

MINUTES OF PRE-BID MEETING

Brief Description of Procurement	Procurement of Methadone Syrup (5 mg/ml) with Dispensing Units
IFB No.	SAMS/NACP/Methadone/05/2015
Date and Time of Pre-Bid Meeting	12 th January, 2016 at 15:00 Hrs.
Venue of Pre-Bid Meeting	Strategic Alliance Management Services Pvt. Ltd. 1/ 1B, Choudhary Hetram House, Bharat Nagar, New Friends Colony, New Delhi 110025

The following Bidders' Representatives attended the pre-bid meeting:

Sr. No.	Name and Designation	Name of Prospective Bidder/Firm
1	Dr. Pushkar Singh	M/s Rusan Pharma Limited, Mumbai
2	Mr. Arun Sharma	M/s Hospimax Healthcare Pvt. Limited, New Delhi

The following NACO's representatives were present in the pre-bid meeting as observer:

Sr. No.	Name and Designation
1.	None

The following SAMS's officials were present in the pre-bid meeting:

Sr. No.	Name and Designation
1.	Mr. Anil K. Bhutani, Team Leader (Procurement)
2.	Mr. Satya P. Verma, Procurement Specialist
3.	Ms. Jyoti Singh, Senior Manager (Procurement)

Proceedings of the pre-bid meeting are as follows;

1. At the outset, Sr. Manager (Procurement), SAMS briefed about purpose of the pre-bid meeting.
2. Thereafter, prospective bidders were requested to put up their queries related to scope and terms and conditions given in the Bidding Document.
3. The queries from prospective bidders were appropriately responded. The representatives were also requested to send their queries in writing through e-mail within 2 days.
4. The responses to queries sought from prospective bidders in writing and those asked during the meeting have been compiled as per **Annexure-A**.
5. The Amendments made in pursuance to ITB Para 11 and 12 of the Bidding Documents are enclosed as **Annexure-B**.



(A.K. Bhutani)
Team Leader (Procurement)

ANNEXURE-A

**CLARIFICATION NO. 1 DATED 15.01.2016 AGAINST QUERIES/ SUGGESTIONS
RECEIVED FROM PROSPECTIVE BIDDERS**

- 1. IFB Reference: SAMS/NACP/Methadone/05/2015**
2. Date of Publication/Notification: 23.12.2015
3. Date of Pre-bid meeting: 12.01.2016

As per provisions given in ITB Para 11 of the Bidding Document and the queries/suggestions sought by the prospective bidders, the following responses are being issued:-

Sl. No.	Clause reference / Page reference	Queries / clarifications sought	Response
1	Section VII. Technical Specifications Part A: S. No. I – (page 86)	<p>Part A technical specifications ser. number 3, Mentions the flavor as orange/green apple with sugar. In case of domestic consumption the first batches were taken by the Innovator Company Rusan Pharma in India for supply to the UNODC / AIIMS project from early 2013 onwards and methadone product and patients have been stabilized on the formulation which is Methadone syrup oral concentrate 5mg/ml in one litre plastic bottles with sunset yellow colour and cherry flavor. The following centres are using the product AIIMS, Civil Hospital Kapurthala, Bhatinda, KEM Hospital Mumbai, and RIMS, Imphal, Manipur. Since the project has proved successful in introducing Methadone syrup to the country and now NACO has decided to upscale the program / do national procurement hence the colour and flavor as already accepted by the patients should be included in the specifications and hence the technical specifications should be suitably amended in Physical Characteristics as follows:</p> <p>Flavor: Orange / Green apple / cherry or any other flavor approved in India</p> <p>The characteristics of colour should also be specified as follows:</p> <p>Colour: Sunset yellow or any other colour approved in India</p>	Please refer Sl. No. 1 of Amendment No. 1 dated 15/1/2016
2	Section II Bid Data Sheet ITB 1.1 (page 36) Section VI Schedule of Requirements	The two items required by the procurement agency is Methadone syrup with dispensing bottles. The term “dispensing bottles” is misleading as the product is supplied with a specific number of “dispensers” with requisite calibrations from 1 to 10ml to	Please refer Sl. No. 2 & 3 of Amendment No. 1 dated 15/1/2016

