

PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)

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

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

Amendment No. 2

Ref. No: - PMBI/DRUG/RC-212/2023.

Dated: 31.10.2023

Subject: - Tender No. PMBI/DRUG/RC-212/2023 dated 22.09.2023 for Supply of Drugs to Pharmaceuticals and Medical Devices Bureau of India (PMBI).

Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for "Supply of Drugs for the year 2023-2025", vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-212/2023 dated 22.09.2023. 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.

The following amendment in Tender Document is hereby authorized through Part-A, Part-B, Part C and Part D: -

Part- A

Sr. No.	Tender Clause/ Reference	Queries/Suggestions	Clarification/Amendment
1	Clause 3 D. (e); of Eligibility Criteria (Technical Bid - Cover - "A") At page 9 of the tender document.	Bidders have raised their query in reference to the submission of Three (3) years of Market Standing Certificate against the products where patent has recently been released i.e., DC-2555, 2595, 2596, 2597, 2598 and others (if any).	It is to clarify that submission of Market Standing Certificate (MSC) in case of new drugs or drugs for which patent has been released recently (in 2021-2023) may be exempted. However, if the patent is expired before 2020-21 financial year, bid of such drugs may be accepted with Two-year Market Standing Certificate and CoPP certificate. Submission of Certificate of Pharmaceutical Products (CoPP) may also be exempted for the drugs where patent has been expired recently 2022 and new drugs but bidder shall submit the CoPP as soon as possible if awarded the contract.
2	Clause 3 Eligibility Criteria (Technical Bid - Cover - "A"): G (at page 9 of tender document).	Bidder has requested to accept the WHO-Product list in BP for the quoted items instead of CoPP Certificate	No Change Tender condition prevails.
3	Clause 3 Eligibility Criteria	Bidder has requested to get confirmation on consideration of	No Change

	(Technical Bid – Cover – “A”): E & I at Page 9 of tender document	Medium Scale Industries with valid UDYAM Registration certificate for Bid-Security Exemption as per new guidelines of MSME.	Tender condition prevails. It is to clarify that exemption is allowed for Micro and Small Enterprises (MSEs) only as per Tender Clause no. 3.A and Clause no. 6
4	Clause 19 Supply Conditions (Technical Bid- Cover- “A”): J	Bidder has requested to accept 18 months shelf-life in case of New Drugs, where the patent has been released recently.	It is to clarify that in case of New Drugs, where the patent has been released recently, bids may be accepted with 18 months shelf-life for limited period or as decided by the authority. However, the bidders should take initiative to increase the shelf-life up to minimum 24 months to fulfil the department requirement under tender clause no. 19 (shelf-life).
5	Clause 19 Supply Conditions (Technical Bid- Cover- “A”): C.3	Bidder has requested to provide 60 days delivery period from the date of receipt of order for drugs which require sterility testing i.e., Injectables/ Infusions/ Vials etc.	<u>No Change</u> Tender Condition prevails.
6	Clause 22. (QUALITY TESTING & QUALITY CONTROL):	Bidder has requested to consider valid GLP Certificate towards In-house generated Test Report (COA) to confirm the Quality of In house Laboratories as per Good Laboratories practices. GLP Certificate issue by Drug Licensing Authority against Tender clause: A. All the batches of the drugs supplied shall be supported by test/ analysis reports furnished by independent NABL Accredited Drugs Testing Laboratory/ Central Drug Testing Laboratory/In House Quality Control Laboratory. The Tender Inviting Authority has the right to get the drugs tested at the laboratories of his choice for further verifications, from PMBI empanelled laboratories.	<u>No Change</u> Tender Condition prevails.

Part – B

The following Amendment in Specification is hereby authorized: -

Sl. No	Tender Clause/ Reference	Drug Code	Generic Name of the Drug	Detailed Specification	Unit Size	Bidders Query	Amendment
1	Annexure - XII Clause 18 (M)	DC -2337	Olopatadine Hydrochloride 0.4% w/v and Ketorolac 0.1 %	Each 5 ml contains Olopatadine Hydrochloride equivalent To Olopatadine 0.4% w/v	5ml Drop bottle in Mono	Bidder has requested to amend the strength in detailed	Specification: The following strength is amended with detailed specification: Generic Name of the Drug:

