



CENTRAL MEDICAL SERVICES SOCIETY

(An Autonomous Body, Ministry of Health & Family Welfare, Govt. of India)

2nd Floor, Vishwa Yuvak Kendra, Teen Murti Marg,

Chanakypuri, New Delhi-110021.

Website: www.cmss.gov.in, Tel. 011-21410905/6

Dated: 21-07-2025

AMENDMENT NO.01

Tender No: CMSS/PROC/2025-26/NTEP/016 Dt.30-06-2025

(CPP ID: 2025_CMSS_866435_1)

Tender for: - Rate Contract for Procurement of Tablet Pretomanid 200mg for NTEP

PRE-BID MEETING held on 07-07-2025 at 11:00 AM (IST)

Points raised by the Representatives of prospective bidders during the Pre-bid meeting held on **07-07-2025 at 11:00 AM (IST)** were discussed. The following amendments are hereby made to above referred tender document: -

- 1) **SECTION VI: Technical Specifications and Quality Assurance; Clause-K (Packaging); PAGE 65;**

FOR: -

The drug is initially packed in a white high-density polyethylene (HDPE) bottle with child resistant polypropylene (PP) closure with induction seal her and each HDPE bottle shall contain 30 tablets of Pretomanid -200mg. 144 such HDPE bottles would be further packed in white coloured Millboard/Grey board boxes and ultimately packed in a 5-Ply Shipper.

AMENDED TO BE READ AS:

The drug is initially packed in a white high-density polyethylene (HDPE) bottle with child resistant polypropylene (PP) closure with induction seal her and each HDPE bottle shall contain **26 tablets** of Pretomanid -200mg. 144 such HDPE bottles would be further packed in white coloured Millboard/Grey board boxes and ultimately packed in a 5-Ply Shipper.

Note: - Accordingly, all labels/ artworks to be amended as “26 Tablets” in place of “30 tablets”.

- 2) **SECTION VI: Technical Specifications and Quality Assurance; Clause-N (Labelling) & Clause-P (Labelling on 5-Ply Shipper); PAGE 67 & 69;**

FOR: -

TB TREATMENT DRUG CONTAINS PRODUCT CODE 76
PRETOMANID 200 MG

AMENDED TO BE READ AS:

**DR TB TREATMENT DRUG CONTAINS PRODUCT CODE 76
PRETOMANID 200 MG**

3) SECTION V: SCHEDULE OF REQUIREMENTS; B. DELIVERY SCHEDULE; PAGE 61;

FOR: -

B.1) For 1st Purchase Order:

Lot 1:	To be delivered within 90 days from the date of Purchase Order.
Lot 2:	To be delivered within 91 to 180 days from the date of Purchase Order.

AMENDED TO BE READ AS:

B.1) For 1st Purchase Order:

Lot 1:	To be delivered within 90 days from the date of Purchase Order.
Lot 2:	To be delivered within 181 to 210 days from the date of Purchase Order.

4) SECTION VIII: SPECIAL CONDITIONS OF CONTRACT; Clause: GCC 5.8 PAGE 136;

FOR: -

1. Within fourteen days of issue of Letter of Award, Performance Security against Rate Contract, equivalent to EMD amount and valid till 45 days beyond validity period of the Rate Contract shall be furnished.
2. Also, within fourteen days of award of Purchase Order against the Rate Contract, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the Purchase Order value (inclusive of all duties and taxes) valid till expiry of shelf life of the last consignment supplied under the contract. Accordingly, PBG validity will be as under:

Particulars	Sch. I (Pretomanid-200mg)
a) Last date of delivery as per Purchase Order	180
b) Shelf life	365*2 days
c) B.G. Extension	60 days
Total Performance security validity	970 days

3. Separate PBG shall be furnished as per Para “2” above for all Purchase Order issued under the Rate Contract.

AMENDED TO BE READ AS:

1. Within fourteen days of issue of Letter of Award, Performance Security against Rate Contract, equivalent to EMD amount and valid till 45 days beyond validity period of the Rate Contract shall be furnished.
2. Also, within fourteen days of award of Purchase Order against the Rate Contract, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the Purchase Order value (inclusive of all duties and taxes) valid till

expiry of shelf life of the last consignment supplied under the contract. Accordingly, PBG validity will be as under:

Particulars	Sch. I (Pretomanid-200mg)
a) Last date of delivery as per Purchase Order	210
b) Shelf life	365*2 days (Subject to change as per higher shelf life offered)
c) B.G. Extension	60 days
Total Performance security validity	1000 days

3. Separate PBG shall be furnished as per Para “2” above for all Purchase Order issued under the Rate Contract.

- 5) The **IMPORTANT TIMELINES** for the above referred tender have further been extended/amended as follows:

Particulars	Existing	Amended As
Last date and time for bid submission	23-07-2025 till 03:00 PM	28-07-2025 till 03:00 PM
Last date and time for submission of original documents	24-07-2025 till 03:00 PM	29-07-2025 till 03:00 PM
Date and time for tender opening (technical bid)	24-07-2025 at 04:00 PM	29-07-2025 at 04:00 PM

Note: -Apart from above, all other terms and conditions of bid document shall remain unchanged.

