CENTRAL MEDICAL SERVICES SOCIETY

(An Autonomous Body, Ministry of Health & Family Welfare, Govt. of India)
2nd Floor, Vishwa Yuvak Kendra, Teen Murti Marg,
Chanakyapuri, New Delhi-110021.
Website: www.cmss.gov.in, Tel. 011-21410905/6

Dated: - 12/08/2024

MINUTES OF PRE-BID MEETING

Tender For: - Procurement of Tab. Bedaquiline-100MG used under NTEP

Tender no.:- CMSS/PROC/2024-25/ NTEP/002 Dt.22.04.2024

Pre-bid meeting held on 29.04.2024 at 11:00 AM (IST)

1. Following officials were present during the Pre-bid meeting:-
   I. Sh. Alok Mathur, Addln. DDG (NTEP)
   II. Sh. Pramod B. Somnathe, GM (Proc.), CMSS
   III. Sh. Lalit Sharma, AGM (Proc.), CMSS
   IV. Ms. Akanksha Jain, AGM (QA), CMSS

2. Following representatives from prospective bidders were present in the pre-bid meeting:-

Sr.No.	Organization Name	Name of Representative
1.	M/s Lupin Ltd.	1. Sh. Amarjeet Patnaik, DGM
		2. Sh. Pawan Thakran, Sr. Exe.
		3. Sh. Ram Ayer, Vice President thru. VC
2.	M/s Mylan Laboratories Ltd.	Sh. Arun Kr. Sharma, GM
3.	M/s Macleods Pharmaceuticals Ltd.	Ms. Rohini Karde thru. VC

3. Points raised by the representative of prospective bidders were discussed. After due consideration of the received queries, the clarifications/ amendments are enclosed herewith.

Sd/-
GM (Procurement)

ANNEXURE

Tender No.:- CMSS/PROC/2024-25/NTEP/002 Dt.24.04.2024
Tender for:- Procurement of Tab. Bedaquiline-100mg used under NTEP
Pre-bid meeting held on :- 29.04.2024 @ 11:00 AM

Sr. No.	Tender document Pg. No. and Clause	Tender Descriptions	Bidder's Concern/ Query / Suggestion	Clarifications / Amendments
1	Pg. No. 34, Annexure 1: Supply /Delivery Schedule	1(30%):- To be delivered within 60 days from the date of issue of Letter of Acceptance. 2(35%) To be delivered within 61 to 90 days from the date of issue of Letter of Acceptance. 3(35%) To be delivered within 91 to 120 days from the date of issue of Letter of Acceptance.	We request you to kindly consider the Delivery Schedule as proposed below, since it is a first commercial supply of Bedaquiline in the country and we would require leadtime to align the requisite API and packaging requirements for the same.. Our proposed schedule is as follows: Tranche - 1 : 30 % quantity to be delivered within 120 days from the date of issuance of LOA at CMSS Stores. Tranche - 2 : 35% quantity to be delivered within 120 to 180 days from the date of issuance of LOA at CMSS Stores. Tranche - 3 : 35% quantity to be delivered between 181 to 240 days from the date of issuance of LOA at CMSS Stores.	**Amended As:-** **Revised Delivery Schedule as below :** Tranche 1 (20%):- To be delivered within 60 days from the date of issue of Letter of Acceptance. Tranche 2 (20%) To be delivered within 61 to 90 days from the date of issue of Letter of Acceptance. Tranche 3 (30%) To be delivered within 91 to 120 days from the date of issue of Letter of Acceptance. Tranche 4 (30%) To be delivered within 121 to 150 days from the date of issue of Letter of Acceptance. (All tranches - PDI Methodology with conditional dispatch clearance)
			We hereby request you to kindly allow the change in delivery period which is detailed below: 1. Tranche I 30% To be delivered within 90 days from the date of issue of Letter of Acceptance. 2. Tranche II 35% To be delivered within 91 to 150 days from the date of issue of Letter of Acceptance. 3. Tranche III 35% To be delivered within 151 to 210 days from the date of issue of Letter of Acceptance.	
			Refer to clause we hereby request you to kindly amend. a) Tranche I 30% to goods readiness at factory within 120 days from the date of issuance of LOA. b) Tranche II 35% to goods readiness at factory within 121 - 150 days from the date of issuance of LOA. c) Tranche III 35% to goods readiness at factory within 151 - 180 days from the date of issuance of LOA.	