Sl. No.	Clause reference / Page reference	Queries / clarifications sought	Response
	(page 84) Section VII Technical Specifications (page 86)	measure the dispensed dose. Hence, it should read as “2 appropriate dispensers” which can be screwed on the formulation bottles.	
3	Section VII Part B - Technical Specifications General (page 87)	Technical specification Part B 1, 1.2. Methadone syrup of 5mg/ml comes in oral concentrate form as Methadone Hydrochloride oral concentrate BP/USP or relevant pharmacopeia and is not at present in the Indian Pharmacopeia, however the API is in IP and therefore the licenses submitted by the manufacturer should be verified by the DCGI if found in variance to this.	No change in the requirement stated in the Bid Document
4	Section II Bid Data Sheet ITB 7.1 (a) A (i) pt 4 (ii) c and e Section VII - Part A Technical Specification	Section II bid data sheet ITB 7.1 (a) A (i) pt. 4 (ii) c and e and part A technical specification Para 5 are contradictory. The procurement agency requires the shelf life of the product to be 3 years and that there should be a valid WHO COPP. The condition stated in the bid document is “should have manufactured the product at least once. This is a contradiction as a minimum of three validation batches need to be taken and samples kept at 6 months accelerated conditions at 30 degree Celsius/65% humidity and 40/75 to give a shelf life of 2 years if found stable in order to obtain a WHO, COPP. In order to have a shelf life of 3 years there should be a minimum of 3 years real time stability data at 30/65 as required in India and the same data need to be submitted as part of documents required. Hence the relevant para should be amended to read as “should have manufactured the requisite number of batches as required to obtain valid WHO COPP and meet necessary conditions to claim a shelf life of 3 years.	Please refer Sl. No. 4 of Amendment No.1 dated 15/1/2016
5	--	Methadone is a controlled narcotic drug and has been declared as one of the Essential Narcotic drugs by Gazette Notification by the Government of India. Hence it is important that complete transparency in Quota allocation from Central Bureau of Narcotics, GOI Gwalior and use of the allotted quota for manufacturing of formulations is disclosed by the domestic companies submitting bids for this tender. A copy of the CBN letter which states the quota allocation to the concerned manufacturer, in the year of manufacturer as	No change in the requirement stated in the Bid Document

Sl. No.	Clause reference / Page reference	Queries / clarifications sought	Response
		<p>well as the annual return submitted to CBN which confirms the fact that the methadone which has been allocated is drawn from the API source specified by the CBN and the same used to manufacture formulation batches needs to be part of the obligatory documents that need to be submitted as part of the bid submission . Hence Methadone is under INCB control the same type of documents need to be submitted by International bidders also.</p>	
6	<p>Section VI Schedule of Requirements (page 84)</p>	<p>Section VI schedule of requirements mentions in second heading, Schedule of requirements tablets Methadone syrup. The word “tablet” needs to be deleted. Please also specify in whose favour the Bid guarantee has to be submitted. Item 2 Dispensing bottles need to be amended and the 2nd and 3rd lot of delivery cannot be in fractions as 328.5 bottles. This need to be amended as 329 and 327 bottles.</p>	<p>Please refer Sl. No. 5 & 6 of Amendment No. 1 dated 15/1/2016</p>
7	<p>Section V Special Conditions of Contract (SCC) Para 9.1(a).</p>	<p>Please refer to Section V SCC 9.1(a). The supplier shall put up the goods for such inspection to the Purchaser’s inspectors 15-25 days (depending on the time required for pre-dispatch inspection & testing) ahead of the contractual delivery period, so that deliveries to the consignees are completed as per contractual delivery period.</p> <p>When the above is read in conjunction with Schedule of Requirements and delivery schedule of first lot supply then there is mismatch as Lot-1 has to be supplied within one month of award of contract and put up for inspection 15-25 days ahead of contractual delivery period thus giving an extremely short production time of 5 days.</p> <p>The delivery period should be amended to read as follows:</p> <p>First supply lot to be supplied within 2 months of issue of notification of award.</p>	<p>Please refer Sl. No. 6 of Amendment No. 1 dated 15/1/2016</p>
8	<p>Section II – Bid Data Sheet Para 7.1(a) sub-para VII (page 41)</p> <p>Section V ; Special Conditions of Contract (SCC) GCC Para 3.1</p>	<p>Please refer to page 41 of the bid document Section 2. Bid data sheet point VII enumerated below:</p> <p><i>“The bidder and the manufacturer whose product is offered by the bidder shall disclose instance of previous past performance of his and the manufacturer whose product is procured by the bidder,</i></p>	<p>Please refer to ITB Para 7.1(a) (A) (i) 1 and II (c) and ITB Para 7.1(a) (B) a) along with Form 11 “Proforma for Performance Statement..”</p> <p>There is no change in the requirement given in Bid</p>