Sd/-
GM (Procurement-I/C)

Tender No.:- CMSS/PROC/2025-26/NTEP/016, Dt.30-06-2025
Tender for:- Rate contract for Procurement of Tablet Pretomanid 200mg for NTEP
Pre-bid meeting on:- 07-07-2025 @ 11:00 AM

Sr. No.	Pg. No. and Clause as per Tender document	Tender Brief Descriptions	Bidder's Query / Suggestion / Proposed modification	Clarification(s)/ Amendment(s)
1	Schedule I – Pretomanid 200mg – D – Quality Assurance (Pg #63 of 185)	The product has been manufactured as per WHO GMP requirements	Refer to this clause; we request you to consider Sch I – Pretomanid 200mg tablets WHO Pre Qualified or ERP approved. Product has to be of same quality for safety of people as it's a new drug.	Clarified as: As per Technical Specification
2	Refer to Sch I– clause # C – Protocol & Testing – Microbial Count (Pg # 63 of 185)	Microbial Testing:- Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements	Request to allow Skip Test of Microbial limits. So please remove the Micro testing in each batch. As per WHO guideline Microbial test is done on first five Commercial batches of the year & then after every 10th batch. We are requesting just to minimize the batch release timeline so that we can use the manpower at the QA/QC labs efficiently which may help in increasing the per month batch release output.	Clarified as: As per Technical Specification
3	Refer to Section VI, clause H-Shelf Life – 24 months (Page 64 of 185),	Shelf Life should be minimum 24 months from the date of manufacture	Request you to make the shelf life requirement of 36 month for Sch I - Pretomanid. Companies who have experience in manufacturing and getting the product prequalified by WHO, have 36-month shelf life. Thus, request you not to compromise with the standard of the product.	Clarified as: Minimum Shelf-life requirement is 24 months as per technical specifications. Higher shelf-life is also acceptable subject to submission of requisite stability data and other requisite information as per the tender document.
4	Refer to Clause: - SECTION VIII: SPECIAL CONDITIONS OF CONTRACT – Point # GCC 8.7.5 (Page # 137 of 185):	The contractor shall ensure that at least 5/6th of shelf-life remains balance on delivery date.	Please refer to this condition; instead of 5/6th (83%), we ask that the consignee be given a minimum of 75% shelf life at the time of delivery for Sch I. As because our shelf life for Sch I Pretomanid is 36 months, even if remaining shelf life is 75% still the product shelf life will have 27 months RSL which is still convenient for patient. We manufacture in lots at once, and it takes time for those batches to be released, followed by PDI and further dispatches post CMSS's clearance. Because of this drawn-out process, approximately one-fifth of the shelf life is lost. We assure CMSS to dispatch the goods from fresh production only. However, as the goods are required in multiple tranches, in the cases of left over quantity due to batch size or batch yield from Tranche I that we plan to allocate in Tranche II, while waiting for remaining quantity of Tranche II to get produced, the RSL of these small quantities may get below 5/6th. Hence the request to give provision for accepting 75% RSL of goods, on case to case basis.	Clarified as: As per Technical Specification

