Questions and answers on the results of pre-bid conference,
conducted on March 13, 2018 at UNDP office in Kyiv

Procurement of anti- hepatitis C medicines (REF: 94-2017-UNDP-UKR-HP)

Deadline for the Bids submission on ITB 94-2017-UNDP-UKR-HP has been extended till – April 2, 2018, 09:00 Kyiv time (UTC +3:00), inclusively.

ATTENTION!!!

The following amendments were made to the ITB document: Lots #5-6 have been added to be procured under project of UNDP Kazakhstan "Procurement of medicines for treatment of socially significant diseases (Kazakhstan)":

Lot #	International nonproprietary name	Pharmaceutical presentation	Strength	Quantity	Delivery Destination
Procurement Support Services to the Ministry of Health in Ukraine					
1	Sofosbuvir	tablets	400 mg	62 361	Ukraine
2	Sofosbuvir/ Ledipasvir	tablets	400 mg/90 mg	170 894	Ukraine
3	Daclatasvir	tablets	60 mg	52 703	Ukraine
4	Sofosbuvir/ Velpatasvir	tablets	400 mg/100 mg	49 633	Ukraine
Procurement of medicines for socially significant diseases (Kazakhstan)					
5	Sofosbuvir	tablets	400 mg	354 144	**Kazakhstan**
6	Daclatasvir	tablets	60 mg	354 144	**Kazakhstan**

All interested companies are highly encouraged to apply for newly announced lots #5-6 in order to cover patients with Hepatitis C in Kazakhstan.

ITB document has been revised and changes are highlighted in yellow.

Second pre-bid conference will be conducted on March 22, 2018. For details please refer to the revised ITB.

Bids submission – electronic on https://etendering.partneragencies.org
Clarifications shall be addressed to: health.procurement.ua@undp.org; yana.dovga@undp.org

No.	Question	Answer
1.	Taking into account that UNDP might sign LTA with awarded companies, which factors influence UNDP's decision with whom LTAs would be signed?	Based on the results of competitive process, UNDP might consider signing LTA with reliable and financially stable companies and in case the proposed prices are deemed competitive within tender and vs found referent prices.
2.	How will the prices reference check be conducted in terms of value for money assessment?	For the reference check prices published in the EU and CIS countries where available in the public domain and reports on pricing issued by other organizations will be used.
3.	**For lots: 1-4 only.** What is the best way for application from the non-residential manufacturer and local distributor, which has no license for wholesale trade in Ukraine?	The offer might be submitted either by distributor or manufacturer or consortium of the both companies (as per p.19 of ITB Document). Section 6 of ITB document should be filled in case bid is submitted by consortium. But please note that in case bid is submitted either by local distributor or consortium where local distributor is act as a main company, VAT for lots #1-4 shall be included.
4.	Is the package with Ukrainian language for lots 1-4 and Kazakh language for lots #5-6 is mandatory for shipment?	• **UKRAINE (LOTS #1-4):** Each package shall contain instructions for the use of the medicinal product in Ukrainian (preferably) or the original language. 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 paper 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). In case product is not registered, Ukrainian instruction submitted for registration purposes shall correspond to one approved by SRA authorities (e.i. prescription and indication for the use). • **KAZAKHSTAN (LOTS #5-6):** Each package shall contain instructions for the use of the medicinal product in Russian and Kazakh (preferably) or in original language. In case medicines are delivered in original packaging with instructions for the use in the original language, Russian and Kazakh translation of instruction for the use shall be provided in the electronic format at the time of supply and marking by stickers in Russian and Kazakh might be required.

