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RFQ Ref. No. SAMS/PROC/VS/2019/01

Dated: 07 Mar 2019

Request for Quotation (RFQ) for Procurement of Antihypertensive Medicines for Ethiopia

1. Resolve to Save Lives, an initiative of Vital Strategies, USA is supporting Government of Ethiopia in hypertension control and it is intended to procure certain Antihypertensive Medicines against which this Request for Quotation (RFQ) is issued.
2. Strategic Alliance Management Services Pvt. Ltd. (SAMS), acting as Procurement Service Provider on behalf of Vital Strategies, USA now invites quotations for Procurement of Antihypertensive Medicines as under. Detailed Technical Specifications are given in **Annexure-A**.

Schedule No.	Name of Medicines	Pharmacopeia Standard	Unit Pack Size	Quantity (No. of Packs)
I	Tab. Lisinopril 20mg	International or British or US Pharmacopeia	10 x 10 Tabs	8,200
II	Tab. Hydrochlorothiazide 12.5mg		10 x 10 Tabs	50,000

3. The salient instructions for preparation and submission of quotations and terms & conditions of Purchase Order are given below:

A. Quotation Prices:

- a) Bidders have the option to quote for “any one” or “both” the Schedules / Medicines given in Para 2 above.
- b) Prices shall be quoted in Indian Rupees(INR) only and as per format given in Price Schedule given in **Annexure-C**.
- c) Prices shall be quoted on FOB Addis Ababa (Ethiopian Airlines) basis.
- d) GST payable on supply of Medicines, if the contract is awarded to the Bidder should be mentioned separately.
- a) Prices quoted shall be fixed during performance of the contract and not subject to variation on any account.

- B. **Validity of Quotation:** Quotations shall remain valid for 30 days after due date for submission of quotation.

- C. **Quotation Documents:** Quotation submitted by firm shall comprise of the following documents:

- a) Letter of Quotation as per format given in **Annexure-B**, duly filled with all requisite information, printed on Bidder Firm’s letter-head;
- b) Statement of compliance/deviation to Technical Specifications against the requirements given in Annexure-A.
- c) Copy of manufacturing license and cGMP certificate issued by relevant regulatory authority for the Medicine(s) quoted.

- d) copy of a valid WHO GMP certificate for the Manufacturing site, issued by relevant regulatory authority.
- e) In case, bidder or its manufacturer has Agent / Registration in Ethiopia for the quoted medicines, the details of Agent / Registration should be provided.
- f) In case bidder is not a manufacturer, it should submit (in addition to the documents listed at sub-para a) to e) above), an authorization letter issued by manufacturer for submission of quotation on behalf of the Manufacturer.
- g) Price Schedule as per format given in **Annexure-C**, duly filled with all requisite information for the Medicine(s) quoted.

D. Submission of Quotation:

- a) Quotation comprising of all the documents listed in Para C. above should be mailed to the Purchaser at email: vermas@samsconsult.com latest up to **17:00 Hrs. (IST) on 14th March, 2019**
- b) All the documents including Price Schedule should be submitted as “**single password protected PDF file**”.
- c) The subject line of the mail should be “*Procurement of Antihypertensive Medicines for Ethiopia*”.

E. Opening and Evaluation of Quotations:

- d) The bidders who have submitted their quotations up to the due date and time for submission of quotations, as per Para D shall provide “password” of the quotation / file on 15th March, 2019 from 10:00 Hrs. (IST) to 17:00 Hrs. (IST) over to email vermas@samsconsult.com .
- e) The quotations shall be opened on 15th March, 2019 at 17:30 Hrs. (IST), in presence of representatives of bidders who choose to attend quotation opening.
- f) The quotations shall be evaluated based on documents submitted as per para C. above.
- g) The comparison of quotation prices shall be for each of the two schedules separately.

F. Terms of Delivery: FOB Addis Ababa (Ethiopian Airlines)

G. Delivery Schedule: Medicines should be delivered at Addis Ababa International Airport within 90 days from the date of issue of Purchase Order.

