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9 May 2016
Geneva, Switzerland

CLARIFICATIONS No. 2 TO UNDP'S ITB/REF/GFATM05-2016
Reference Number 29416

<table>
<tr><td rowspan="2">1</td><td>QUESTION:</td><td>Is it is possible for UNDP to consider extending the closing date of the tender to comply with the submission requirements?</td></tr>
<tr><td>UNDP:</td><td>Yes, the deadline of the tender has been extended to Monday, 23rd May at 16:00 local Copenhagen time.</td></tr>
<tr><td rowspan="2">2</td><td>QUESTION:</td><td>Could you please share the actual volumes procured by MOH/NMSF in 2014 and 2015 of the items sought under this tender?</td></tr>
<tr><td>UNDP:</td><td>Yes, please refer to p.4 of these clarifications for an overview of 2014 and 2015 volumes we understand to have been procured by MOH/NMSF.</td></tr>
<tr><td rowspan="2">3</td><td>QUESTION:</td><td>Could you please provide Excel files for both the Technical Bid Form and the Price Schedule Form for ease of completion?</td></tr>
<tr><td>UNDP:</td><td>Yes, please find the forms available on:
http://procurement-notices.undp.org/view_notice.cfm?notice_id=29416</td></tr>
<tr><td rowspan="2">4</td><td>QUESTION:</td><td>Could you please advise on the requested type of Antihemophilic Factor (Factor 8, Factor 9 or other) sought under Items 6 and 7 of the Required Medicines (p. 26 of the ITB)?</td></tr>
<tr><td>UNDP:</td><td>As to Items 6 and 7 part of the Required Medicines, Medical and Laboratory Equipment and Consumables, the correct specifications are 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>6</td><td>Antihemophilic Factor VIII/von Willebrand Factor Complex (Human)</td><td>Injection</td><td>vial</td><td>500 IU</td><td>Vial</td><td>12,000</td></tr>
<tr><td>7</td><td>Antihemophilic Factor VIII/von Willebrand Factor Complex (Human)</td><td>Injection</td><td>vial</td><td>250 IU</td><td>Vial</td><td>2,000</td></tr>
</table></td></tr>
<tr><td rowspan="2">5</td><td>QUESTION:</td><td>Regarding the Articles of Incorporation and the Certificate of Registration, which are issued in Arabic; could you please clarify if the Arabic certificates will be acceptable or must they be translated to English?</td></tr>
<tr><td>UNDP:</td><td>We would suggest to please send the certificates in their original language and indicate in English as to their authenticity.</td></tr>
<tr><td rowspan="2">6</td><td>QUESTION:</td><td>Can we still bid for products which do not match the concentration for the products listed in the tender?</td></tr>
<tr><td>UNDP:</td><td>Please refer to p. 17 of the ITB - Alternative bids to product specifications will NOT be accepted.</td></tr>
<tr><td>7</td><td>QUESTION:</td><td>Can we bid for products in vials instead of ampoules?</td></tr>
</table>

	UNDP:	Please refer to p. 17 of the ITB - a Bidder may submit an alternative Bid for packaging presentations (e.g., blister pack vs. bottles, tablets vs. capsules) only. Alternative Bids must meet the base case (i.e., compliance with the product specifications requested by UNDP in this ITB). UNDP shall only consider the alternative Bids offered by the Bidder whose Bid for the base case was determined to be the Bid with the highest evaluated score.
8	QUESTION:	In the answer of the question #4 to the earlier issued Clarifications, you have wrote "The tender stipulates the quality standards that are sought of the medicines and health commodities, in that they must have approval of a Stringent Drug Regulatory Authority (SRA) as defined by WHO." a. Does it mean that, we can participate only if we are approved or certified by SRA? On page 21-22, Instruction to Bidder "DATA SHEET" Point no. 27, in the Product questionnaire, you have mentioned "Registration certificate from the SRA". b. So, is this mandatory? Because in the same point no. 27, you have also mentioned requirement for "GMP certificate by WHO, SRA, PIC.s or UN Agency. c. So, please clarify this, whether we can take part with WHO-GMP certificate, or we cannot take part?
	UNDP:	The Clarifications to ITB/Ref/GFATM05-2016 issued 28 April 2016, reiterate that the product quality standard that must be in place is that the medicine must be approved by a Stringent Drug Regulatory Authority (SRA) as defined by WHO, and would refer you to p. 28 of the ITB itself. The product questionnaire does request both the SRA endorsement and GMP certificate along with a number of other documents are submitted pursuant to each product you intend to bid for. Please note, GMP certification alone will be insufficient for purposes of compliance.
9	QUESTION:	While I am preparing the product technical questionnaire (section 8), I have a question on the copy of registration certificate from Stringent Regulatory Authority (SRA). Is it mandatory to submit the certificate or optional that will be advantageous to win the bidding if we have?
	UNDP:	Regarding the documentation requirements, including certificates from SRAs, please note these must be provided as part of the tender. If not provided, an offer may risk being disqualified for non-compliance.
10	QUESTION:	The products which we want to participate in this tender are manufactured in Country XYZ. The products are not approved by a stringent regulatory authority (like USA, EU, Japan or Australia) and they are also not registered with the NMPB in Sudan. Can we still participate?
	UNDP:	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).
11	QUESTION:	We are a pharmaceutical manufacturer and we do not have products you require; however, our sister company manufacturers some of the required products, do we need a Letter of authorisation from our sister company to allow us to bid?