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2	Pg. No. 29; Clause: 18 (Liquidated Damages and Other Penalties), Sub-clause 18.2	If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.	Our Submission is as follows: If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 0.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost." We hereby request you to kindly remove liquidated damages clause as CMSS has floated the tender for this new and novel product for the first time, whose manufacturing time is long.	**Amended As:-** if the contractor/ Supplier fails to deliver any or all of the Goods or fails to perform the incidental Works/ Services within the time frame(s) incorporated in the contract, the Procuring Entity shall, without prejudice to other rights and remedies available to the Procuring Entity under the contract, deduct from the contract price, as agreed liquidated damages, but not as a penalty, a sum equivalent to the ½ % (half percent) of the delivered price (including elements of GST & freight) of the delayed Goods and/ or incidental Works/ Services for each week of delay to be applied proportionately on per day basis for first four weeks of delay. For subsequent delays, a sum equivalent to 2.5% (two and half percent), instead of 0.5%, for each week of delay to be applied proportionately on per day basis of delivered price shall be deducted as liquidated damages. The maximum deduction on account of LD shall not exceed 10% of the delayed goods or incidental works/service contract price(s).
3	Pg. No. 10; Clause 4 (d) (Eligibility Criteria) And Pg. No. 14; Clause 6.2 (f) (Technical Bid-"Packet 1")	For all regulated products, the bidder should have at least last two years, i.e., 2021-22 and 2022-23 OR 2022-23 and 2023-24, of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) in less than two years ago. A permission from DCG(I) shall be required for all new regulated products to this effect. Only for the drugs introduced in Indian Pharmacopoeia in the recent past last 2yrs), Market standing certificate for previously approved Pharmacopoeia or In house Standards (Export/ Domestic) shall be accepted, as the case may be. For the recently introduced drugs in the country (introduced in the last two years), the requirement for Market standing certificate shall be waived off. Manufacturing and Market Standing Certificate issued by	1) Bedaquiline has been licensed by CDSCO on 14th Jan`2015. However, Bedaquiline was under patent till July 2023 hence no commercial supplies were made till July 2023. The commercialization of the product is initiated in 2024 hence the product Hence the relevant manufacturing and marketing experience is not there for 2 years. Hence this needs to be waived. 2)The product is more than 4 years old hence the DCGI license is not required. The manufacturing license is issued by local FDA. Although the product was introduced in India in 2015, the primary patent expired only in July 2023, thus we do not have prior manufacturing or marketing information for this product. Also, this product is not published in IP 2022 and Addendum 2024 to IP 2022. And also this product is not present in both BP and USP monograph, thus request you to waive off Market Standing Certificate requirement.	**Amended As:-** **The requirement of 02 years of Manufacturing & Marketing experience/Certificate of the particular items is deleted**.