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5.	Shall we include WHO prequalification and GF conclusion as part of bid submission?	Yes, at least one of them should be submitted. In such case it is preferably to include both of them.
6.	Are there any specific conditions for electronic submission?	Before submission you should register in the system, following the guidance provided. Should you have any difficulties with registration – let us know as soon as possible before the deadline. You're highly recommended to submit your bids at least 1 day before the deadline.
7.	**For lots: 1-4 only.** Do the medicines' shelf life or prescription change in registration dossier after PO acceptance impact the delivery?	Shelf life change should be supported by manufacturer's official letter; regarding prescription - medicine should be appropriate for hepatitis C treatment.
8.	Are the criteria for bid submission equal for all Lots?	There are 3 Options for LOT 1 and 5 and 4 Options for LOT 2, 3, 4. Please refer to the Section 3 of ITB for details.
9.	Will UNDP check the voluntary licenses for medicines in case it is granted by patent holder?	UNDP reserves the right to request the license if it was not submitted. In case the voluntary license is confidential, the confirmation from patent holder should be presented.
10.	Is the medicine delivery possible if the registration in Ukraine is ongoing but not finalized?	Delivery to Ukraine is not possible before registration certificate obtaining (for lots #1-4). For lots #5-6: By the time of supply, the products must be either registered with the Ministry of Health of the Republic 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. "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. Failure to obtain registration and submit the required documents for obtaining one-time import permit will serve, at no claim to UNDP, as a ground for contract termination, liquidating Bid or Performance Security amount and either awarding the next qualified Bidder or initiating a new bidding process. The decision to transfer the award or initiate a new ITB will be at the discretion of UNDP. While indicating delivery dates in

No.	Question	Answer
		the Bid, timelines required for the registration process or process of obtaining one-time import permission should be considered.
11	SECTION 4: Statement of Satisfactory Performance from the Top 3 Clients in terms of Contract Value the past 3 years. Is this a letter of reference or does this refer to as a self-statement from the Bidder on their Top 3 clients which they believe were satisfactory with the Bidder's performance/service?	At least 3 reference letters shall be provided from the third Parties (partners) to prove experience in similar nature of contracts.
12	For non WHO PQ products to prove eligibility, with Filled-in Interagency finished product questionnaire attached as Annex 5 with copies of requested documents do we also need to submit CTD along with this or only filled interagency questionnaire will suffice?	You can provide either filled-in Interagency finished product questionnaire attached as Annex #3 to ITB with copies of requested documents or ICH Common Technical Document (CTD) for the product/s quoted. As well you can provide both of requested documents.
13	With reference to requirement "Please provide the detailed Implementation Schedule" in ITB in form 7 please confirm will it be sufficient if we give the lead time against each product quoted, and please clarify what document is required as a supporting document for lead time.	You could either fill-in required information in Annex 5 or provide it as a per of Section 7. Supporting documents are not required.
14	Please clarify the unit of measurement (tablets or packs) for the solicited products	QTY is indicated in tablets.
15	From ITB we understand supplies can be made with original packing (Anglo-French) and extra leaflet to be supplied separately individually with each pack, please can you elaborate on packing requirement	Original pack is allowed. • UKRAINE (LOTS #1-4): Each package shall contain instructions for the use of the medicinal product in Ukrainian (preferably) or the original language. 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 paper 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). In case product is not registered, Ukrainian instruction submitted for registration purposes shall correspond to one approved by SRA authorities (e.i. prescription and indication for the use).

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16	For Lots 1-4 we intend to initiate filing for unregistered products in Ukraine that are under assessment for FPP prequalification with WHO, will submission with Ukraine Health Authorities suffice your requirement or approval is required?	UNDP could accept non-registered products, if they correspond to quality requirements reflected in the ITB. However prior to supply products must get registration in Ukraine for lots 1-4. <u>For lots #5-6:</u> By the time of supply, the products must be either registered with the Ministry of Health of the Republic 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 . “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. Failure to obtain registration and submit the required documents for obtaining one-time import permit will serve, at no claim to UNDP, as a ground for contract termination, liquidating Bid or Performance Security amount and either awarding the next qualified Bidder or initiating a new bidding process. The decision to transfer the award or initiate a new ITB will be at the discretion of UNDP. While indicating delivery dates in the Bid, timelines required for the registration process or process of obtaining one-time import permission should be considered.
17	In Option5 E+F: List of previous supplies of product/s quoted. Do we need to furnish the data of supplies made to Ukraine or supplies across the globe?	Under above supplies across the globe are meant.