Establishment of Long Term Agreements with Quality Control Laboratories for testing of pharmaceuticals in support of the UNDP Country Offices implementing Health Project	DATE: June 5, 2020 **REFERENCE:** 151-2020-HIST-RFP-LTA-QCLABS	

Subject: Pre Proposal Minutes of Meeting and Clarifications No. 1

Date: 2nd June 2020

Time: 11:00 am (Copenhagen time)

Venue: Zoom

Present from UNDP:

Zafar Yuldashev - Procurement Specialist
Jean-Michel Caudron – QA Specialist
Zaynab Rashan – Procurement Analyst

Present from Bidders:

Name of Company	Country
National Institute of Drug Quality Control of Vietnam NIDQC	Vietnam
TUV SUD PSB Pte LTD	Singapore
Institute for Pharmaceutical and Applied Analytics GmbH (InphA)	Germany
Medicines Control Authority of Zimbabwe (MCAZ)	Zimbabwe
USP	Ghana
Institute of Drug Quality Control Ho Chi Minh city (IDQC HCMC)	Viet Nam
SGS Lab Simon SA	Belgium
Mission for Essential Drugs and Supplies MEDS Centre	Kenya
INCQS - Instituto Nacional de Controle de Qualidade em Saúde	Brasil
CHMP	France

Upon having companies introduce themselves, UNDP provided a presentation on the following:

1- Background and the purpose for establishment of the Long Term Agreements.
2- Instructions to Bidders.
3- How the evaluation will be conducted.
4- Award criteria.
5- Submittal requirements and Returnable Bidding Forms.

Questions and Answers:

Bidder Question No. 1:

1/ Term of reference (Section 5)
- Item 3.2, page 29 said "*The specifications / methods for analysis to be used are the ones defined by the manufacturer*". In case, specifications / methods for analysis are specified in International Pharmacopoeia (Int'P), British Pharmacopoeia (BP), US Pharmacopoeia (USP) and Manufacturer also has In-house specification/ methods for analysis for this product, so:

A-Products will be tested following Pharmacopoeia or In-house specification/ methods for analysis? Do we need to wait for approval form Manufacturer to select specification/ methods for analysis?

B- Priority required for selecting Pharmacopoeia of Int'P, BP, USP or EP?

C-With regard to test parameters, it should be conducted the full tests as specified in the specifications (Including Compendial and In-house) or just the tests that are indicated in Form F. We have found that some tests such as Particulate matters, Constituted solution, Melting point and Optical rotation that may require by Pharmacopoeia have not been included in Form F.

UNDP Answer No. 1:

A- UNDP will ask the QC lab (awarded bidder) to test a product against the manufacturer's stated specification; if it states "In House" the testing will be done against "In House" specs, even if monographs are published in the BP, USP, EP or Int. Pharm.

B- Same answer as in A above: the product will be tested against the manufacturer's stated pharmacopoeia.

C- Yes, please refer to Section 3.2. "Analysis of Samples" in the Terms of Reference where it stipulates "The specifications / methods for analysis to be used are the ones defined by the manufacturer and confirmed either on a manufacturer's Certificate of Analysis or submitted as a specification sheet by the manufacturer. The laboratory will use the monograph from the International Pharmacopoeia, the British Pharmacopoeia, the US Pharmacopoeia or the European Pharmacopeia if these are the declared specifications, or in case of In-House specifications, the lab is expected to transfer and validate the method given by the manufacturer prior to performing the quality control analysis".

Bidders are required to quote their prices for the testing of the parameters specified in Form F based on the existing above mentioned Pharmacopoeia, excluding In-House (IH) specifications, since the testing against IH specifications might require additional steps (including transfer and validation of the method given by the manufacturer prior to performing the quality control analysis), at this stage it is difficult to predict the estimated costs associated to perform such quality control tests. Therefore, for the evaluation purposes the price schedules (Form F) should be submitted by proposers.

Bidder Questions No. 2:

2/ RFP form
- Can we change information in RFP form? For example, in final row of **Form B**, can we only listed documents that are attached to this Form

- Can we change template of RFP form? For example, **Form F**, we would like to add more columns or rows for Reference Substances cost or additional tests that not been specified in Form F?
Could we rearrange the table in **Form F** into rows instead of column as below?

Product Type	Parameters	Routine testing costs per batch (USD)	Costs complete testing (USD)
"Name of medicine"	Appearance	A	
	Identification	B	
	Assay by HPLC	C	
	……	…	A+B+C…

UNDP Answer No. 2:

Please refer to UNDP Answer No. 1 Section C, since it was similar question. Furthermore, the form should remain unchanged. The provided Form is a standard form to follow, which represents the parameters to be evaluated under this bidding process. As part of a secondary bidding processes among the LTA holders, additional test parameters might be reflected in Requests for Quotations (RFQs) as appropriate.

Bidder Question No. 3:
- Item 3.2, page 29 said: "The individual **testing report** should include a standardized management summary including information regarding the country, the product, batch number, the manufacturer, the sample data, the key findings of the analytical test and a conclusion on the compliance or non-compliance of the product tested with the specifications. Attached to the report should be the **full analytical report** duly signed by the authorized signatory".
What is different between "Testing report" and "Full analytical report"?
Is "Full analytical report" following WHO Model Analytical Test Report?

UNDP Answer No. 3:
"Testing report" is the summary of the testing: product, manufacturer, batch number, requesting entity and country, outcome of the test and conclusion.

"Full analytical report" is in accordance with the WHO model

Bidder Questions No. 4:
3/ Submission
-BDS No.16 said: "*Format: PDF files only*", do we need for upload .xml file as the RFP form?

UNDP Answer No. 4:
Proposers may submit in other formats, However, all documents that require the signature and stamp of the Proposer must be submitted in PDF.

Bidder Question No. 5:
Are Bidders allowed to submit quotations for the other Regions even if the company is not located in that Region?

UNDP-Answer No. 5:

Proposers are welcomed to submit their proposals for any or all of the Lots that they consider applicable. UNDP will evaluate and award the contracts as per the award criteria set in the RFP document. Please refer to page 20, BDS No. 17 as well as page 21, BDS No. 35 for details.

Bidder Question No. 6:
Do the number of Batches of 380 referred to in the Terms of Reference under "Section 6. ***List of products for cost estimates for laboratory analysis"*** cover all the Regions?

UNDP-Answer No. 6:
RFP specifies the historical data of the tests performed per annum covering all regions. The future number of tests is expected to be approximately similar or even higher.

Bidder Question No. 7:
Please explain the duration of the Long Term Agreement as there seemed to be a contradiction in the sentences provided: page 20, Section 19 where it stipulates that LTA(s) shall be established for three years and shall be renewed on yearly basis subject to satisfactory performance, then on page 30 it stipulates "Extension of LTAs can be done up to a maximum of 3 years in total".

UNDP-Answer No. 7:
The initial LTA will be signed for one year, with the possibility of prolongation for additional 1+1 years, subject for satisfactory performance.

No additional questions were asked, so the pre bid conference was closed. All participants were thanked for joining the event and proposers were advised to avoid last minute submission through the e-tendering platform and to upload the files of Proposals well in advance.