

**PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)**  
**(Set up under the Department of Pharmaceuticals, Govt. of India)**  
B-500, B-Tower, 5th Floor, Nauroji Nagar, World Trade Center, New Delhi-110029

**Amendment No. 2**

**No: PMBI/DRUG/RC-217/2024.**

**Dated: 31/07/2024**

**Subject: - e-Tender No. PMBI/DRUG/RC-217/2024 dated 03/07/2024 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-217/2024 dated 03/07/2024. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on Central Public Procurement Portal; [www.eprocure.gov.in](http://www.eprocure.gov.in) as well as PMBI Website; [www.janaushadhi.gov.in](http://www.janaushadhi.gov.in).

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

**Part- A**

Sr. No.	Tender Clause/ Reference	Queries/Suggestions	Clarification/Amendment
1	Clause 22: QUALITY TESTING & QUALITY CONTROL: (Technical Bid – Cover – “A”) at page 25 of the tender document.	Bidder has requested to ask valid Good Laboratory Practices (GLP) certificate against in-house generated test report/ Certificate of Analysis (CoA) to confirm the genuineness and quality.	<b><u>No Change</u></b> Tender condition prevails.
2	Clause 19: C: [Sl. No. iii (in table)] Supply Conditions (Technical Bid Cover – “A”): at page 21 of tender document.	Bidder has requested to <i>amend 'Delivery Schedule against first Purchase Order</i> to 60 days as against 45 days for all drugs except Injectable/Infusion/Vials (Products do not required sterility testing).	<b><u>No Change</u></b> Tender condition prevails.
3	Clause 3: G and L: ELIGIBILITY CRITERIA (Technical Bid -Cover “A”): At page 9-10 of tender document.	Bidder has requested to relax the submission of Batch Manufacturing Record (BMR), stability study data, CoPP and DMF with Technical Bid (Cover-A), whereas some other intending bidders have requested to allow them to submit the aforementioned documents for the awarded drug codes.	<b><u>No Change</u></b> Tender condition prevails.  However, bidders may be asked to submit Drug Master File (DMF) of all or any drug if so required by PMBI after award of contract.
4	Clause 3: G: ELIGIBILITY CRITERIA (Technical Bid -Cover “A”): at page 9 of tender document.	Bidder has requested to relax the submission of WHO-GMP Certificate & CoPP for drug code DC-2243.	<b><u>No Change</u></b> Tender condition prevails.

5	Clause 3: I: ELIGIBILITY CRITERIA (Technical Bid -Cover "A"): at page 9 of tender document.	Some of the intending bidders during pre-bid meeting and over mail (pre-bid query) have requested to reduce the requirement of annual average turnover for three consecutive years of the last four financial years from Rs. 50 Crores (Fifty crore).	<b><u>No Change</u></b> Tender condition prevails.
6	Clause 3: G: ELIGIBILITY CRITERIA (Technical Bid -Cover "A"): at page 9 of tender document.	One of the intending bidders has requested to relax the submission of WHO-GMP certificate & CoPP for drug codes DC-715 & DC-2634.	<b><u>No Change</u></b> Tender condition prevails.
7	Clause 19: J: Supply Conditions (Technical Bid – Cover – "A"): at page 22 of tender document.	Bidder has requested to accept the product DC-2243 with 15 months shelf-life.	DC-2243 may be accepted with shelf-life not less than 18 months.
8	Clause 22: LIQUIDATED DAMAGES & OTHER PENALTIES: (Technical Bid -Cover "A") at page 27 of the tender document.	Bidder has requested to reduce the LD (Liquidated Damages) to 0.5% per month	<b><u>No Change</u></b> Tender condition prevails.
9	Clause 21: C: Packing: (Technical Bid – Cover – "A") at page 27 of the tender document.	Bidder has requested to clarify gloss laminated and embossed packing.	It is to clarify that the outer carton/ secondary packaging should be of pearl white duplex board (off white/grey is not acceptable) with a minimum of 350 GSM with Gloss laminated and embossed packing.

## **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 - 2249	Abacavir 600mg, Dolutegravir 50mg and Lamivudine 300mg Tablets	Each Film coated tablet contains: Abacavir Sulphate equivalent Abacavir 600 mg Dolutegravir Sodium equivalent Dolutegravir 50 mg Lamivudine 300 mg	30's in container	Bidder has requested to amend the detailed specification as Abacavir Sulphate USP equivalent Abacavir 600 mg Dolutegravir Sodium equivalent Dolutegravir 50 mg Lamivudine 300 mg USP	<b><u>No Change</u></b> Tender condition prevails.  However, it is to clarify that bidders may participate with requested detailed specification.

