PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(Under the Department of Pharmaceuticals, Govt. of India)

B-500, B-Tower, 5th Floor, Nauroji Nagar, World Trade Centre, New Delhi-110029

Amendment No. 1

No: PMBI/DRUG/RC-219/2024. **Dated: 28/08/2024**

Subject: - e-Tender No. PMBI/DRUG/RC-219/2024 dated 06/08/2024 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 eligible parties for "Supply of Drugs for the year 2024-2026", vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-219/2024 dated 06/08/2024. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on Central Public Procurement Portal; www.eprocure.gov.in as well as PMBI Website; www.janaushadhi.gov.in.

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

Part- A

Sr. No.	Tender Clause/ Reference	Queries/Suggestions	Clarification/Amendment
1	Annexure-I (Check-list), Note (i), at page 34 of tender document	Bidder has requested to amend and relax the submission of Annexure-IV & Annexure-V required in original.	***No Change*** Tender condition prevails.
2	Clause 3: U: ELIGIBILITY CRITERIA (Technical Bid -Cover "A"): At page 10 of tender document.	Bidder has requested to relax the submission of Batch Manufacturing Record (BMR) with Technical Bid (Cover-A), or to allow them to submit the aforementioned documents for the awarded drug codes.	***No Change*** Tender condition prevails.
3	Clause 3: D: (e): At page 9 of tender document.	Bidders have requested to relax the submission of Three (3) years Market Standing Certificate against the drugs where patent has recently been released i.e., DC-1801, 1802, 1803, 1804 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.

- **For:** Tender clause 3.D. (e) *'Market standing certificate & Manufacturing certificate issued by the Licensing Authority as a Manufacturer for each drug quoted for the latest three (3) consecutive years (Certificate should be enclosed with list of items) except for the drugs falling under the category of 'New Drug' as defined by CDSCO*

(Central Drugs Standard Control Organisation). If permission in Form 46 from DCGI has been obtained, then the 3 years Manufacturing & Market standing clause will be relaxed. The provisions of Rule 122 E of Drugs and Cosmetics Act rule 1945 shall be applicable.'

Read: 'Market standing certificate & Manufacturing certificate issued by the Licensing Authority as a Manufacturer for each drug quoted for the latest three (3) consecutive years (Certificate should be enclosed with list of items) except for the drugs falling under the category of 'New Drug' as defined by CDSCO (Central Drugs Standard Control Organisation). If permission in Form 46/ CT-23 from DCGI has been obtained, then the 3 years Manufacturing & Market standing clause will be relaxed. The provisions of Rule 122 E of Drugs and Cosmetics Act rule 1945 shall be applicable.'

Part – B

The following Amendment in detailed Specification/ packaging/ unit size 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 – 6	Chlorzoxazone 500mg, Diclofenac 50mg and Paracetamol 325mg Tablets	Each uncoated tablet contains: Chlorzoxazone 500 mg Diclofenac Potassium 50 mg Paracetamol 325 mg	10's	Bidder has requested to amend the detailed specification as: **Each uncoated tablet contains:** Chlorzoxazone 250 mg Diclofenac Potassium 50 mg Paracetamol 325 mg Also, bidder has requested to amend the detailed specification as: **Film coated tablets** instead of uncoated tablets.	**No change** *Tender condition prevails.*
2	Annexure - XII Clause 18 (M)	DC – 316	Betahistine Tablets IP 8 mg	Each Uncoated tablet contains: Betahistine Hydrochloride IP 8mg	10's	Bidder has requested to amend the unit size as: 15's instead of 10's	**No change** *Tender condition prevails.*
3	Annexure - XII Clause 18 (M)	DC – 440	Metoprolol 50mg (Prolonged release) and Amlodipine Besilate 5mg Tablets IP	Each film-coated bilayered tablet contains: Metoprolol Succinate IP 47.5mg equivalent to Metoprolol Tartrate 50mg Amlodipine Besilate IP equivalent to Amlodipine 5mg	7's	Bidder has requested to amend the unit size as: 10's instead of 7's	**No change** *Tender condition prevails.*

