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29 July 2016  
Geneva, Switzerland

## AMENDMENTS & CLARIFICATIONS No. 1 TO UNDP'S ITB/REF/GFATM14-2016

All Bidders are kindly requested to take note of the following amendment to the above referred ITB and the below clarifications:

### A. AMENDMENT

The INCOTERMS are modified to read as follows: (please note changes outlined in bold).

1	DS No. 32	For evaluation purposes, pricing will be evaluated on basis of CIP (named airport) prices will be factored as per tables in Section 7: Price Schedule Form, in order to consider applicable prices for consolidated volume procurement. <b>CIF</b> prices are solicited should sea freighting options provide advantages over air transport.
2	Section 3, Technical Specifications, para. F – Delivery Requirements	CIP, Khartoum Airport (air shipments) <b>CIF</b> , Port Sudan (sea shipments)
3	Section 7 – Price Schedule Form	The bidders should quote prices for each product and in a separate column freight costs. All items must be quoted in USD or EUR on CIP Khartoum Airport and <b>CIF</b> Port Sudan basis. Bid currency should be clearly indicated. The ability (and/or inability) to comply with the stated delivery requirements and Incoterms for AIR or SEA shipments will be factored into the evaluation process.
4	Section 7 – Price Schedule Form	See p.5-6 of this notice for a revised Price Schedule Form.

### B. CLARIFICATIONS

1	QUESTION:	Could you please explain the difference between tenders ITB/GFATM05-2016 and ITB/GFATM14-2016?
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	UNDP:	<p>The quality standards sought of the medicines and health commodities under ITB GFATM/05-2016 necessitated that the medicines and health commodities <b>must have approval</b> of a Stringent Drug Regulatory Authority (SRA) as defined by WHO. Please note this quality criterion applies in the case as well as of ITB GFATM/14-2016 launched on 18 July.</p> <p>In light of several offers not passing this threshold, 29 items have been cancelled from the first round and a second round ITB GFATM/14-2016 launched. Concerning ITB-GFATM/05-2016, notice of cancellation for 29 items is posted at: <a href="http://procurement-notices.undp.org/view_awards.cfm">http://procurement-notices.undp.org/view_awards.cfm</a>. The results of the balance items pursuant to GFATM/05-2016 will be announced shortly.</p> <p>A Stringent Regulatory Authority (SRA) as defined by WHO is 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 <a href="http://www.ich.org">www.ich.org</a>); 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). ICH members include: the EU Member States, Japan, the US.</p>
2	QUESTION:	We supply Clopidogrel besylate 75mg, film-coated tablets. Would you consider besylate an acceptable alternative to hydrogen sulfate, which is listed in the solicitation document?
	UNDP:	<p>The specification sought for Clopidogrel 75mg is in fact hydrogen sulfate. Whilst we will accept bids for alternate packaging presentations, we are unable to accept bids for alternate specifications, such as Clopidogrel 75mg besylate.</p> <p>Please refer to DS. No. 6 of the ITB - a Bidder may submit an alternative Bid for packaging presentations (e.g., blister pack vs. bottles, tablets vs. capsules) <b>only</b>. 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.</p>
3	QUESTION:	How does my company register with UNGM?
	UNDP:	<p>In order to register as a potential vendor of UN organizations, please follow the instructions below:</p> <ol style="list-style-type: none"> <li>1. Go to <a href="http://www.ungm.org">www.ungm.org</a>.</li> <li>2. Click on the 'Login and New registration' box or on the 'Register' link located at the top right corner of the page.</li> <li>3. Click on the 'New registration' button.</li> </ol>