Sr. No.	Tender document Pg. No. and Clause	Tender Descriptions	Bidder's Concern/ Query / Suggestion	Clarifications / Amendments
		the Licensing Authority as a manufacturer for each item quoted for the last 2 years, i.e. 2021-22 & 2022-23 OR 202223 & 2023-24 for compliance of tender clause no. 4 (d).	Manufacturing and Marketing Certificate (MMC): We hereby request you to waive the Manufacturing and Marketing Certificate (MMC) as the product Tab Bedaquiline 100 mg was under the patent upto July 2023.	
4	Pg. No. 35; Clause C (Quality Assurance) of Annexure 1 A:	Compliance: The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f) **the product shall meet the quality standards as required under WHP PQP / SRA / Evaluated to meet the quality standards by an Expert Review Panel (ERP)**. *Only one of the selected pharmacopeia to be indicated.	Kindly confirm if only WHOPQ approved product / manufacturers are eligible to participate in this tender.	**Clarified As:-** As per Technical Specifications
			Request you to please confirm whether only WHO PQP / SRA / ERP approved products are required to participate or NON WHO PQP / SRA are also eligible to participate this tender, Kindly confirm.	
			For Subclause-F: we have WHO-GMP plant. Kindly accept WHO-GMP plant & certificate	
5	Pg. No. 37; Clause E (Shelf life) of Annexure 1 A:	Shelf life should be minimum 36 months from the date of manufacture.	Since Bedaquiline is a new drug, Shelf life to be considered as minimum 24 months from the date of manufacture.	**Amended As:-** Shelf life should be minimum 24 months from the date of manufacture.
			As per technical specification and tender conditions, the shelf life of the product mentioned is 36 months. However, the available shelf life is 24 months. We hereby request you to kindly amend the shelf-life clause to 24 months from the existing 36 months.	
			As this is new product, so request you to consider 24 month Shelf life.	
6	Pg. No. 39; Clause H (Labelling) of Annexure 1A:	**General requirements of the labels:** • Shall meet WHO GMP standards. • All labels should be peel proof • "RNTCP- Central Government Supply- NOT FOR SALE" to be imprinted on the labels of Millboard / Greyboard and 5 Ply Shippers.	Kindly confirm if it should be RNTCP or NTEP.	**Amended As:-**
			As per technical specification, Labelling RNTCP – Central Government Supply -NOT FOR SALE is to be imprinted on Labels. But as per the logogram it is mentioned as NTEP-Central Government Supply-Not for Sale. Kindly clarify and amend.	The Label should be as follows : "NTEP- Central Government Supply - NOT FOR SALE"
			Kindly confirm should we have to mention "RNTCP-Central Government Supply-NOT FOR SALE" or "NTEP -Central Government Supply- NOT FOR SALE", as in the artwork it is asked to mention NTEP. So please confirm.	

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7	Pg. No. 35; Clause B (Description) of Annexure 1A:	Bedaquiline tablets shall conform to the general requirements of tablets and the requirements under individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions. Each uncoated tablet of Bedaquiline contains: Bedaquiline - 100mg, Pharmacopeia* (IP/BP/USP/any other International Pharmacopeia). The quality of Bedaquiline should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions. Protocols and Testing: The supplier has to share all testing protocols and procedures being followed for the analysis of drug and will have to share Certificate of Analysis of each batch with the purchaser.	The pharmacopoeia of the product is available is In-House. We hereby request to kindly amend the clause to In-House pharmacopoeia.	**Clarified As:-** In-house standards are acceptable subject to submission of undertaking by prospective suppliers that this drug is not available in any national / international pharmacopoeia at the time of bid submission.
8	Pg. No. 14, Clause 6.2(i) (Technical Bid-"Packet 1")	A valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP/IHS (In-House Standard) and a valid WHO-GMP.	We understand we can submit COPP in any Pharmacopeia of any country. Please confirm.	**Clarified As:-** Accepted.
9	Pg. No. 14; Clause 6(j) (Performance Statement) & Annexure IV on Pg. no. 49	**Performance Statement:** Performance Statement **to establish 2 years market standing** as per format given in Annexure-IV.	Performance Statement as per Ann IV : We hereby request you to waive the Performance Statement as per Ann IV as the product Tab Bedaquline 100 mg was under the patent upto July 2023.	**Clarified As:-** Performance Statement to be provided for same or similar items, as per tender terms. **Similar Items here relate to the following:-** Similar item means quoted/any anti-TB drugs.
10	Pg. No. 30; Clause: 18 (Liquidated Damages and Other Penalties), Sub-clause 18.4(a)	The supplier will not dispatch/supply stocks/goods after the last date of scheduled delivery of the Lot/Tranche without PO amendment issued by procurement wing.	Request you to ease these criteria as Bedaquiline product is new for the supplier to manufacture (as the patent has just expired).	**Clarified As:-** No Change

