CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health and Family Welfare (Government of India)
2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg,
Opposite Police Station Chankaya Puri, New Delhi-110021
Telephones: +91-11-21410905, 21410906

Dated 01.02.2023

AMENDMENT NO. 09

Tender No- CMSS/PROC/2022-23/NTEP/022 for Procurement of TB Preventive Therapy Drugs for NTEP.

The following amendment in the subject bid document is made.

Sr. No	Queries	Existing Entry as per amendment no 5 dt. 04.01.2023	Response
1	**Queries raised by M/s Lupin-** As per documents mentioned in Clause 6.1c, we have CT 23 and Form 28 Mfg license for Schedule 1 - Rifapentine 300 mg + Isoniazid 300 mg tablets. In case of Schedule 2 - Rifapentine 150 mg tablets, we have Form 28 manufacturing license I hope this will be OK. **Queries raised by M/s Svizera-** Remove the requirements of DCGI Form 46 (for companies having License from State Drug Authorities) and also the Market Standing Certificate (as these are new drugs). **Queries raised by M/s J. Duncan-** For Sch. I- Agreed with amendment no 5 dt. 04.01.2023. For Sch. II- Tenderer shall be a manufacturer of the quoted product and have a valid own manufacturing license (For Domestic) in the indicated pharmacopeia (in the technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP/IHS. The manufacturing license & COPP should be valid on the date of tender opening packet 1. Clause no 6.1.c:-The Tenderer should furnish the Manufacturing License (For domestic in form of 25 or 28 issued from State Licensing Authority) valid	For Sch. I & II:- Tenderer shall be a manufacturer of the quoted product and have a valid own manufacturing license (For Domestic) in the indicated pharmacopeia (in the technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP/IHS. The manufacturing license & COPP should be valid on the date of tender opening packet 1. Clause no 6.1.c:-The Tenderer should furnish the Manufacturing License (For domestic in form of 25 or 28 issued from State Licensing Authority) along with the approval of DCGI in form of 46 or CT-23 as new drug approved by DCGI valid on tender opening for each item quoted been duly renewed	**No Change as per confirmation received from DCGI, CDSCO HQ, New Delhi**

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	on tender opening for each item quoted been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only. For drugs that are not available in IP, other official Pharmacopeia (s) are applicable. If a drug is not available in any of the official pharmacopeias, 'In House' standards are applicable as per the Drugs and Cosmetics Act 1940 and the Rules there. Bidder is requested to submit an undertaking that the drug is not available in IP or any other approved pharmacopeia. Reasons:- 1. Drug Rifapentine 150mg film quoted tablet duly approved by DCGI in year 2019. 2. Four year period criteria not applicable as per D & C Act. Drug approved in 2019 (2019,2020, 2021, 2022). 3. Form CT 23/ Form 46 or permission issued by DCGI if for new drug approved less than 4 yrs period. 4. Manufacturing Lic always issued by Concerned SLA to manufacturer the product at plant in their states. Tender requirement should be Manufacturing License of the quoted product issued by SLA. 5. As general practices SLA are empowered to issue Manufacturing Lic for Govt. Tender purpose after getting all compliance by plant. SLA requires form 46/ CT 23 to issue manufacturing license for domestic retail market for drug new approved in India.	up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only. For drugs that are not available in IP, other official Pharmacopeia (s) are applicable. If a drug is not available in any of the official pharmacopeias, 'In House' standards are applicable as per the Drugs and Cosmetics Act 1940 and the Rules there. **Bidder is requested to submit an undertaking that the drug is not available in IP or any other approved pharmacopeia.**	

All other terms and conditions of the bid document shall remain unchanged.

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GM (Procurement)
Central Medical Services Society