2	Annexure - XII Clause 18 (M)	DC – 1	Aceclofenac 100mg and Paracetamol 325mg Tablets	Each film-coated tablet contains: Aceclofenac 100mg Paracetamol 325 mg	10's	Bidder has requested to amend the detailed specification as uncoated tablets instead of film coated tablets	<b><u>No Change</u></b> Tender condition prevails.
3	Annexure - XII Clause 18 (M)	DC – 2536	Diclofenac Diethylamine 1.16% w/w, Sesame oil 2.5% w/w, Linseed oil 0.5% w/w, Methyl Salicylate 10% w/w & Menthol 5% w/w Gel	Composition: Diclofenac Diethylamine 1.16% w/w, Sesame oil 2.5% w/w, Linseed oil 0.5% w/w, Methyl Salicylate 10% w/w Menthol 5% w/w	30gm tube	Bidder has requested to amend the detailed specification.	<b>Detailed specification of the Drug:</b> The detailed specification of the drug is hereby amended as follows: Composition: Diclofenac Diethylamine 1.16% w/w, Sesame oil 2.5% w/w, Linseed oil 3% w/w, Methyl Salicylate 10% w/w Menthol 5% w/w
4	Annexure - XII Clause 18 (M)	DC – 2653	Vildagliptin 100mg and Metformin Hydrochloride (sustained release) 1000mg Tablets	Each uncoated bilayered tablet contains: Vildagliptin 100mg Metformin Hydrochloride 1000mg (As Sustained release)	10's	Bidder has requested to amend the detailed specification.	<b><u>No Change</u></b> Tender condition prevails.
5	Annexure - XII Clause 18 (M)	DC – 2654	Vildagliptin 100mg and Metformin Hydrochloride (sustained release) 500mg Tablets	Each uncoated bilayered tablet contains: Vildagliptin 100mg Metformin Hydrochloride 500mg (As Sustained release)	10's	Bidder has requested to amend the detailed specification.	<b><u>No Change</u></b> Tender condition prevails.
6	Annexure - XII Clause 18 (M)	DC – 2517	Citicoline Oral Drops 100ml per ml	Each ml contains: Citicoline Sodium eq. to Citicoline 100mg	30ml Bottle	Bidder has requested to amend the detailed specification.	<b>Generic Name of the Drug</b> The generic name of the drug is hereby amended as follows: Citicoline Oral Drops 100mg per ml However, the detailed specification prevails as per tender.
7	Annexure - XII Clause 18 (M)	DC – 574	Rabies Vaccine, Human IP	Rabies vaccine for Human use. Potency not less than 2.5 IU per single human dose	0.5 ml vial with diluent in Mono pack	Bidder has requested to amend the unit size	<b>Unit Size of the Drug</b> The following is hereby amended with unit size of the drug as:

							1 ml vial with diluent in Mono pack
8	Annexure - XII Clause 18 (M)	DC - 2534	Denosumab (r-DNA origin) 60mg per ml in Pre-filled Syringe	Each 1ml pre-filled syringe contains: Denosumab (r-DNA origin) 60mg	1ml Prefilled Syringe	Bidder has requested to relax the submission of Market Standing Certificate for DC-2534	Market Standing Certificate for New Drugs is relaxed as per provision under Tender Clause 3.D. (e)
9	Annexure - XII Clause 18 (M)	DC - 2249	Abacavir 600mg, Dolutegravir 50mg and Lamivudine 300mg Tablets	Each Film coated tablet contains: Abacavir Sulphate equivalent Abacavir 600 mg Dolutegravir Sodium equivalent Dolutegravir 50 mg Lamivudine 300 mg	30's in container	Bidder has requested to relax the submission of Market Standing Certificate for DC-2249	Market Standing Certificate for New Drugs is relaxed as per provision under Tender Clause 3.D. (e)
10	Annexure - XII; <b>Clause 18 (M)</b> and Annexure - XIII Clause No. 1(ii)(c), 20(B) & 21(A)	DC-2086	Carica papaya leaf Extract 1100mg, Goat Milk 250mg and Tinospora Cordifolia 250mg Extract Tablets	Each Tablet contains Carica Papaya Leaf Extract 1100 mg , Goat Milk Powder 250 mg Tinospora Corditolia Extracts 250 mg	10's	Bidders has requested to accept GMP under Schedule T for DC-2086.	The Drug Code 2086 is hereby deleted from the tender document and BOQ.
11	Annexure - XII; <b>Clause 18 (M)</b> and Annexure - XIII Clause No. 1(ii)(c), 20(B) & 21(A)	DC-2087	Papaya Leaf Extract 1100mg Tablets	Each film coated tablet contains: Carica Papaya Leaf extract 1100mg	15's	Bidders has requested to accept GMP under Schedule T for DC-2087.	The Drug Code 2087 is hereby deleted from the tender document and BOQ.
<b>Note:</b> 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.)							

