

PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(Set up under the Department of Pharmaceuticals, Govt. of India)

8th& 9th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

Amendment no. 2

No.: -PMBI/DRUG/RC-207/2023/-II

DATE: 01/03/2023

Tender No. PMBI/DRUG/RC-207/2023 dated 02/02/2023 for supply of Drugs to Pharmaceuticals & Medical Devices Bureau of India (PMBI) for two years under rate contract.

**Reference: - i. Queries of Pre-Bid meeting held on 08/02/2023 at 15:00 Hours in the premises of PMBI.
ii. Bidders query received through mails.**

Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for "e- Tender for Supply of Drugs for the year 2023- 2025", vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-207/2023. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website of Central Public Procurement Portal; www.eprocure.gov.in and PMBI Website; www.janaushadhi.gov.in.

After considering the suggestions/ queries received from the prospective bidders, the clarifications/ amendments regarding the specification and packing in tender document have been made as per Part-A, Part-B & Part- C. All other technical specifications, terms, and conditions along with the tender schedule as mentioned in tender document shall remain unchanged.

The following amendment in Tender Document is hereby authorized:

Part-A

Sl. No.	Tender Clause/Reference	Query/Suggestion	Clarification/ Amendment
1	Clause no. 3. A Eligibility criteria (Technical bid -cover "A") at page 8 of the tender document.	The bidders requested to relax the EMD amount for companies under MSME category.	<u>No Change</u> Clarification: EMD is relaxed for the companies only falling under Micro and Small category.
2	Clause no. 3. G Eligibility criteria (Technical bid -cover "A") at page 9 of the tender document.	The Existing clause no. 3. G, is as follows:- WHO-GMP (WHO-Good Manufacturing Practice) as per revised Schedule- 'M' and Certificate of Pharmaceutical Product (CoPP) of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department. The WHO-GMP certificate and CoPP certificate must be valid as on the last date of submission of tender. Self-attested copies are to be submitted in hard copy.	Clause no. 3. G is hereby amended as: <u>WHO-GMP (WHO-Good Manufacturing Practice) as per revised Schedule- 'M' of the manufacturing unit and Product wise CoPP certificate</u> issued by the Licensing Authority/ Drugs Control Department. The WHO-GMP certificate and CoPP (product wise) must be valid as on the last date of submission of tender. Self-attested copies are to be submitted in hard copy.

3	Clause no. 3. Note (vi) Eligibility criteria (Technical bid -cover "A") at page 10 of the tender document.	The Existing clause no. 3. Note (vi), is as follows: - In case, if renewal application for Manufacturing License has been filled by the bidder or joint inspection has been carried out by the concerned Licensing Authority and for the renewal of WHO-GMP certification and/or CoPP certification, scanned copy of same duly receipted by drug authorities must be uploaded along with the validity certificate from State Licensing Authority (SLA). It shall be issued before the last date of submission of tender by the Licensing Authority.	Clause no. 3. Note (vi) is hereby amended as: In case, if renewal application for Manufacturing License has been filled by the bidder or joint inspection has been carried out by the concerned Licensing Authority for the renewal of WHO-GMP certification and/or CoPP certification (as per official pharmacopoeia reference for such drug), scanned copy of same duly receipted by drug authorities must be uploaded along with the validity certificate from State Licensing Authority (SLA). <u>All above mentioned certificates should be issued before the last date of submission of tender by the Licensing Authority.</u>
4	Clause no. 3. I Eligibility criteria (Technical bid -cover "A") at page 9 of the tender document.	The Existing clause no. 3. I, is as follows: - The bidders requested to reduce the average annual turnover to 20 crores as against required annual average turnover for any three of the last four consecutive financial years not less than 25 Crores	<u>No Change</u> Tender condition prevails.
5	Clause no. 19. J Supply conditions at page 22 of the tender document.	The Existing clause no. 19. J, is as follows: - Bidder must comply to the shelf life of each quoted drugs in accordance with Schedule P of Drugs and Cosmetics Rules, 1945. In case drug/medicine not covered in Schedule P of Drugs and Cosmetics Rules, 1945, the bidder must supply the drug/medicine with minimum 24 months shelf life. Bidders must declare the required shelf-life detail in Para VI of Annexure II.	<u>No Change</u> Tender condition prevails.
6	Clause no. 1 (ii) (c), Clause No. 20 (B) & Clause No. 21 (C) of the tender document.	The bidders requested to clarify the primary packaging type for drugs invited in mono carton.	<u>No Change</u> Tender condition prevails. Clarification: It is clarified that the 5 th column (Pack size) under Annexure XII denotes primary packaging be it eye/ear drop bottle or vial or vial with WFI or lami tube or bottle (as the case may be) including mono carton wherever specified. The second number in that denotes the number of units in a secondary packaging. It means that the unit pack in mono carton (wherever mentioned) is considered as primary packaging and which has to be further packed in corresponding quantity of unit packs as mentioned in one secondary packaging. <i>Wherever syrup/suspension/solution/drops etc. are mentioned in the specification, measuring cap/ hermetically sealed dropper shall be provided inside the mono-carton.</i>

