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. 1

No: - PMBI/DRUG/RC-213/2024 **Dated: 16/04/2024**

Subject: - Tender No. PMBI/DRUG/RC-213/2024 dated 22.03.2024 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 parties for "Supply of Drugs for the year 2024-2026", vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-213/2024 dated 22.03.2024. 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 & Part D: -

Part- A: -

Sr. No.	Tender Clause/ Reference	Queries/Suggestions	Clarification/Amendment
1	Clause 3 Eligibility Criteria (Technical Bid – Cover – "A"): G at Page 9 of tender document	Bidder has requested to accept the WHO-GMP Certificate with approved list of dosage forms against tender requirement of approved drug list under WHO-GMP certificate product wise issued by Drug Licensing Authority/Drug Control Department.	**The clause is amended as under:** WHO-GMP (WHO-Good Manufacturing Practice) as per revised Schedule- 'M' of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department. The WHO-GMP certificate must be valid as on the last date of submission of tender. Self-attested copies are to be submitted in hard copy.
2	Clause 3 Eligibility Criteria (Technical Bid – Cover – "A"): U at Page 10 of tender document	Bidder has requested to accept BMR for items where contract will be awarded instead of tender requirement of each quoted Drugs. Further, Bidder has requested exemption from submission of BMR for Drugs falling under "New Drug" category.	***No Change*** Tender condition prevails.
3	Clause 4 General Conditions (Technical Bid – Cover – "A"): G at Page 12 of tender document	Bidder has requested exemption from submission of Certificate of Analysis of last two batches of all API for DRUGs falling under "New Drug" category.	***No Change*** Tender condition prevails.

4	Clause 3 Eligibility Criteria (Technical Bid – Cover – "A") A At page 8 of the tender document.	Bidder has requested for clarification on submission of EMD for the institutes falling under MSME category.	It is to mention that exemption is allowed for MSEs only as per Tender Clause no. 3.A and Clause no. 6 including orders/OM/circular if any issued by the concerned ministry.
5	A sub-clause 16. E for Agreement signing after issuance of Letter of Acceptance (LoA) under tender Clause no. 16. 'AWARD OF CONTRACT' is hereby included through this Amendment No.1 in the tender document along with format for signing of agreement. The clause may be read as under: *"The bidder shall execute an agreement on a non-judicial stamp paper of value of Rs. 100/- (to be paid by tenderer) within 15 days from the date of intimation from PMBI informing that their tender has been accepted/ the issuance of the LoA. The specimen form of agreement is available as Annexure-XVII".* Agreement Format is attached herewith the amendment as Annexure XVII.		
6	A Modification in Annexure V (Mandate Form) is authorized and modified format is attached here with this Amendment no. 1.		

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 – 2750	Tadalafil Oral Disintegrating Strips 10 mg	Each orally disintegrating strip contains: Tadalafil 10mg	4's in Mono-carton	Bidder requested to amend the Unit Size and Pack Size	***Unit Size and pack size are amended as under:*** Unit Size: 1's Pack Size: 1's X 10
2	Annexure - XII Clause 18 (M)	DC – 2751	Tadalafil Oral Disintegrating Strips 20 mg	Each orally disintegrating strip contains: Tadalafil 20mg	4's in Mono-carton	Bidder requested to amend the Unit Size and Pack Size	***Unit Size and pack size are amended as under:*** Unit Size: 1's Pack Size: 1's X 10
3	Annexure - XII Clause 18 (M)	DC – 1686	Levosalbutamol 100mcg and Beclomethasone 100mcg Rotacaps	Each Capsule Contains: Levosalbutamol Sulphate equivalent to Levosalbutamol 100mcg Beclomethasone Dipropionate 100mcg	30's container	Bidder requested to amend the Unit Size	***Unit Size is amended as under:*** 60's in container
4	Annexure -	DC -	Levosalbutamol 100mcg	Each Capsules contains:	30's	Bidder requested to	***Unit Size is amended as***