H. Inspection and Testing: Prior to commencement of supplies, an Agency nominated by the Purchaser shall conduct inspection and testing of the Medicines offered for supply. The inspection and testing shall be performed in the following manner:

- a) Two sets of samples of required quantity of each item will be drawn at random from each batch by the Purchaser’s Inspector at the manufacturer’s premises & sealed before dispatch;
- b) One set of sealed sample will be sent to an independent laboratory selected by the purchaser for conducting the required test to confirm whether the samples conform to the prescribed specification. Another set of sealed sample will be retained with the testing lab as counter sample till the shelf life;
- c) Dispatch Clearance Certificate (DCC) will be issued by the inspector on the basis of test report, accepting or rejecting the batch as the case may be;
- d) The Medicines will be dispatched only after the above inspection procedure has been followed and DCC issued to accept the consignment;
- e) The Purchaser/Consignee shall have the right to draw samples at random from the consignment anytime during the shelf life of the Medicine and get them retested to satisfy whether the Medicine conform to the laid down

specifications. In the event of the product failing to conform to specifications, the consignee shall reject that batch of supply and inform the supplier for arranging replacement of the rejected batches at supplier's cost;

- I. **Payment Terms:** The 100% payment of the Medicines supplied shall be released within 60 days of submission claim along with proof of delivery.
4. You are hereby requested to submit your quotation as per instructions contained above and up to the scheduled date and time for submission of quotations.

For and on behalf of Strategic Alliance Management Services Pvt. Ltd.



(Satya Verma)
General Manager (Procurement Services)

Annexure-A

Technical Specifications

PART A: PRODUCT SPECIFICATIONS

	Schedule No.	I
1.	Generic Name of Medicine	Lisinopril
2.	Strength	2 mg
3.	Dosage Form	Tablet
4.	Pharmacopeia Standard	International or British or US Pharmacopeia
5.	Standard Shelf-life (Min.)	2 years (24 months)

	Schedule No.	II
1.	Generic Name of Medicine	Hydrochlorothiazide
2.	Strength	12.5 mg
3.	Dosage Form	Tablet
4.	Pharmacopeia Standard	International or British or US Pharmacopeia
5.	Standard Shelf-life (Min.)	2 years (24 months)

PART B: PACKING AND LABELLING SPECIFICATIONS

Sr. No.	Minimum Requirements
1	Packing:
1.1	The Supplier shall provide such packing of the Medicines as is required to prevent their damage or deterioration during transit to their final destination;
1.2	The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage;
1.3	Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Medicines' final destination and the absence of heavy handling facilities at all points in transit;
1.4	Primary Packing: Aluminum Blister containing 10 Tablets
1.5	Secondary Packing: Paper carton containing 10 Blisters (10x10)
1.6	Tertiary Packing: Suitable carton as per quantity to be delivered at final consignee location
2.	Labelling:
2.1	The label of Medicine shall meet the WHO GMP standard and include: <ol style="list-style-type: none"> 1) the INN or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name; 2) the active ingredient per unit, dose, tablet etc. 3) the applicable pharmacopeia standard; 4) content per pack 5) instructions for use

	6) special storage requirements 7) batch number 8) date of manufacture and date of expiry
2.2	The outer carton should also display the above information.
2.3	Additional labelling requirement: The Purchase may prescribe text, as appropriate, to be printed in Primary, Secondary and Tertiary packing at the time of issue of Purchase Order.
2.4	All cases should prominently indicate the following: 1) the generic name of the product 2) date of manufacture and expiry 3) batch number 4) quantity per case No case should contain Medicine from more than one batch
2.5	Bar-coding requirements: As per Annexure 1