Sr. No.	Pg. No. and Clause as per Tender document	Tender Brief Descriptions	Bidder's Query / Suggestion / Proposed modification	Clarification(s)/ Amendment(s)
5	SECTION VI TECHNICAL SPECIFICATIONS AND QUALITY ASSURANCE K. Packing (Pg #65 of 185)	Each HDPE Bottle shall contain 30 Tablet of Pretomanid 200 mg	We request to change in the packing Specification from 30 tablets to 26 tablets per bottle for Pretomanid 200 mg Requirement of All Technical/Regulatory documents including Long terms stability data shall be in 26 Tabs HDPE bottle	Please refer to Amendment No. 01
		Refer to Section VI – technical Specifications and Quality Assurance – Clause # K. Packaging -	Refer to packaging – We can supply in 30's i.e as 10 x 3 blister.	Clarified as: As per Technical Specification Please refer to Amendment No. 01
6	SECTION VI TECHNICAL SPECIFICATIONS AND QUALITY ASSURANCE N Labelling	TB TREATMENT DRUG CONTAINS (Product Code 76) PRETOMANID-200mg	It has been asked in TC that Labelling in HDPE Bottle and 5-ply Shipper as "TB TREATMENT DRUG CONTAINS DELAMANID-50mg (Product Code 76)". Need confirmation	Please refer to Amendment No. 01
7	SECTION V SCHEDULE OF REQUIREMENTS B.2) Detailed Quantities to be delivered as per above Lots: - (Pg #61 of 185)	Delivery Schedule given as : Quantity to be delivered : within 90 Days from the date of PO ie 38,96,178 Within 91to 180 Days from the date of PO i.e 38,96,178	Tentative Tender Quantity mentioned as 30190420 Tabs We suggest you to give Delivery schedule for entire Tender Quantity , so that supplier can Plan for API /Packing Material and production which will help timely supply.	Clarified as: Being a rate contract, initial 07 months requirement will be procured and is indicated in the Tender Document. Based on further requirement of Programme division, the subsequent PO(s) will be placed.
			Refer to Sch # I – Pretomanid 200mg – We request to consider the delivery period as :- Tranche I – 250 days instead of 90 days depending upon the procurement of KSM + API production + Finished product + release + additional 15 days for logistic transportation. We understand approx 15% of the tender quantity is required to deliver in 90 days. It takes time for arranging the raw materials as its In-house production, packing materials, excipients itself will take 7-8 months. Once all the materials are available further 10-15 days for granulation, compression, coating, packing and additional 15 days batch release by QA/QC. Once the goods are additional time for PDI. We cannot anticipate in how many days we will receive the greenlight from NTEP/CMSS to ship the goods to the warehouses. Thus delivering the goods to the destination within 90 days is challenging. Request you to extend the delivery period for both the tranches as mentioned above.	Please refer to Amendment No. 01

Sr. No.	Pg. No. and Clause as per Tender document	Tender Brief Descriptions	Bidder's Query / Suggestion / Proposed modification	Clarification(s)/ Amendment(s)				
8	Clause 9.2.1 (3.d): Deletion of Market standing Certificate requirements (Pg # 27 of 185).	Market Standing Certificate for last 2 years - Deleted	Request you to include this clause with a clause of MSC for manufacturing and marketing experience of atleast 1 year. As these are new products and very challenging to manufacture considering the 8 step process only to manufacture API and further complications in manufacturing finished formulation. As BPaL, BPaLM regimen is recently introduced in INDIA; CMSS & MOH shouldn't see failure from new supplier who doesn't have experience of manufacturing or marking these products and whose products efficacy is not known.	Clarified as: No Change				
9	Refer to Form 4 – Qualification Criteria, Point j - Annual Turnover Statement of previous years in the Form 4.2. Point # k - Audited Annual Reports of previous years (Pg # 59 of 185).	<p>The tenderer must have average annual turnover of last three F.Y. 2021-22, 2022-23 & 2023-24 OR 2022-23, 2023-24 & 2024-25 more than the followings:</p> <table><tr><th>Schedule No.</th><th>Amount (in Rs.)</th></tr><tr><td>I</td><td>66,09,28,675</td></tr></table> <p>Annual turnover statement for last three financial years i.e. F.Y. 2021-22, 2022-23 & 2023-24 OR 2022-23, 2023-24 & 2024-25 should be furnished in the format given in Section IX Form 4.2 duly certified by the practicing Chartered Accountant. The certifying Chartered Accountant must indicate the details along with its UDIN. The MSEs and Startups bidders are exempted from aforesaid minimum turnover requirement.</p> <p>Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account for the last three years i.e. F.Y. 2021-22, 2022-23 & 2023-24 OR 2022-23, 2023-24 & 2024-25 duly certified by a practicing Chartered Accountant, where ever applicable.</p>	Schedule No.	Amount (in Rs.)	I	66,09,28,675	<p>Regarding Annual Audited documents, we request you to allow us to submit Annual Turnover Statement, Balance Sheet & Profit Loss account details only of last 3 years instead of full Audited Annual reports. As our audited balance sheet copies for 3 years are, approximately 500 pages (Total), due to which we have to compress the pdf file until its gets below 40MB limit to uploaded it on the portal. In many cases due to this compression of the PDF file, several pages are not legible, on which we keep on receiving queries during technical evaluation.</p> <p>Alternatively, we request you to increase the total limit to upload the documents on the portal.</p>	Clarified as:- Accepted, However, CMSS reserves the right to seek submission of complete or partial document from any bidder at any stage during the evaluation process or at any time during the contract period at the case may be.
Schedule No.	Amount (in Rs.)							
I	66,09,28,675							
10	Refer to Section V – List of products & Their Technical Specification – (Pg #60 of 185	Inspection Methodology : PDI for all Tranches	<p>Refer to this, we hereby request you to make all the Tranches as NON PDI, so that we can dispatch the goods immediately once the batches are released and shall delivered the goods on time.</p> <p>As PDI takes, time to provide confirmation to dispatch, so to save time, request to consider NON PDI for all Tranches.</p>	Clarified as:- Conditional dispatch clearance shall be provided on case to case basis.				