	XII Clause 18 (M)	1690	and Ipratropium 40mcg Rotacaps	Levosalbutamol Sulphate equivalent to Levosalbutamol 100mcg Ipratropium Bromide equivalent to Ipratropium Bromide (anhydrous) 40mcg	container	amend the Unit Size	***under:*** 60's in container.
5	Annexure - XII Clause 18 (M)	DC - 1689	Levosalbutamol 1.25mg and Budesonide 0.5mg respules	Each 2ml respules contains: Levosalbutamol Hydrochloride eq. to Levosalbutamol 1.25mg Budesonide 0.5mg	2ml Respules	Bidder requested to amend the Pack Size	**Pack Size is amended as under:** 1's X 5
6	Annexure - XII Clause 18 (M)	DC – 1908	Amitriptyline Hydrochloride 25mg Chlordiazepoxide 10mg Tablets	Each Film Coated Tablet Contains: Amitriptyline Hydrochloride IP equivalent to Amitriptyline 5 mg Chlordiazepoxide IP 10 mg	10's	NA	**Detailed specification is amended as under:** Each Film Coated Tablet Contains: Amitriptyline Hydrochloride IP equivalent to Amitriptyline **25 mg** Chlordiazepoxide IP 10 mg
7	Annexure - XII Clause 18 (M)	DC – 2706	Metformin Hydrochloride Tablets IP 250 mg	Each uncoated tablet contains: Metformin Hydrochloride IP 200mg	10's	NA	**Detailed specification is amended as under:** Each uncoated tablet contains: Metformin Hydrochloride IP 250mg
8	Annexure - XII Clause 18 (M)	DC – 2723	Olmesartan Medoxomil 20mg, Cilnidipine 10mg and Chlorthalidone 6.25mg Tablets	Each film coated tablet contains: Olmesartan Medoxomil 20mg Cilnidipine 10mg Chlorthalidone 6.5mg	10's	NA	**Detailed specification is amended as under:** Each film coated tablet contains: Olmesartan Medoxomil 20mg Cilnidipine 10mg Chlorthalidone **6.25mg**
9	Annexure - XII Clause 18 (M)	DC – 2725	Oseltamivir Phosphate Capsules IP 30mg	Each hard gelatin capsule contains: Oseltamivir Phosphate IP eq. to Oseltamivir 75mg	10's	NA	**Detailed specification is amended as under:** Each hard gelatin capsule contains: Oseltamivir Phosphate IP eq. to Oseltamivir **30mg**
10	Annexure -	DC -	Rebamipide Tablets 100	Each film coated tablet	10's	NA	**Detailed specification is**

	XII Clause 18 (M)	2728	mg	contains: Rebamipide 5mg			**amended as under:** Each film coated tablet contains: Rebamipide 100mg
11	Annexure - XII Clause 18 (M)	DC - 2715	Octroide long-acting release Injection 20mg (Lyophilised)	Each box contains: 1 Vial of Octroide as free peptide 20mg (in form of microspheres) 1 purified syringe of 2ml: Vehicle for 2ml suspension 1 Vial adapter 1 Sterile Injection needle	Vial	NA	**Generic Name and Detailed Specification is amended as under:** **Generic Name** Octreotide long-acting release Injection 20mg (Lyophilised) **Detailed specification:** Each box contains: 1 Vial of Octreotide as free peptide 20mg (in form of microspheres) 1 purified syringe of 2ml: Vehicle for 2ml suspension 1 Vial adapter 1 Sterile Injection needle
12	Annexure - XII Clause 18 (M)	DC - 2716	Octroide long-acting release Injection 30mg (Lyophilised)	Each box contains: 1 Vial of Octroide as free peptide 30mg (in form of microspheres) 1 purified syringe of 2ml: Vehicle for 2ml suspension 1 Vial adapter 1 Sterile Injection needle	Vial	NA	**Generic Name and Detailed Specification is amended as under:** **Generic Name** Octreotide long-acting release Injection 30mg (Lyophilised) **Detailed specification:** Each box contains: 1 Vial of Octreotide as free peptide 20mg (in form of microspheres) 1 purified syringe of 2ml: Vehicle for 2ml suspension 1 Vial adapter 1 Sterile Injection needle
For all other queries regarding the specification of invited products i.e., DC- 699, 1703, 1707, 2676, 2677, 2678, 2700, 2740, 2741, 2755, 2756 & 2768 there is no change in the specification and the tender condition prevails.							