4	Annexure - XII Clause 18 (M)	DC – 502	Deflazacort Tablets 6 mg	Each uncoated tablet contains: Deflazacort 6mg	6's	Bidder has requested to amend the unit size and pack size as: 10's and (10's x 10) respectively.	**No change** *Tender condition prevails.*
5	Annexure - XII Clause 18 (M)	DC - 648	Diclofenac Dithylamine 1.16%w/w, Linseed Oil 3%w/w, Methyl Salicylate 10%w/w and Menthol 5%w/w Spray	Composition: Diclofenac Diethylamine IP 1.16% Eq. to Diclofenac Sodium 1% w/w Linseed oil BP (Oleum Lini) 3%ww Methyl Salicylate IP 10%W/W Menthol IP 5% W/W Excipients & propellant qs. to 100% w/w	35 gm	Bidder has requested to amend the detailed specification as: ***Each ml contains:*** *Diclofenac Diethylamine IP.....1.16% w/w (eq. to Diclofenac Sodium 1.00% w/w)* *Methyl Salicylate IP 10.00%w/w* *Menthol IP 5.00%w/w* *Linseed Oil BP 3.00 % w/w* *Absolute Alcohol IP 15.00 % w/w* ***In Topical Solution Base (Non-Aqueous) q.s.***	**No change** *Tender condition prevails.*
6	Annexure - XII Clause 18 (M)	DC – 779	Alpha Lipoic Acid 100mg, Vitamin D3 1000IU, Folic Acid 1.5mg, Pyridoxine 3mg and Methylcobalamin1500 mcg Tablets	Each film coated tablet contains: Alpha Lipoic acid 100mg Vitamin D3 1000 IU Pyridoxine Hydrochloride 3mg Folic acid 1.5mg Methylcobalamin 1500mcg	10's	Bidder has requested to amend the generic name and detailed specification as: *Each hard gelatin capsule contains:* *Methlycobalamin (as stabilized form) 1500mcg* *Alpha Lipoic Acid USP 300mg* *Chromium Polynicotinate equivalent to elemental Chromium 25mcg,* *L-Selenomethionine USP, equivalent to elemental selenium 40mcg,* *Zinc ascorbate equivalent to elemental zinc 3.15mg,* *Calcium Pantothenate 12.5mg, Pyridoxine Hydrochloride IP 3mg, Folic acid IP 1.5mg*	**No change** *Tender condition prevails.*
7	Annexure - XII Clause 18 (M)	DC – 976	Nebivolol Tablets IP 2.5mg	Each uncoated tablet contains: Nebivolol Hydrochloride IP 2.5 mg	10's	Bidder has requested to amend the detailed specification as Film	**No change** *Tender condition prevails.*

						coated tablets instead of uncoated tablets.	
8	Annexure - XII Clause 18 (M)	DC – 1541	Calcium 1250mg, Calcitriol 0.25mcg and Vitamin K2-7 45mcg Capsules	Each soft gelatin capsule contains: Calcium Carbonate 1250 mg (equivalent to Elemental Calcium 500 mg) Calcitriol 0.25 mcg Vitamin K2-7 45 mcg	10's	Bidder has requested to amend the generic name and detailed specification as: *Each film coated tablet contains: Calcium citrate malate equivalent to Elemental calcium 250mg, Calcitriol IP 0.25mcg, Vitamin K2-7 (0.1% stabilized) 50mcg*	**No change** *Tender condition prevails.*
9	Annexure - XII Clause 18 (M)	DC – 2083	Calcium Citrate Malate 250mg, Vitamin D3 100IU and Folic Acid 50mcg Tablets	Each film coated tablet contains: Calcium Citrate Malate eq. to elemental Calcium 250mg Cholecalciferol 100IU Folic Acid 50mcg	10's	Bidder has requested to amend the generic name and detailed specification as: *Each bi-layer tablet contains: Calcium Citrate Malate equivalent to Elemental calcium 250mg, Vitamin D3 (Cholecalciferol) IP 1000 IU*	**No change** *Tender condition prevails.*

- For the received queries regarding the packing specifications against DC –8, 465, 504, 1801, 1802, 1803 & 1804 there is no change in the packing specifications and the tender condition prevails.
- However, 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).
- 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.

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 this Amendment No. 1 dated 28/08/2024.

Sd/-

DGM (Procurement & Quality)
For & on behalf of PMBI
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