Sl. No.	Clause reference / Page reference	Queries / clarifications sought	Response
		<p><i>that may have resulted into adverse actions taken against the bidder during the last two years. Such adverse actions taken against the bidder or manufacturer may be treated as unsatisfactory performance history while deciding the award of contract. If no adverse action has been taken against the Bidder, the Bidder must provide a statement in its bid saying that there has been no such previous past performance resulting in adverse actions being taken against him."</i></p> <p>As we understand it this point pertains to any adverse performance which the bidder manufacturer or supplier has received in the Domestic supplies to any agency of Central Government, State Government, PSU's, Railways, Defence etc. in India in previous 2 years for any reason whatsoever.</p> <p>In addition as per World Bank norms list names of Bidders for Goods and Services as enumerated on page 71 para GCC 3.1 of the Bid document.</p>	Document



Anil Kr. Bhutani
GM (Procurement) & Team Leader

Ministry of Health & Family Welfare
National AIDS Control Organization

Through

PROCUREMENT AGENT
Strategic Alliance Management Services Pvt. Ltd. (SAMS)
1/ 1B, Choudhary Hetram House, Bharat Nagar, New Friends Colony,
New Delhi 110025, INDIA

AMENDMENT No. 1 Dated: 15.01.2016

National AIDS Control Programme Phase-IV (NACP-IV)
International Competitive Bidding

- 1) **IFB Reference:** SAMS/NACP/Methadone/05/2015
- 2) **Date of Publication/Notification:** 23.12.2015
- 3) **Date of Pre-bid meeting:** 12.01.2016

As per ITB Para Nos. 11 & 12, the following amendments of the bidding document are being made:-

Sl. No.	Clause reference / Page reference	Existing	As amended
1	Section VII. Technical Specifications Part A: S. No. I – (page 86)	“Physical Properties: Orange/Green apple flavor with sugar”	“Physical Properties: Orange/Green apple / Cherry or any other flavor and colour with sugar approved by regulatory authority in India”.
2	Section II Bid Data Sheet ITB 1.1 (page 36) Section VI Schedule of Requirements (page 84) Section VII Technical Specifications (page 86)	“Dispensing Bottle”	“Dispensing Unit”
3	Section VII Technical Specifications sr. no. II. 1 (page 86)	“The Dispensing Bottle with bottle top calibrated manual dispenser pump should be provided by the successful bidder. Details regarding the same will be shared at the time of award of contract.”	“The bottle top Dispensing Unit which can be screwed on the methadone syrup bottle with adjustable delivery nozzle to facilitate bubble free dispensing. It should have calibrations from 1 to 10ml to measure and dispense methadone dose. The dispensing unit should be fully autoclavable. The parts of the Dispensing Unit should be made of PTFE, FEP and Glass”
4	Section II Bid Data Sheet ITB 7.1 (a) A (ii) (c)	“has manufactured and marketed the specific good covered by the bidding document for at least One (1) year , and for similar goods for at least three (3) years . In support of this, data on past performance should be submitted as per Form 11 in Section VIII.”	“has manufactured and marketed the specific good covered by the bidding document for at least one (1) of the last three years , and for similar goods for at least five (5) years . In support of this, data on past performance should be submitted as per Form 11 in

Sl. No.	Clause reference / Page reference	Existing					As amended				
							Section VIII.”				
5	Section VI Schedule of Requirements. Heading text	‘Schedule of Requirements for tablet Methadone Syrup’					‘Schedule of Requirements for Methadone Syrup’				
6	Section VI Schedule of Requirements - Delivery Schedule	Supply lot	Month of supply	Quantity to be supplied in Litres			Supply lot	Month of supply	Quantity to be supplied in Litres		
		First (50% of the total quantity) + and Dispensing Bottles – 2 Nos.	within one (1) month of issue of Notification of Award.	657.0			First (approx. 50% of the total quantity) + and Dispensing Bottles – 2 Nos.	within two (2) month of issue of Notification of Award.	660		
		Second (25% of the total quantity)	within four (4) months of issue of Notification of Award.	328.5			Second (approx. 25% of the total quantity)	within four (4) months of issue of Notification of Award.	330		
		Third (25% of the total quantity)	within eight (8) months of issue of Notification of Award.	328.5			Third (approx. 25% of the total quantity)	within eight (8) months of issue of Notification of Award.	324		
7	Section VI Schedule of Requirements	Item No.	Description of Goods	Unit	Quantity	Bid Security in Indian Rupees	Item No.	Description of Goods	Unit	Quantity	Bid Security in Indian Rupees
		I	Methadone Syrup (5mg/ml)	Ltrs	1,314	40,000	I	Methadone Syrup (5mg/ml)	Ltrs	1,314	40,000
		II	Dispensing Bottles	Nos.	2		II	Dispensing Units	Nos.	6	

All other terms and conditions of the Bid Document shall remain unchanged.



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