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 – 2688	Feracrylum mouth wash/Gargle 1% w/v (Mint Flavour)	Spray pump PET dosing mouth bottle	Market Standard	Bidder requested to amend the packing type.	Bottle with measuring cup	Market Standard
2	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC - 2689	Feracrylum Sterile Antiseptic Solution 1% w/v	HDPE bottle with dispenser in monocarton	Market Standard	Bidder requested to amend the packing type.	LDPE bellow bottle with nozzle in monocarton	Market Standard
3	Annexure-XIII Clause 1(ii)(c), 20(B) & 21(A)	DC – 2732	Rivaroxaban Tablet 2.5 mg	NA	NA	NA	Blister	Transparent Blister

For queries regarding the packing of invited products i.e., DC –829, 2677, 2678, 2700, 2722, 2755, 2756 & 2768 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.)

Part – D: - Amendment in last date of online submission of tender on CPP Portal is hereby authorized as per below table:

Sr. No.	Details	Existing Schedule	Amended Schedule
1	Last date and time for submission of Online Bid i.e., Bid Submission End Date and time	On 19.04.2024 (Friday) up to 17.00 Hours	On 26.04.2024 (Friday) up to 17.00 Hours
2	Last Date and time for submission of *Bid Security Declaration and Original Required Documents as per ANNEXURE I (Check List), in physical Form* in office of Bureau of Pharma PSUs of India, 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055	On 22.04.2024 (Monday) at 15.00 hours	On 29.04.2024 (Monday) at 15.00 hours
3	Time and date of opening of Technical Bid	On 22.04.2024 (Monday) by 16.00 hours	On 29.04.2024 (Monday) by 16.00 hours

For: -

2. LAST DATE AND TIME FOR SUBMISSION OF ONLINE TENDER:

i. (a) Online Bids [in two separate Cover {Technical bid (Cover "A") and price bid (Cover "B")}] shall be submitted till 17.00 Hours up to 19.04.2024 (Friday) on CPP portal i.e., https://eprocure.gov.in.

Read: -

2. LAST DATE AND TIME FOR SUBMISSION OF ONLINE TENDER:

i. (a) Online Bids [in two separate Cover {Technical bid (Cover "A") and price bid (Cover "B")}] shall be submitted till 17:00 Hours up to 26.04.2024 (Monday) on CPP portal i.e., https://eprocure.gov.in.

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 16.04.2024.

ANNEXURE-V (Modified)

Ref. clause 3 (K) & 23. (B)

MANDATE FORM

Sl. No.	Details Required	Information to be filled for correspondence
1.	**Company Name:**	
2.	Postal Address of the Company	
	GST No.	
	Telephone No.	
	Fax No.	
	E-mail ID (Registered)	
	Email ID (on Company Website)	
3.	Name of the Managing Director / Director / Manager	
	Mobile No. / Phone No	
	E-mail ID	
4.	Name and Designation of the authorized company official	Name: Designation:
	Mobile No.	
	E-mail ID	
5.	Name and Designation of the company official Authorised for communication in respect of technical documents.	Name: Designation:
	Mobile No.	
	E-mail ID	
6.	Name and Designation of the company official Authorised for communication in respect of status of Purchase Orders/artwork.	Name: Designation:
	Mobile No.	
	E-mail ID	
7.	**For Vendor Portal Registration**	
	Permanent E-mail ID	
	Permanent Mobile No.	
8.	**Bank Details**	
	a) Name of the Bank	
	b) Branch Name & address	
	c) Branch Code No.	
	d) Branch Manager Mobile No.	
	e) Branch Telephone no	
	f) Branch E-mail ID	
	g) 9-digit MICR code number of the bank and branch appearing on the MICR cheque issued by the bank	
	h) IFSC Code of the Branch	
	i) Type of Account (Current / Savings)	
	j) Account Number (as appear in cheque book)	

(In lieu of the bank certificate to be obtained, please **attach the original cancelled cheque** issued by your bank for verification of the above particulars).