**Part - C:**

Sl. No.	Tender Clause/ Reference	Tender Clause	Amendment
1	Clause 3	<p>Clause 3. A) Earnest Money Deposit (EMD): EMD of Rs. 10,00,000.00/- (Rupees Ten Lakh only as specified in Clause 6 of the Tender document in the form of Bank Guarantee or National Electronic Fund Transfer (NEFT) or Bankers Cheque or Demand Draft from Nationalized/Scheduled Bank favoring "PHARMACEUTICALS &amp; MEDICAL DEVICES BUREAU OF INDIA" payable at Delhi, which is to be submitted in original to PMBI, New Delhi on or before the date and time stipulated in tender document. Name &amp; full address of the bidder may be written at the back of the Demand Draft/Pay Order. Signed and scanned soft copy of the EMD instrument must be uploaded (ANNEXURE III) to the e-Procurement portal. EMD in any other form like Cheque/cash/postal order etc. will not be accepted. The Bid (in case not exempted for EMD as mentioned in tender document) without EMD shall be summarily rejected.</p> <p>Clause 3. Note: (i) Tenderer may be exempted from the payment of EMD for MSEs, if valid registration certificate from MSME / Udyam Registration Certificate is uploaded and submitted self-attested copy with Technical Bid for the product for which bidder has submitted quotation.</p>	<p>Clause 3. (A) is hereby amended as follow: A) Earnest Money Deposit (EMD): EMD of Rs. 10,00,000.00/- (Rupees Ten Lakh only as specified in Clause 6 of the Tender document in the form of Bank Guarantee or National Electronic Fund Transfer (NEFT) or Bankers Cheque or Demand Draft from Nationalized/Scheduled Bank favoring "PHARMACEUTICALS &amp; MEDICAL DEVICES BUREAU OF INDIA" payable at Delhi, which is to be submitted in original to PMBI, New Delhi on or before the date and time stipulated in tender document. Name &amp; full address of the bidder may be written at the back of the Demand Draft/Pay Order. Signed and scanned soft copy of the EMD instrument must be uploaded (ANNEXURE III) to the e-Procurement portal. EMD in any other form like Cheque/cash/postal order etc. will not be accepted. The Bid without EMD shall be summarily rejected.</p> <p>Note: (i) is hereby deleted from Clause. 3.</p>
2	Clause. 6. B	Clause. 6. B); Tenderer may be exempted from the payment of EMD, if valid registration certificate from MSME is uploaded for the product for which bidder has submitted quotation.	Clause 6. (B) is here by deleted from the tender document.
3	Serial Number 4 of Annexure I (Check list)	<p>Serial No. 4 of Checklist (Annexure-I);</p> <p>MSE certificate/ Udyam Registration Certificate (If claimed to be under MSE category) as per Clause No. 3.A Note.</p>	Serial No. 4 of Checklist (Annexure-I) is hereby deleted from tender document
4	Annexure- IV	<p>Para (IV) of Annexure IV; Ref. Clause No. 3. (I).</p> <p>(IV) Further, It is certified that M/S .....is Micro and Small Enterprises (MSEs) and registered with Director of Industries of concerned State/UT or appropriate</p>	Para (IV) of Annexure IV, Ref. Clause No. 3. (I) is hereby deleted from the tender document.

		authorities for quoted drugs against PMBI tender No. PMBI/DRUG/RC-217/2024 and eligible for exemption of submission of Bid Security/Earnest Money Deposit.	
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**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 25/07/2024 and this Amendment No. 2 dated 31/07/2024.**

Sd/-

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