should be obtained in accordance with Order of the Ministry of Health and Social Development of Kazakhstan #668 dd 17.08.2015[1]. "SK-Pharmacy", LLP will submit the documents for obtaining of one-time import permit, however selected company should provide documents required as per above Order upon request.
7.	Bid Security could be one for Ukraine and Kazakhstan?	One Bid Security could be provided.
8.	Is it possible to apply with the medicine that is not WHO-prequalified, not GF approved, not registered and doesn't have the experience of supply into Ukraine/Kazakhstan?	Yes, if it is not a Sofosbuvir's lots #1 and 5, you can apply with such medicines, and UNDP will evaluate such medicines within the option 4. To prove supply experience, you shouldn't mandatory link to Ukraine or Kazakhstan, it could be worldwide.
9.	What is the contact person in UNDP in relation to this tender?	Please, refer to p. 18 of the ITB: yana.dovga@undp.org with CC health.procurement@undp.org
10.	The deadline of the bid submission is not fixed in ITB.	It is fixed in the e-tendering system: April 02, 2018; 9am by Kyiv time.
11.	How should price proposal be filled-in in the e-tendering system?	It should be filled in as per instructions provided.
12.	How we will understand that the submission through the system is correct?	The system will send you confirmation of bid submission.
13.	What is the LTA?	UNDP might enter into a long-term agreements (LTA) with the selected suppliers as a result of this ITB. The initial agreement/s shall be concluded for a period of 1 (one) year and may be extended for additional 2 (two) years, subject for satisfactory performance of the supplier/s. UNDP plans to place Purchase Orders for the quantities mentioned below (indicated in the Chapter "Products Specification"). The future volumes are expected to remain in the same ranges, however UNDP does not guarantee placement of Purchase Orders for any quantities.
14.	Do we need to submit an Authorization certificate in case if Manufacturer applies?	It's not required in case if the manufacturer applies.
15	Subsection 3.3 PERSONNEL (3.1 , 3.2,3.3): please confirm if the details and CV of key account manager who handles UNDP account should be sufficient.	Yes.

[1] https://online.zakon.kz/Document/?doc_id=36645437#pos=0;0