	UNDP:	The tender stipulates the quality standards that are sought of the medicines and health commodities, in that they must have approval of a Stringent Drug Regulatory Authority (SRA) as defined by WHO. As a representative of pharmaceutical supply (e.g., distributor, wholesaler), should your company represent manufacturers with the requisite quality threshold specific for this Sudan tender, you are eligible to participate. For purposes of representation, yes, a valid letter of authorization will be necessary to exemplify the relationship maintained amongst the parties (agent and principal).
12	QUESTION:	As an agent of more than one principal company, with each principal company able to quote for some products; should we submit one bid or multiple bids on behalf of each principal company we represent?
	UNDP:	Please submit one bid in its entirety in your capacity as an agent, each product however, will require its own set of documentation as outlined in Section 8 of the ITB.
13	QUESTION:	Could you please clarify what is needed to address point 15.2 of your invitation document?
	UNDP:	Clause 15.2 basically requests compliance with the Technical Specifications outlined in Section 3 of the ITB and the documentation requirements set forth in Data Sheet 26 and 27. Further, if any import or export licenses are required by your company, that such is indicated as well as your company's ability to obtain these licenses and if any goods you intend to bid on would be construed as "dangerous goods," this too is specified.
14	QUESTION:	Regarding the payment process, will it be through bank to bank transactions (i.e., the beneficiary will submit the original document to the nominated bank and got back their payment according to agreed upon banking terms)?
	UNDP:	As to the payment terms, these are summarized in Section 10 of the tender outlining UNDP's General Terms and Conditions – with payment to be effected 30 days net of receipt of the Supplier's invoice for the goods and copies of the shipping documents specified in issued Purchase Orders. UNDP does not issue letters of credit.
15	QUESTION:	Who will be in charge for performing the importation/clearance processes (including the issuance of the importation & clearance licenses)?
	UNDP:	As per the Incoterms (2010) for CIP (airbound) and CPT (seabound) shipments, MOH/NMSF will be responsible to clear the goods for import at the named air/seaport of destination.
16	QUESTION:	We understand the general regulation for biological products and their residual shelf life is 2/3 upon arrival while UNDP is requesting 75%, please advise.
	UNDP:	Supplier products shall comply with the shelf life approved by the relevant SRA (if unregistered) or by the NMPB (where registered). UNDP requires a minimum of 85% remaining shelf life at the date of dispatch and not less than 75 % remaining shelf life on arrival to The Sudan.
17	QUESTION:	We understand that UNDP has requested copies of shipping documents to be sent to UNDP 15 working days prior to shipment, this is not applicable for sea shipments as the Bill of Lading is issued after shipment departure, and further the Certificate of Origin takes time in issuance and authentication and an AWB may be canceled during the 15 days, kindly check & advise.
	UNDP:	We refer you to p.30 of the ITB – For air shipments, shipping documents shall be provided 15 business days in advance of dispatch to the NMSF to enable customs clearance and simultaneously a copy issued to the UNDP Sudan Country Office. For sea shipments, shipping documents shall be provided 10 business days in advance of dispatch. Any impediment to delivery must be advised in writing to MOH/NMSF and UNDP Sudan as soon as possible.