		<p>4. Please select the type of registration by clicking on the relevant box. Please click on the 'Companies' box.</p> <p>5. Introduce your company details and accept the UN Supplier Code of Conduct. Then, click on the 'Register' button.</p> <p>6. After creating your account, you will need to activate it. Go to your personal email inbox corresponding to the email address provided when creating your account. You should have received an activation email. Please click on the activation link provided in this email.</p> <p>7. Once your account is activated, please click on the 'Registration' link in the left-hand menu to access the registration form. Complete your vendor registration form in UNGM. When finished, please do not forget to click the 'Submit' button.</p> <p>We also invite you to review the 'Registration Process' link in the left hand side menu for further information and detailed instructions on how to proceed in order to complete your UNGM Registration.</p> <p>In addition, please find below the following video guideline on how to successfully register your company on UNGM: <a href="https://www.ungm.org/Public/Video/View/3">https://www.ungm.org/Public/Video/View/3</a></p>
4	QUESTION:	Is it obligatory to be the member of the system of procurement through UNDP or it is possible to provide you with our commercial offer for supplying medicines to the Sudanese market?
	UNDP:	<p>ITB GFATM/14-2016 is an open invitation to entities for the supplies of medicines to Sudan. As the solicitation documents state the conditions for eligibility, we draw your attention to the following points:</p> <ul style="list-style-type: none"> <li>▪ In the context of this ITB, UNDP will only procure medicines that have been approved by a Stringent Drug Regulatory Authority (SRA) as defined by WHO.</li> <li>▪ It is not compulsory that one has an agent or local representative in Sudan for purposes to partake in the tender.</li> <li>▪ Effective registration with the National Medicines and Poisons Board, Sudan is not an exclusionary requirement to participate in the tender; however bidders will be encouraged to obtain registration with the NMPB to ensure continuity of supply over the term of the LTA.</li> </ul>
5	QUESTION:	Our company maintains a WHO-GMP compliant manufacturing facility and our products are registered in a number of countries, which justify the quality standards of our products; however not in a SRA country. Are we eligible to participate in this tender?
	UNDP:	<p>Should your company maintain the requisite quality threshold specific for this Sudan tender, you are eligible to participate and submit all documentation an offer in response to ITB GFATM/14-2016. Pharmaceuticals, otherwise without the approval of a SRA as defined by WHO will <b>not</b> be compliant with the quality threshold.</p>
6	QUESTION:	How does my company participate in the tender?

	UNDP:	<p>Kindly be informed all tender documentation is available both on our UNDP procurement portal as well as through the UNGM platform.</p> <p>UNDP: <a href="http://procurement-notices.undp.org/view_notice.cfm?notice_id=31366">http://procurement-notices.undp.org/view_notice.cfm?notice_id=31366</a>  UNG M: <a href="https://www.ungm.org/Public/Notice/47627">https://www.ungm.org/Public/Notice/47627</a></p> <p>Please note the following important issues when considering submission of your offer in response to this ITB:</p> <ul style="list-style-type: none"> <li>a) As stated in the ITB, offers shall be received (by electronic submission to <b><u>ps o.bidtender@undp.org</u></b>) before <b>Tuesday, 5 August 2016, 12.00 Copenhagen local time</b></li> <li>b) Supplier eligibility and minimum qualification requirements have been indicated in the ITB. Your offer shall include all requested documentation to assess fulfilment of these.</li> <li>c) <b>In the context of this ITB, UNDP will <u>only</u> procure medicines that <u>have been approved</u> by a Stringent Drug Regulatory Authority (SRA) as defined by WHO.</b></li> <li>d) As indicated in the ITB the deadline for bidders to submit requests for clarifications / questions is 5 working days before the submission date – 29 July 2016</li> </ul>
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## Section 7 – AMENDED PRICE SCHEDULE FORM