Sr. No.	Tender document Pg. No. and Clause	Tender Descriptions	Bidder's Concern/ Query / Suggestion	Clarifications / Amendments
11	Pg. No. 36; Clause C (Quality Assurance) of Annexure 1A	**Inspection:** The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product. The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, warehouse, and quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.	Refer to this clause, kindly confirm is this applicable for all 3 Tranches supplies?	**Clarified As:-** No Change
12	Pg. No. 44 (Annexure-1B) & Pg. No. 45 (Annexure-1C)	Annexure-1B:- CMSS Warehouse & Mapped States Annexure-1C:- Consignee list and Schedule of Requirement (SOR)	Request to confirm whether we have to supply the goods to Annexure 1B list of 18 locations or to Annexure 1C list of 35 locations.	**Amended As:-** The consignee location is CMSS Warehouses and **Annexure IC** (Consignee list & Schedule of Requirement) to the tender document is being revised and is hereby attached. Thus, supply of goods to be made at Revised 09 nos. of CMSS warehouses as per Annexed.
13	Pg. No. 71; Annexure-XVIII	Undertaking on Letter head to Compliance to Ministry of Finance, DOE order No- 6/18/2019-PPD dated 23.07.2020 and No.F.7/10/2021-PPD (1), dated 23.02.2023	Request you to kindly provide the correct visible draft as some of the matter is not visible in the tender format.	**Clarified As:-** For accurate visibility of the content, we kindly request you to download our tender document from the CPP portal and the CMSS official website only.
14	Pg. No. 72; Annexure XIX	Consignee Receipt Certificate	We request to remove this certificate to submit along with Post Shipment documents. This is because, refer to past supplied tender, we are unable to get the CRC copy from each consignee & due to which we are unable to submit the bills and so our payments are stucked. So allow us to submit the POD's instead of CRC along with Post Shipment documents.	**Clarified As:-** No Change
15	Pg. No. 03, Notice Inviting Tender (NIT)	Bid documents may be scanned with 100 dpi with black and white option which helps in reducing size of the scanned document. Not more than one bid shall be submitted by one contractor or contractors having business relationship.	Request you to increase the dpi, as because in 200 dpi scan documents also the documents are not a clear copy & then same is asked to submit in Technical clarification points, so please increase the dpi size and file size to 60 to 70 mb to upload the documents in portal.	**Clarified As:-** May please contact CPP portal Helpdesk for the same.
16	Pg. No. 34; Annexure –I	**Order Distribution Criteria:** 70:30 as per clause no. 13	Here we request you to consider the order distribution criteria as 50: 30: 20. This is because as the quantity is huge and so the supplier (L2 & L3) can get the opportunity to supply the product.	**Clarified As:-** No Change

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17	Pg. No. 38; Clause G (Packaging) of Annexure 1A	The drug is initially packed in a white high density polyethylene (HDPE) bottle with child-resistant polypropylene (PP) closure with induction seal liner. Each HDPE bottle shall contain 188 tablets of Bedaquiline-100mg. 25 such HDPE bottles would be further packed in white coloured Millboard/Grey board boxes and 40 such Millboard / Greyboard boxes are ultimately packed in a 5-Ply Shipper. Quality Assurance is according to Norm ISO 9001 for all the packaging material.	Please consider Stability Data in Blister pack too.	**Clarified As:-** As per Technical Specifications
18	Pg. No. 35, Clause B (Description) of Annexure-1A,	Each uncoated tablet of Bedaquiline contains: Bedaquiline - 100mg, Pharmacopeia* (IP/BP/USP/any other International Pharmacopeia)	Kindly allow "FILM COATED" tablet too	**Amended As:-** Uncoated and Unscored tablet

Signature valid

Digitally signed by LALIT SHARMA
Date: 2024.08.12 17:15:32 IST
Location: eProcure-ERROC