Part - B: -**I: The following Amendment in Specification is hereby authorized: -**

Sl. No.	Tender Clause/ Reference	Sl. No. in the tender document	Drug Code	Generic Name of the Drug	Detailed Specification	Unit Size	Bidders Query	Amendment
1	Annexure - XII Clause 18 (M)	190	DC-830	Chlordiazepoxide 10mg and Trifluoperazine 1mg Tablets	Each uncoated tablet contains: Chlordiazepoxide 10mg Trifluoperazine HCL IP equivalent to Trifluoperazine 1mg	10's	The bidder requested to amend as Film coated tablet	Each film coated tablet contains: Chlordiazepoxide 10mg Trifluoperazine HCL IP equivalent to Trifluoperazine 1mg
2	For all other queries regarding the specification of invited products i.e. DC- 2, 3, 28, 29, 47, 207, 252, 291, 466, 598, 599, 830, 922, 974, 1059, 1098, 1106 & 1152 there is no change in the specification and the tender condition prevails.							
3	For queries regarding the pack size of invited products i.e. DC- 214, 289, 301, 332, 380, 384, 391, 403, 414, 426, 432, 445, 670, 1129, 1130 & 1221 there is no change in the pack size and the tender condition prevails.							

Part - C: -**I: The following Amendment in Specification is hereby authorized: -**

ANNEXURE – XIII
{Ref:- Clause No. 1(ii)(c), 20(B) & 21(A)}

(1)	(2)	(3)	(4)	(5)	(6)
S.N.	Drug Code	Generic Name of Item	Unit Size	Packing Type	Amended packing Type
1	DC-580	Ginseng, Multivitamins and multi minerals Capsules	10's	ALU-ALU	Blisters
2	DC-581	Calcium Carbonate 500mg, Calcitriol 0.25mcg and Zinc 7.5mg Capsules	10's	ALU-ALU	Blisters
3	DC-815	Calcitriol Capsules IP 0.25mcg	10's	ALU-ALU	Blisters
4	DC-974	Natural Micronized Progesterone Capsules 100mg	10's	ALU-ALU	Blisters
5	For all other queries regarding the packaging type of invited products i.e., DC- 2, 8, 12, 13, 214, 215, 220, 266, 269, 291, 312, 384, 414, 418, 435, 450, 516, 517, 556, 580, 581, 673, 815, 837, 840 & 1106 there is no change in the packaging type and the tender condition prevails.				

All other contents of tender document remain unaltered. Bidders are requested to quote their rates considering all the terms and condition of the tender document including Amendment no. 1 dated 17/02/2023. Bidders are also requested to refer MoM of the pre-bid meeting for other clarifications.

Sd/-
DGM (Procurement& Quality)
For & on behalf of PMBI
PH: 011-49431811