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Item #	Pharmaceutical Substance (INN)	Route of Administration	Dosage Form	Strength	Unit of Measure (UOM)	Total Quantity in UOM	Actual Volumes Procured 2015	Actual Volumes Procured 2014
1	Aciclovir	Injection	vial	250mg (as sodium salt)	Vial	17,000	6,000	6,000
2	Adrenaline	Injection	1 ml ampoule	1mg/ml	Ampoule	600,000	1,235,600	0
3	Adult Haemodialysis Kit compatible to Gambro Machine	see kit components below			Kit	110,000	200,000	150,000
4	Albumin (Human) 20%	Injection	100 ml infusion bottle	20g	Bottle	10,000	60,000	25,000
5	Amiodarone	Injection	3ml ampoule	50mg (hydrochloride)/ml	Ampoule	20,000	26,995	25,000
6	Antihemophilic Factor VIII/von Willebrand Factor Complex (Human)	Injection	vial	500 IU	Vial	12,000	2,499	0
7	Antihemophilic Factor VIII/von Willebrand Factor Complex (Human)	Injection	vial	250 IU	Vial	2,000	2,000	0
8	Atropine	Injection	1ml ampoule	1mg (sulfate)	Ampoule	700,000	360,200	0
9	Carbamazepine	oral administration	100ml bottle	100 mg/5ml	Bottle	30,000	50,000	20,000
10	Ceftazidime	Injection	vial	250mg (as pentahydrate)	Vial	40,000	0	0
11	Cefuroxime	Injection	vial	750mg	Vial	500,000	800,144	386,000
12	Clopidogrel*	oral administration	tablet	75mg (as hydrogen sulfate)	Tablet	340,000	750,000	1,306,000
13	Dexamethasone	Injection	1ml ampoule	4 mg (as sodium phosphate)/ml	Ampoule	2,000,000	1,999,375	336,000
14	Digoxin	Injection	2ml ampoule	250 µg/ml	Ampoule	40,000	0	20,000
15	Enoxaparin sodium	Injection	solution for injection	20mg (equivalent to 2,000 IU anti-Xa activity)	Pre Filled Syringe	80,000	3,000	15,000
16	Enoxaparin sodium	Injection	solution for injection	40mg (equivalent to 4,000 IU anti-Xa activity)	Pre Filled Syringe	80,000	6,324	30,000
17	Enoxaparin sodium	Injection	solution for injection	60mg (equivalent to 6,000 IU anti-Xa activity)	Pre Filled Syringe	60,000	4,000	10,000
18	Enoxaparin sodium	Injection	solution for injection	80mg (equivalent to 8,000 IU anti-Xa activity)	Pre Filled Syringe	80,000	7,572	17,000
19	Ephedrine Hydrochloride	Injection	1ml ampoule	30mg/ml	Ampoule	700,000	174,700	0
20	Furosemide	Injection	2ml ampoule	10mg/ml	Ampoule	3,000,000	1,965,150	1,059,700
21	Heparin sodium	Injection	1ml ampoule	5000 IU/ml	Vial	1,000,000	300,000	699,994
22	Hydralazine	Injection	2ml ampoule	20 mg (hydrochloride)	Ampoule	30,000	10,000	30,000
23	Hydrocortisone	Injection	vial	100 mg (as sodium succinate)	Vial	3,000,000	1,562,680	1,955,100
24	Immune Globulin Intravenous	Injection	vial	5gm	Bottle	5,000	11,586	4,720
25	Insulin injection (soluble)	Injection	10ml vial	100 IU/ml	Vial	30,000	40,000	105,000
26	Intermediate-acting insulin	Injection	10ml vial (as isophane insulin)	100 IU/ml	Vial	200,000	0	0
27	Intermediate-acting insulin	Injection	10ml vial (as compound insulin zinc suspension)	100 IU/ml	Vial	8,000	20,000	13,000
28	Ketamine	Injection	10 ml vial	50 mg(as hydrochloride)/ml	Vial	100,000	0	180,000
29	Levothyroxine (sodium salt)	oral administration	tablet	50µg	Tablet	7,500,000	10,049,900	3,750,000
30	Levothyroxine (sodium salt)	oral administration	tablet	100µg	Tablet	7,500,000	10,025,000	2,575,000
31	Noradrenaline	Injection	1ml ampoule	2 mg(acid tartrate)/ml	Ampoule	200,000	100,000	99,900
32	Ondansterone	Injection	2ml ampoule	2mg (as hydrochloride)/ml	Ampoule	100,000	78,450	0
33	Oxytocin	Injection	1 ml ampoule	10 IU/ml	Ampoule	1,000,000	1,977,980	1,720,980
34	Phenytoin	Injection	5 ml ampoule	50 mg (sodium salt)/ml	Ampoule	200,000	99,897	100,000
35	Ranitidine	Injection	2ml ampoule	25mg/ml	Ampoule	50,000	19,800	0
36	Salbutamol Sulphate	oral administration	60ml bottle	2 mg/5ml	Bottle	1,000,000	69,912	177,422
37	Salbutamol Sulphate	oral administration	metered dose aerosol (200 count)	100µg	Canister	500,000	184,987	449,972
38	Salbutamol Sulphate	oral administration	20ml bottle	5mg/ml	Bottle	250,000	219,819	120,145
39	Sirolimus*	oral administration	capsule	1mg	Capsule	15,000	5,010	6,910
40	Sodium Valproate	oral administration	300ml bottle	200mg/5ml	Bottle	10,000	0	8,000
41	Somatropin	Injection	vial	4 IU (1.33mg)	Pre Filled Syringe	3,500	0	8,500
42	Tacrolimus*	oral administration	capsule	0.5mg	Capsule	150,000	250,000	290,000
43	Tacrolimus*	oral administration	capsule	1 mg	Capsule	1,000,000	1,750,000	1,506,600
44	Tacrolimus*	oral administration	capsule	5 mg	Capsule	30,000	30,000	0
45	Terlipressin acetate	Injection	vial	1mg	Vial	7,500	7,000	11,400
46	Valproic acid (sodium valproate)*	oral administration	enteric coated tablet	200mg (sodium salt)	Tablet	3,000,000	691,200	3,020,000
47	Valproic acid (sodium valproate)*	oral administration	enteric coated tablet	500mg (sodium salt)	Tablet	800,000	352,800	800,000
48	Warfarin (sodium salt)*	oral administration	tablet	1mg	Tablet	2,000,000	199,600	0
49	Warfarin (sodium salt)*	oral administration	tablet	3mg	Tablet	2,500,000	0	1,000,000
50	Warfarin (sodium salt)*	oral administration	tablet	5mg	Tablet	1,300,000	250,000	0