United Nations Development Programme

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18 May 2016
Geneva, Switzerland

CLARIFICATIONS No. 3 TO UNDP'S ITB/REF/GFATM05-2016
Reference Number 29416

1	QUESTION:	Could you clarify if any vendor registration procedure needs to be completed in furtherance of this submission?
	UNDP:	In so far as vendor registration, we would recommend that you register yourselves in the United Nations Global Marketplace, if you have not already done so.
2	QUESTION:	Concerning Section 6 of the ITB - Technical Bid Form can we provide you with a signed letter covering points: 1.1 Brief Description of Bidder as an Entity 1.2. Financial Capacity 3.1 Management Structure: 3.2 Primary Contact Person(s) 3 Qualifications of Key Personnel. And what type of information is required to cover the point in section 6: 2.1.1 Freight Forwarder Details and Arrangements Lastly, there is not an indicated place to sign the document for section 6 and 7, would you please confirm that the document shall be sent unsigned to you.
	UNDP:	Section 6 of the ITB – the Technical Bid Form requires the following: 1. Expertise of your company a. Brief description of your company b. Financial capacity c. Track record & experience (a table of which is provided on p.37 to capture the relevant attributes) 2. Scope of Supply a. Completion of the table on p.39 (an Excel file is available at the below link for ease of completion). b. Freight forwarder details and arrangements – outlining the freight and insurance providers your company will utilize for deliveries into Sudan pursuant to the 2010 Incoterms CIP, CPT and if no capacities, please clearly indicate so in response to this section. c. Technical and Quality Assurance Mechanisms d. Disclosures pursuant to the Instructions to Bidders (Section 2) inclusive of export licenses, dangerous goods e. And any other relevant information pertaining your technical capacities overall. 3. Management a. Management structure b. Primary contact person(s) c. Qualifications of key contact person

<table>
<tr><td></td><td></td><td>http://procurement-notices.undp.org/view_notice.cfm?notice_id=29416

It would be advisable as you prepare the above documentation that signatures are afforded to each write-up, table, etc. as part of your submission.</td></tr>
<tr><td rowspan="2">3</td><td>QUESTION:</td><td>We would refer to Page 26 of the ITB, and the required medicines table - Item 21 Heparin Sodium – the dosage form is noted as 1ml ampoule – but the unit of measure is cited as a vial. Could you please clarify?</td></tr>
<tr><td>UNDP:</td><td>The correct specifications for Item 21 to the list of medicines and health products sought under this tender is as follows:

<table>
<tr><th>Item #</th><th>Pharmaceutical Substance (INN)</th><th>Route of Administration</th><th>Dosage Form</th><th>Strength</th><th>Unit of Measure (UOM)</th><th>Total Quantity in UOM</th></tr>
<tr><td>21</td><td>Heparin sodium</td><td>Injection</td><td>5ml vial</td><td>5000 IU/ml</td><td>Vial</td><td>1,000,000</td></tr>
</table>
</td></tr>
<tr><td rowspan="2">4</td><td>QUESTION:</td><td>We would like to bid for one product, but it will take 2 to 3 weeks to get the CPP from the Federal Agency. My question is can we still bid for this product and send the CPP once we receive it or that would disqualify us?

Another question is regarding the disqualification, is it done item by item or all items together. Is disqualifying for one product would make us loose the whole Tender?</td></tr>
<tr><td>UNDP:</td><td>We would presume from your question, you may be without a valid Certificate of Pharmaceutical Product specific to one of the items sought under this tender. If you are unable to provide such CPP, we would suggest in the product questionnaire to the relevant product, this point is noted and when a CPP can be expected. The ability (and/or inability) to comply with the documentation requirements will be factored into the evaluation process.

If one CPP for a specific product is not provided as may be the problem per your question, it may should not affect consideration of other products, assuming all requested documentation to the balance of products you intend to bid for is provided in full.</td></tr>
<tr><td rowspan="2">5</td><td>QUESTION:</td><td>Would you please clarify if Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK is considered as Stringent Regulatory Authority (SRA)?</td></tr>
<tr><td>UNDP:</td><td>For purposes of this tender, a Stringent Regulatory Authority is defined by WHO as a regulatory authority which is: (a) a member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (as specified on www.ich.org); or (b) an ICH observer, being the European Free Trade Association (EFTA), as represented by Swissmedic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time).

Specifically, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK would be considered a SRA.</td></tr>
<tr><td rowspan="2">6</td><td>QUESTION:</td><td>We have seen the recent posted clarification of the LTA entity being UNDP in NY USA and the purchase orders would be released by UNDP Sudan.

But would our commercial invoices indicate a "Bill to" & "Ship to" entity as NMSF Sudan? In other words, who is the buyer? And who is the receiver of the goods?</td></tr>
<tr><td>UNDP:</td><td>For purposes of establishing the Long Term Agreements (LTAs), the UNDP party will be: Procurement Support Office, Bureau of Management (Headquarters)</td></tr>
</table>

		1 United Nations Plaza, 17th floor New York, NY 10017 USA Once LTAs are established and Purchase Orders are to be placed, the contracting (buyer) and invoicing party will be: UNDP Sudan Gama'a Avenue,House 7,Block 5 P.O. Box 913 Postal Code 11111 Khartoum Sudan Goods will be consigned and shipped to: NATIONAL MEDICAL SUPPLIES FUND P.O. BOX 297, KHARTOUM, SUDAN
7	QUESTION:	Do we need to submit bidder qualification documents?
	UNDP:	Yes, pursuant to the tender, all eligibility documentation requirements outlined in Data Sheet #26 and 27 on pages 20-22 of the ITB must be provided.
8	QUESTION:	We have a question on Item number 3 Adult hemodialysis kit; which states firstly that should be compatible to Gambro. Why is Gambro mentioned by name? And can you please clarify the specification of the dialyzers as well as the product quality standard required for the consumables?
	UNDP:	With regards to Item 3 – Adult Hemodialysis Kit please be advised that the consumables should be suitable for use on Gambro or other dialysis machines. • Dialysers used for haemodialysis treatment shall be approved by a stringent regulatory authority and with the specifications of a surface area 1.7mm². • Blood tubing sets used for haemodialysis treatment shall be approved by stringent regulatory authority. • Arterio-venous needles used for haemodialysis treatment shall be approved by stringent regulatory authority. • Dialysates used for haemodialysis treatment shall be approved by stringent regulatory authority and shall be accompanied at the time of delivery by a certificate of analysis from an accredited laboratory.