

**PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)**  
**(Set up under the Department of Pharmaceuticals, Govt. of India)**  
8<sup>th</sup> Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

**Amendment No. 2**

**Ref. No: - PMBI/DRUG/RC-211/2023.**

**Dated: 10.10.2023**

**Subject: - Tender No. PMBI/DRUG/RC-211/2023 dated 11.09.2023 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 “e- Tender for Supply of Drugs for the year 2023-2025”, vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-211/2023 dated 11.09.2023. 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](http://www.eprocure.gov.in) and 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 3 Eligibility Criteria (Technical Bid – Cover – “A”) D. (e) At page 9 of the tender document.	Bidder has raised query in reference to the submission of 3 years of Market Standing Certificate against the products where patent has recently been released.	It is to clarify that as per tender clause bidders are exempted from submitting Market Standing Certificate in case of new drugs. Please refer clause no. 3. D (e).
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	<b><u>No Change</u></b> Tender condition prevails.
3	Clause 3 Eligibility Criteria (Technical Bid – Cover – “A”): E & I at Page 9 of tender document	Bidder has requested exemption from the submission of turnover and prior experience for MSMEs.	<b><u>No Change</u></b> Tender Condition prevails.
4	Clause 4 General Condition (Technical Bid – Cover – “A”): G At page 12 of tender document. Annexure I Checklist Sr. No. 26.		The manufacturer shall declare the Active Pharmaceutical Ingredients (API) polymorphic form used in formulation for all quoted drugs and declare that it is internationally accepted active polymorph when ask by PMBI. Bidder shall submit the source of API and Certificate of Analysis (CoA) of last two consecutive purchase of all API against quoted drug codes with the online bid and self-attested hard copy in sealed envelope.

			<b>Note:</b> <i>In source of API bidder shall submit the details of vendor with complete address on the letter head duly signed by Authorised Signatory.</i>
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## 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 –3	Pregabalin Capsules IP 75 mg	Each hard gelatin capsule contains: Pregabalin IP 75g	10's	Bidder requested to amend the strength in detailed specification.	<b>Specification:</b> Each hard gelatin capsule contains: Pregabalin IP 75mg
2	Annexure - XII Clause 18 (M)	DC – 574	Rabies Vaccine, Human IP	Anti Rabies Vaccine (Purified Chick embryo cell) 2.5 IU, 1ml vial	1 ml Ampoule	-----	<b>Specification:</b> Rabies vaccine for Human use. Potency not less than 2.5 IU per single human dose <b>Unit Size:</b> 0.5 ml vial with diluent in Mono pack
3	Annexure - XII Clause 18 (M)	DC – 834	Cholecalciferol (Vitamin D3) Drops 400 IU per ml	Each ml contains: Vitamin D3 IP 400IU (Cholecalciferol) In a flavoured base qs.	15 ml	Bidder requested to amend the base requirement	<b>Specification:</b> Each ml contains: Vitamin D3 IP 400IU (Cholecalciferol) In a flavoured syrup base qs.
4	Annexure - XII Clause 18 (M)	DC – 1689	Levosambutamol 1.25mg and Budesonide 0.5mg respules	Each 2.5ml respules contains: Levosambutamol Hydrochloride equivalent to Levosambutamol 1.25mg Budesonide 0.5mg	2.5 ml	Bidder requested to amend the unit size.	<b>Specification:</b> Each 2ml respules contains: Levosambutamol Hydrochloride equivalent to Levosambutamol 1.25mg Budesonide 0.5mg <b>Unit Size:</b> 2ml respules
5	Annexure - XII Clause 18 (M)	DC – 1794	Salbutamol Rotacaps 200mcg	Each Capsule contains: Salbutamol Sulphate equivalent to Salbutamol 200mcg	30's	Bidder requested to amend the unit size	<b>Unit Size:</b> 60's in Container

For all other queries regarding the specification of invited products i.e., DC- 269, 424, 452,438, 598, 570, 746, 766, 781, 1686, 1690, 1704, 1707, 1792, 1793, 1854, 1861, 1945, 1961, 1962, 2034, 2044 and 2047 there is no change in the specification and the tender condition prevails.

Further DC – 359 is being deleted from the product list.

**Part – C**

The Following amendment in the packing is hereby authorized: -

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 – 8	Serratiopeptidase 10mg and Diclofenac Sodium 50mg Tablets	Blister	ALU-ALU	-----	ALU-ALU	ALU-ALU
2	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC – 574	Rabies Vaccine, Human IP	Monocarton	Market Standard	-----	Mono carton containing 0.5 ml vial, diluent and package insert containing information regarding dosage instructions, frequency, contraindications etc.	
3	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC – 687	Lactulose 10gm per 15ml	Amber Colour Bottle	Amber Colour Bottle	Bidder requested to amend the packing	Bottle with laminated label	Market Standard
4	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC – 1794	Salbutamol Rotacaps 200mcg	Market Standard	Market Standard	-----	HDPE Container	Market Standard
5	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC – 1957	Risperidone Tablets 1 mg IP	Blister	Alu-Alu	-----	Blister	Blister
6	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC - 1958	Risperidone Tablets 2 mg IP	Blister	Alu-Alu	-----	Blister	Blister

7	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC – 2008	Simethicone 40mg, Dill Oil 0.005Ml And Fennel Oil 0.0007Ml Drops	Amber Colour Bottle	Amber Colour Bottle	Bidder requested to amend the packing	Amber Colour Bottle in a monocarton	Amber Colour Bottle in a monocarton
8	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC – 2050	Amlodipine Tablet IP 10mg	Blister	Alu Foil Strip	-----	ALU-ALU	ALU-ALU

For queries regarding the packing of invited products i.e., DC – 25, 52, 269, 285, 432, 434, 447, 570, 687, 834, 1283, 1485, 1597, 1860, 1865, 1866, 1868, 1904, 1906, 1943, 1945 and 1948 there is no change in the packing and the tender condition prevails.

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 22.09.2023 and this Amendment no. 2 dated 10.10.2023.**

Pharmaceuticals & Medical  
Devices Bureau of India

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