			w/v Ophthalmic Solution	Ketorolac Tromethamine IP 0.1 % w/v	Carton	specification.	Olopatadine Hydrochloride 0.1 % w/v and Ketorolac 0.4% w/v Ophthalmic Solution Detailed Specification: Each 5 ml contains Olopatadine Hydrochloride equivalent to Olopatadine 0.1 %w/v Ketorolac Tromethamine IP w/v 0.4%
2	Annexure - XII Clause 18 (M)	DC-2452	Pazopanib Tablets 200mg	Each Film coated tablet contains: Pazopanib Hydrochloride 216.7 mg equivalent to Pazopanib 200 mg	30's Bottle	Bidder has requested to amend the strength in detailed specification	Specification: The following strength is amended with detailed specification: Each Film coated tablet contains: Pazopanib Hydrochloride equivalent to Pazopanib 200 mg
3	Annexure - XII Clause 18 (M)	DC-2505	Azilsartan Medoxomil Tablets 80mg	Each Uncoated Tablet contains: Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil 80mg	10's	Bidder has requested to amend the strength in detailed specification	Specification: The following strength is amended with detailed specification: Each Uncoated Tablet contains: Azilsartan Kamedoxomil eq. to Azilsartan Medoxomil 80mg
4	Annexure - XII Clause 18 (M)	DC-2527	Deferasirox Dispersible Tablets 250mg	Each uncoated dispersible tablet contains: Deferasirox 250mg	10's	Bidder has requested to amend the Unit size	Specification: The following Unit size is amended: 30s
5	Annexure - XII Clause 18 (M)	DC-2530	Deferasirox Dispersible Tablets 500mg	Each uncoated dispersible tablet contains: Deferasirox 500mg	10's	Bidder has requested to amend the Unit size	Specification: The following Unit size is amended: 30s
6	Annexure - XII Clause 18 (M)	DC-2531	Deferiprone Capsules 250 mg	Each hard gelatin capsule contains: Deferiprone 250mg	10's	Bidder has requested to amend the unit size	Specification: The following Unit size is amended: 50s
7	Annexure - XII Clause 18 (M)	DC-2532	Deferiprone Capsules 500 mg	Each hard gelatin capsule contains: Deferiprone 500mg	10's	Bidder has requested to amend the unit size	Specification: The following Unit size is amended: 50s
8	Annexure - XII Clause 18 (M)	DC-2614	Nitrofurantoin Sustained Release Tablets 100mg	Each film coated sustained release tablet contains: Nitrofurantoin IP 100mg	10's	Bidder has requested to amend the unit size	Specification: The following Unit size is amended: 15s
9	Annexure - XII Clause	DC-2655	Vildagliptin 50mg and Metformin	Each uncoated bilayered tablet contains:	10's	Bidder has requested to amend	Specification: The following Unit size is amended:

	18 (M)		Hydrochloride (sustained release) 1000mg Tablets	Vildagliptin 50mg Metformin Hydrochloride IP 1000mg (As Sustained release)		the unit size	15s
10	Annexure - XII Clause 18 (M)	2656	Vildagliptin 50mg and Metformin Hydrochloride (sustained release) 500mg Tablets	Each uncoated bilayered tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 500mg (As Sustained release)	10's	Bidder has requested to amend the unit size	Specification: The following Unit size is amended: 15s
11	Annexure - XII Clause 18 (M)	2134	Ribavirin Capsules USP 200mg	Each hard gelatin capsule contains: Ribavirin IP 200mg	4's	Bidder has requested to amend the pack size	The pack size is amended as under: 4's X 10 instead of 1's X 10

For all other queries regarding the specification of invited products i.e., DC-2524, 2584, 2655, 2656, 2630, 759, 2372 there is no change in the specification and the tender condition prevails.

DC-834 stands deleted from the tender and bidder shall not bid for the same.

Part - C

The Following amendment in the packing is hereby authorized: -

Pharmaceuticals & Medical

Sl. No	Tender Clause/ Reference	Drug Code	Generic Name of the Drug	Packing type	Packaging Standard of PVC/PVD C colour /Bottle/ Lamitube	Bidder Query	Amendment	
							Packing type	Packaging Standard of PVC/PVD C colour /Bottle/ Lamitube
1	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC - 2630	Sildenafil Tablets IP 20 mg	ALU-ALU	ALU-ALU	Bidder requested to amend the packing type	Blister	Blister
2	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC-2351	Tapentadol Tablets 50mg	ALU-ALU	ALU-ALU	Bidder requested to amend the packing type	Blister	Blister

For queries regarding the packing of invited products i.e., DC -759, 206, 266, 904, 2452, 2453, 2501, 2502, 2505, 2524, 2548, 2584, 2645, 2646, 2655, 2656 there is no change in the packing and the tender condition prevails.

Part -D:

An additional warehouse situated at Bangalore, India has been functional and added as another delivery destination: Bidders shall consider this address as well while bidding in the subject **Tender Clause 19. SUPPLY CONDITIONS: A:** the Address is as follow:

*“Regional Warehouse Bengaluru
Plot No 162 163, KIADB Industrial Area,
Hi Tech Defence Aerospace Park,
Devanahalli,
Bengaluru Rural -562110”*

- Where ever any category of medicine requires insert in the final packaging as per Drug & Cosmetics Rule 1945, the bidder shall supply the medicine with insert containing proper information.
- If bidder offers advance packaging over the tender requirement, it shall be accepted. (e.g., Packing of ALU-ALU shall be accepted in case of blister is required as per tender.)

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 16.10.2023 and this Amendment no. 2 dated 31.10.2023.



Sd/-

DGM (Procurement & Quality)
For & on behalf of PMBI
Ph: 011-49431800 (811)