I / We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all the reasons of incomplete or incorrect information, I would not hold **Pharmaceuticals & Medical Devices Bureau of India (PMBI)** responsible. I have read the conditions of the tender / Rate contract entered and agree to discharge the responsibility expected of me / from the company as a tenderer / successful tenderer.

Date: Signature :

Name :

Designation:

Place: Company Seal (Name of the person signing & designation)

CERTIFIED THAT THE PARTICULARS FURNISHED ABOVE BY THE COMPANY ARE CORRECT AS PER OUR RECORDS.

Signature of the authorized official of the bank

Bank Seal with address:

Note: Without bank seal and signature document shall not be accepted.

ANNEXURE - XVII

Reference Clause No. 16.E

AGREEMENT

THIS AGREEMENT is executed on …….. Between Pharmaceuticals and Medical Devices Bureau of India, 8th Floor, Videocon Tower, Jhandewalan, New Delhi-110055 (hereinafter called as "PMBI")

AND

……(Name of Supplier)……(City and Country of Supplier) …… (hereinafter called "SECOND PARTY"):

Party under this agreement means individual party to this however Parties mean all parties or more than one party to this agreement collectively.

WHEREAS **"Pharmaceuticals & Medical Devices Bureau of India"** hereinafter referred to as "**PMBI**" is a Society registered under the Societies registration act XXI of 1860, having its Registered Office at Videocon Tower, 8th Floor, E-I, Jhandewalan Extension, New Delhi-110055 is under the aegis of Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India. PMBI is the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojna (PMBJP), scheme of Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers. PMBI deals in the distribution of Janaushadhi Medicines and fulfil the needs of medicines of Janaushadhi Kendras throughout India".

AND WHEREAS, PMBI has floated a Tender reference No. PMBI/DRUG-…… for the supply of Drugs/ Goods mentioned in the said tender.

AND WHEREAS (Name of Second Party) has submitted the tender and has been declared as successful bidder for the tender Reference No. PMBI/DRUG-…… and bid has been accepted by PMBI for supply of those goods and services for the sum of …….. (Contract Price in Words and figure) (hereinafter called "the Contract Price").

NOW THIS AGREEMENT WITNESSES AS FOLLOWS:

1. The words and expressions mentioned in this Agreement shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to, and they shall be deemed to form and be read and construed as part of this agreement. The Tender Document shall also be treated as part of this agreement.

2. The Second Party is not blacklisted/debarred/de-registered/banned by any State Government/ Central Government or Drug procurement agencies due to quality failure of the drugs or any other reasons at the time of entering this agreement.
3. If any information/ declaration made by the Second Party is found false at any stage before or after award of contract or deliberately defraud with PMBI, the Second Party shall be blacklisted for a period of 2 years. Apart from blacklisting, the Earnest Money / Security Deposit submitted by the Second Party shall be forfeited and all its existing contracts would also be cancelled and security deposits in other contracts shall also be forfeited.
4. In case of NSQ or spurious or adulterated or misbranded drugs/products are supplied such batch(s) will be deemed to be rejected and the second party shall be liable for such losses and debit note shall be issued against the same.
5. In case of NSQ, the drug/product shall be tested by empanelled laboratory of PMBI and the full amount debit note may be issued against second party for the invoices/purchase order and product may be returned to the second party at the second party cost if asked.
6. If NSQ by way of Market complaint during shelf life is observed, then the control sample may be tested through empanelled laboratory of PMBI and if the control sample is also found NSQ then full amount debit note shall be issued against the second party and remaining stock may be given back to the second party on demand and logic.
7. In case of DI failure, the second party will put the batch on hold and the batch may be re-called and detailed information shall be sent to the concerned Government authority and as per defined policy, the necessary protocol may be followed.
8. Non-supply shall be considered as serious violation of tender/contract condition. In this case the first party shall use alternate/Risk purchase option to mitigate public demand In lieu of violation of contract condition or as defined in the tender.
9. In consideration of the payments to be made by PMBI to the Second Party as hereinafter mentioned, the Second Party hereby covenants with the PMBI to provide, the goods and services and to remedy defects therein in conformity in all respects with the provisions of the Contract.
10. The PMBI hereby covenants to pay the Second Party in consideration of the provision of the goods and services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.
11. **Signing Authority/ Testifying witness:** The Second party / Signing Authority shall be in capacity of *Proprietor/Managing Partner /Managing Director* of the concerned awarded company/entity as declared in the tender. The Competent Testifying Witness shall be the regular employee of the concerned awarded company/entity.