Annexure 1

BAR CODING REQUIREMENTS

Sr. No.	Description
1	<p>Section A) Primary packaging (Item level and mono carton level)</p> <p>At individual item level (strip of 10 tablets, syrup bottle, injections, vials etc.) and/ or on its mono carton (wherever applicable), are required to have a pre-printed barcode on its product packaging using either of the barcode symbology mentioned below:</p> <p style="padding-left: 40px;">a) GS1 linear barcode symbology (EAN-13/UPC-A/EAN-8) to encode GTIN (Global Trade Identification Number) within the barcode.</p> <p style="text-align: center;">or</p> <p style="padding-left: 40px;">b) GSI Data Matrix symbology to encode 14 digits product code (GTIN14) within the barcode and using (01) application identifier (to be used where printing space is extremely limited).</p> <p>Examples of the same are reproduced at Annexure 'A'.</p> <p>All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements.</p>
2	<p>Section B) Secondary level Packaging (Intermediate packaging)</p> <p>At secondary level packaging (e.g. box of 10 strips containing 10 tabs each, pack of 10 vials, pack of 10 injections etc.), barcode encoding following information to be stickered or preprinted on secondary packaging:</p> <p style="padding-left: 40px;">1) Product identification Code (GTIN-14 of secondary pack) using application identifier (01). 2) Expiry date in YYMMDD format using application identifier (17) 3) Batch/Lot Number using application identifier (10)</p> <p>GSI-128 barcode symbology to be used to generate the barcode.</p> <p>Examples of the same are reproduced at Annexure 'B'.</p> <p>All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements.</p>
3	<p>Section C) Tertiary level packaging (Shipper level packaging)</p> <p>At shipper level packaging, a single label containing two barcodes needs to be generated and stickered. The barcodes will encode following information:</p>

Sr. No.	Description
	<p>The first barcode will contain the following information:</p> <ol style="list-style-type: none"> 1) Product Identification Code (GTIN-14 of shipper level pack) using application identifier (01). 2) Expiry Date in YYMMDD format using application identifier (17) 3) Batch/Lot Number using application identifier (10) <p>The second barcode will contain the following information:</p> <ol style="list-style-type: none"> 1) SSCC (Serial Shipping Container Code) using application identifier (00) <p>Examples of the same are reproduced at Annexure 'C'. All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements.</p>

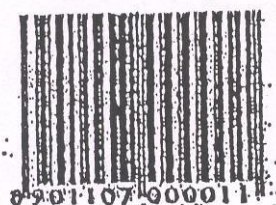
Annexure 'A'

Examples of Primary Level Packaging

For generation of GSI barcode at primary level packaging either of the mentioned symbology can be used, following GSI General Specifications.

The following GSI barcode symbology are available as options :-

- 1) The barcode sample for EAN-13 barcode symbology encoding GTIN-13

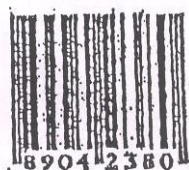


- 2) The barcode sample for UPC-A barcode symbology encoding GTIN-12



Note: Both GTIN-13 GTIN-12 are in extensive use worldwide

- 3) The barcode sample for EAN-8 barcode symbology encoding GTIN-8 (Used where printing space is a constraint)



- 4) The barcode sample for GSI Data Matrix barcode symbology encoding GTIN-14 (Used where printing space is extremely limited)



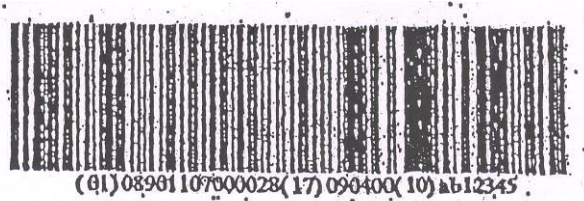
(01)08901107000011

Annexure 'B'

Example of Secondary level Packaging

The barcode will encode :

- 1) Product identification (GTIN 14 of secondary pack) using application identifier (01)
- 2) Expiry date in **YYMMDD** format using application identifier (17)
- 3) Batch/Lot Number using application identifier (10)



Annexure 'C'

Annexure "C"

Example of Tertiary level packaging (Shipper level packaging)

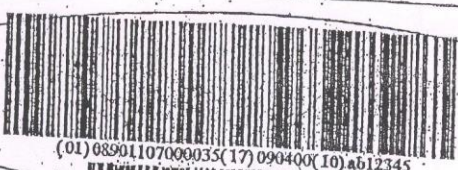
The first barcode will encode the following:

- 1) Product Identification (GTIN 14 of Shipper Pack) using application identifier (01)
- 2) Expiry Date In YYMMDD format using application identifier (17)
- 3) Batch/Lot Number using application Identifier (10)


The second barcode will encode the following:

SSCC (Serial Shipping Container Code)

(Single Label for each Shipper level packaging)



(01)08901107000035(17)090400(10)ab12345



(00)18901107000000018

Product Name	ABCDXYZ
Expiry Date	04/09 (April/09)
Batch No.	ab12345
Shipper carton Serial No.	18901107000000018

Human Readable Information

Complete details on GS1 standards along with technical guidelines are available at www.gs1india.org under "downloads" section.