Item #	Pharmaceutical Substance (INN)	Route of Administration	Dosage Form	Strength	Unit of Measure (UOM)	Total Quantity in UOM	OFFER			CIP, Khartoum Airport [AIR]			CIF- Port Sudan [SEA]		
							Please Specify Unit of Offer (A)	Total Quantity Per Unit	Currency	Unit Price per A, excluding VAT (B)	Freight & Insurance Costs (C)	Total Price = B + C	Unit Price, excluding VAT (D)	Freight & Insurance Costs (E)	Total Price = D + E
<b>EXAMPLE:</b>	<i>Clopidogrel*</i>	<i>oral administration</i>	<i>tablet</i>	<i>75mg (as hydrogen sulfate)</i>	<i>Tablet</i>	<i>340,000</i>	<i>Blister carton (10x10)</i>	<i>100 tablets</i>							
1	Aciclovir	Injection	vial	250mg (as sodium salt)	Vial	17,000									
2	Amiodarone	Injection	3ml ampoule	50mg (hydrochloride)/ml	Ampoule	20,000									
3	Carbamazepine	oral administration	100ml bottle	100 mg/5ml	Bottle	30,000									
4	Ceftazidime	Injection	vial	250mg (as pentahydrate)	Vial	40,000									
5	Clopidogrel*	oral administration	tablet	75mg (as hydrogen sulfate)	Tablet	340,000									
6	Enoxaparin sodium	Injection	solution for injection	20mg (equivalent to 2,000 IU anti-Xa activity)	Pre Filled Syringe	80,000									
7	Enoxaparin sodium	Injection	solution for injection	40mg (equivalent to 4,000 IU anti-Xa activity)	Pre Filled Syringe	80,000									
8	Enoxaparin sodium	Injection	solution for injection	60mg (equivalent to 6,000 IU anti-Xa activity)	Pre Filled Syringe	60,000									
9	Enoxaparin sodium	Injection	solution for injection	80mg (equivalent to 8,000 IU anti-Xa activity)	Pre Filled Syringe	80,000									
10	Heparin sodium	Injection	5ml vial	5000 IU/ml	Vial	1,000,000									
11	Hydralazine	Injection	2ml ampoule	20 mg (hydrochloride)	Ampoule	30,000									
12	Hydrocortisone	Injection	vial	100 mg (as sodium succinate)	Vial	3,000,000									
13	Ketamine	Injection	10 ml vial	50 mg(as hydrochloride)/ml	Vial	100,000									
14	Noradrenaline	Injection	1ml ampoule	2 mg(acid tartrate)/ml	Ampoule	200,000									
15	Oxytocin	Injection	1 ml ampoule	10 IU/ml	Ampoule	1,000,000									
16	Phenytoin	Injection	5 ml ampoule	50 mg (sodium salt)/ml	Ampoule	200,000									

							OFFER			CIP, Khartoum Airport [AIR]			CIF - Port Sudan [SEA]		
Item #	Pharmaceutical Substance (INN)	Route of Administration	Dosage Form	Strength	Unit of Measure (UOM)	Total Quantity in UOM	Please Specify Unit of Offer (A)	Total Quantity Per Unit	Currency	Unit Price per A, excluding VAT (B)	Freight & Insurance Costs (C)	Total Price = B + C	Unit Price, excluding VAT (D)	Freight & Insurance Costs (E)	Total Price = D + E
17	Salbutamol Sulphate	oral administration	60ml bottle	2 mg/5ml	Bottle	1,000,000									
18	Salbutamol Sulphate	oral administration	20ml bottle	5mg/ml	Bottle	250,000									
19	Sirolimus*	oral administration	capsule	1mg	Capsule	15,000									
20	Sodium Valproate	oral administration	300ml bottle	200mg/5ml	Bottle	10,000									
21	Terlipressin acetate	Injection	vial	1mg	Vial	7,500									
22	Valproic acid (sodium valproate)*	oral administration	enteric coated tablet	200mg (sodium salt)	Tablet	3,000,000									
23	Valproic acid (sodium valproate)*	oral administration	enteric coated tablet	500mg (sodium salt)	Tablet	800,000									
24	Warfarin (sodium salt)*	oral administration	tablet	1mg	Tablet	2,000,000									
25	Warfarin (sodium salt)*	oral administration	tablet	3mg	Tablet	2,500,000									
26	Warfarin (sodium salt)*	oral administration	tablet	5mg	Tablet	1,300,000									