12. The following documents shall be deemed to form and be read and construed as part of this Agreement, viz

a. The Letter of Acceptance issued by the First Party.
b. The Notice Inviting Tender
c. The supplier's bid including enclosures, annexures, etc.
d. The Terms and Condition of the Contract.
e. The Schedule of Requirement.
f. The Technical Specification
g. Any other document required and listed in the bid and replies to queries clarifications issued by the First Party, such confirmations given by the bidder which are acceptable to the purchaser and the entire Addendum issued as forming part of the Contract.

13. Brief particulars of the goods and services which shall be supplied / provided by the Second Party are mentioned under:

Sl. No.	Drug Code	Name of Product	Unit Size	Unit Price Exclusive GST	GST	Unit Price inclusive GST
				Total Contract Value (Appx.)		

Total awarded value in words _____

Tender quantity indicated in the tender is for the tender purpose only and it represent the basis of unit for ease of pricing. The actual quantity may vary from zero to maximum required during the contract period. The quantity shall be drawn from time to time during the contract period subjected to various terms and conditions of the tender.

14. PERFORMANCE SECURITY DEPOSIT:

A) On being informed about the acceptance of the tender for Rate Contract, the Performance Security Deposit @ 3% or as defined by the Government through notifications, will be deducted from each running bills and accumulated security deposit will be refunded without any interest by PMBI to the second party within 60 days following the date of completion of second party performance obligations under the contract including the shelf-life obligation.

B) The Security deposit of second party will be returned by PMBI only after the second party has given undertaking to replace such medicines and indemnify PMBI against any losses on account of quality parameters duly notarized.

15. DELIVERY SCHEDULE

Supply shall be completed by the second party within 60 days from the date of issuance of 1st purchase order and within 45 days from the date of issue of subsequent purchase order.

16. DISPUTE RESOLUTION

This agreement shall be deemed to have been made/executed at Delhi for all purposes.

Normally, there should not be any scope of dispute between the PMBI and the Second Party after entering into a mutually agreed valid contract/agreement.

However, due to various unforeseen reasons, problems may arise during the progress of the contract/agreement leading to disagreement between PMBI and the Second Party, then parties shall first try to resolve the same amicably by mutual Consultation and negotiation. If the parties fail to resolve the dispute by such mutual consultation within twenty-one days, then either the PMBI or the Second Party shall give notice to the other party of its intention to commence Arbitration procedure as per Indian Arbitration and Conciliation Act, 1996. Such disputes/differences shall be referred to Sole Arbitrator appointed by the CEO of PMBI. The venue of Arbitration shall be at New Delhi. The award published by the Arbitrator shall be full and final which shall be binding on both the parties.

17. GOVERNING LAW/JURISDICTION

The applicable law governing this agreement shall be the laws of India and the courts of Delhi shall have the exclusive jurisdiction to try any dispute arising out of this agreement.

IN WITNESS where of the parties here to have executed this Agreement in accordance with the laws on the date and year as mentioned above.

Signed, Sealed and Delivered by the

FIRST PARTY – PMBI

In the presence of witnesses

Witness 1 ……

Signature and stamp

Witness 2 ……

Signature and stamp

NAME- (SECOND PARTY)

Address-

Designation-

Seal

In the presence of witnesses

Witness 1: ……

Signature and stamp

Witness 2: ……..

Signature and stamp

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

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