Annexure-B

Letter of Quotation

(to be printed on official stationery / letter-head of bidder firm)

Date: [insert: date of quotation]
RFQ Ref. No. SAMS/PROC/VS/2019/01

To:

Mr. Sanjay Rastogi, Director
Strategic Alliance Management Services Pvt. Ltd. (SAMS),
B01-B03, Vardhaman Diamond Plaza,
D B Gupta Road, Paharganj, New Delhi-110 055, India

Subject: Procurement of Antihypertensive Medicines for Ethiopia

Dear Sir:

Having examined the RFQ Documents, including Addenda Nos. [insert **numbers**], the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Medicines (as per Table) below under the above-named RFQ in full conformity with the said RFQ Documents for the sum as submitted in the Price Schedule (hereinafter called "the Total Quotation Price") or such other sums as may be determined in accordance with the terms and conditions of the Contract.

Schedule No.	Name of Medicine	Quoted / Not Quoted <i>(please insert "Quoted" or "Not Quoted", as appropriate, against each Schedule)</i>
I	Tab. Lisinopril 20mg	
II	Tab. Hydrochlorothiazide 12.5mg	

We undertake, if our quotation is accepted, to deliver the Medicines in accordance with the delivery schedule specified in the RFQ Documents.

We agree to abide by this bid, for the Bid Validity Period specified in Para 3.B. of the RFQ and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

We undertake that, in competing for (and, if the award is made to us, in executing) the above contract, we will strictly observe the laws against fraud and corruption in force in India namely "Prevention of Corruption Act 1988".

We hereby certify that we have taken steps to ensure that no person acting for us or on our behalf will engage in bribery.

We hereby declare that we have not been engaged by Purchaser to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the Medicines described in these RFQ Documents.

We hereby declare that we have not, in the past five years, had an affiliation with or received support from any tobacco product manufacturer or the parent, subsidiary, or affiliate of a tobacco product manufacturer (collectively, the "Tobacco Industry") or the Tobacco Industry's agents or associates, including any person, interest group, advocacy organization, law firm, advertising agency, or other business or organization that represents the interests of the tobacco industry (collectively, "Tobacco Affiliates").

We hereby accept that in case we are selected for award of contract under this RFQ, shall give an undertaking that we currently does not accept and shall not accept financial or other support from the Tobacco Industry or Tobacco Affiliates until at least one year after the end of this agreement. We understand that notwithstanding the other provisions of the contract, failure to comply with this clause may constitute grounds for termination of the contract and Purchaser shall have the right to demand and receive a return of all funds under this agreement, plus interest, as liquidated damages.

We hereby declare that we are not declared debarred / backlisted (as a whole or for the Medicine quoted by us) by any Department, Institutions, Corporation, Agency under administrative control of Govt. of India or State Government, as on the date of bid opening, and are ineligible to participate in the quotation process.

Dated this [*insert: number*] day of [*insert: month*], [*insert: year*].

Signed: _____

Date: _____

In the capacity of [*insert: title or position*]

Duly authorized to sign this quotation for and on behalf of [*insert: name of Bidder*]

Annexure-C

Price Schedule

1	2	3	4	5	6	7	8
Sch edul e No.	Description of Medicine	Unit pack size (Tabs)	Quantit y (No. of Packs)	Price per Unit Pack (FOB Addis Ababa (Ethiopian Airlines) basis) (in INR)	Total Price [Col. 4 x 5] (in INR)	GST Payable on finished product (rate and amount)	
						In %	In Amount (in INR)
I	Tab. Lisinopril 20mg	10 x 10	8,200				
II	Tab. Hydrochlorothiazide 12.5mg	10 x 10	50,000				
	Total						

Signed: _____

Dated: _____

In the capacity of: [insert: ***title or other appropriate designation***]