

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 Center, New Delhi-110029

Amendment No. 2

No: PMBI/DRUG/RC-221/2025/02

Dated: 29/04/2025

Subject: e-Tender No. PMBI/DRUG/RC-221/2025 dated 02/04/2025 for supply of Drugs to Pharmaceuticals & Medical Devices Bureau of India (PMBI).

Pharmaceuticals & Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for Supply of Drugs for the year '2025-2027', vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-221/2025 dated 02/04/2025. 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	Clause 3: I: ELIGIBILITY CRITERIA (Technical Bid -Cover "A"): at page 9 of the tender document.	Some of the intending bidders have requested to relax/ reduce the requirement of annual average turnover for three consecutive years of the last four financial years from Rs. 50 Crores (Fifty crores).	<u>No Change</u> 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.	<u>No Change</u> Tender condition prevails.
3	Clause 3: G: ELIGIBILITY CRITERIA (Technical Bid -Cover "A"): At page 9 of tender document	Bidder has requested to remove the requirement for submission of Certificate of Pharmaceutical Product (CoPP) for each quoted product issued by the Drug Licensing Authority/ Drugs Control Department as per tender clause 3.G, stating that 'CoPP is not a mandatory requirement for bidders holding valid WHO-GMP certificate.'	<u>No Change</u> Tender condition prevails. However, bids may be submitted with duly acknowledged application for Certificate of Pharmaceutical Product (CoPP) against the quoted drugs issued by the concerned Drug Licensing Authority/ State Licensing Authority (SLA)/ Drugs Control Department, and a declaration on company letter-head along with the bid documents. The duly issued CoPP certificates shall be submitted immediately upon receipt.
4	Clause 3: D: (e): At page 9 of tender document.	Bidder has requested for relaxation in submission of Market Standing Certificate (MSC) & Certificate of Pharmaceutical Product (CoPP certificate) in case of New Drugs.	It is clarified that as per tender clause 3.D(f) ' <i>In case of drug where patent has recently been released (in 2021-2024) submission of market Standing Certificate may be exempted. However, if the patent is</i>

			expired before F.Y. 2021-22, bid of such drugs may be accepted with two-year Market Standing Certificate'. and submission of CoPP certificate may be relaxed for the drugs where patent has been recently released.
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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)	29	Aciclovir Tablets IP 400 mg	Each uncoated tablet contains: Acyclovir 400mg	10's	Bidder has requested for amendment in the unit size and pack size as: 5's in blue PVC blister	<u>No change</u> <i>Tender condition prevails.</i>
2	Annexure - XII Clause 18 (M)	48	Azithromycin Dispersible Tablets 100mg	Azithromycin Dispersible Tablets 100mg	10's	Bidder has requested for amendment in the unit as: 3's Tab per strip	Amendment in the unit size is hereby authorized as: Unit size: 3's Pack size: 3's x 10
3	Annexure - XII Clause 18 (M)	65	Cefpodoxime Proxetil Dispersible Tablets 100 mg	Each uncoated dispersible tablet contains: Cefpodoxime Proxetil IP equivalent to Cefpodoxime 100 mg	10's	Bidder has requested for amendment in the packaging specification as: Strip pack instead of Alu-Alu	Amendment in the packaging specification is hereby amended as: Alu-Alu/ Market standard
4	Annexure - XII Clause 18 (M)	120	Fusidic Acid Cream IP 2% w/w	Each gm contains: Fusidic Acid 20 mg Potassium Sorbate 2.7 mg (as Preservative)	5gm Lami-tube	Bidder has requested to amend the detailed specification as: Each gm contains: Fusidic Acid IP 20 mg Chlorocresol IP 0.12mg (as Preservative) in miscible cream base	Amendment in the detailed specification is hereby authorized as follows: Contains: Fusidic Acid IP 2% w/w Suitable cream base q.s.
5	Annexure - XII Clause 18 (M)	207	Omeprazole Gastro-resistant Capsules IP 20 mg	Each Hard Gelatin capsule contains: Omeprazole IP 20 mg (As enteric coated pellets)	10's	Bidder has requested for amendment in the pack size as: 10's x 10	Amendment in the pack size is hereby authorized as: 10's x 10
6	Annexure - XII Clause 18 (M)	391	Moxifloxacin Tablets 400 mg	Each Film coated tablet contains: Moxifloxacin Hydrochloride equivalent to Moxifloxacin 400mg	5's	Bidder has requested for amendment in the unit size as 10's	<u>No change</u> <i>Tender condition prevails</i>
7	Annexure - XII Clause 18 (M)	426	Acenocoumarol Tablets IP 2 mg	Each Uncoated tablets contains: Acenocoumarol IP 2 mg	30's	Bidder has requested for amendment in the unit size as 10's	<u>No change</u> <i>Tender condition prevails</i>

8	Annexure - XII Clause 18 (M)	466	Ursodeoxycholic Acid Tablets IP 300 mg	Each Film Coated Tablet Contains: Ursodeoxycholic Acid IP 300 mg	10's	Bidder has requested to accept uncoated form instead of film-coated form in the detailed specifications.	<u>No change</u> <i>Tender condition prevails.</i>
9	Annexure - XII Clause 18 (M)	477	Chlordiazepoxide 5mg and Clidinium Bromide 2.5mg Tablets	Each sugar-coated tablet contains: Chlordiazepoxide IP 5mg Clidinium Bromide 2.5mg	10's	Bidder has requested to accept film-coated form instead of sugar-coated form in detailed specifications.	<u>No change</u> <i>Tender condition prevails.</i>
10	Annexure - XII Clause 18 (M)	519	Ketorolac Tromethamine Tablets IP 10mg	Each Film coated tablet contains: Ketorolac Tromethamine IP 10mg	10's	Bidder has requested to accept dispersible tablet form instead of film-coated form in detailed specifications.	<u>No change</u> <i>Tender condition prevails</i>
11	Annexure - XII Clause 18 (M)	564	Tiotropium Bromide 18mcg and Formoterol Fumarate Dihydrate 12mcg Rotacaps	Each capsule contains: Tiotropium bromide monohydrate Ip equivalent to Tiotropium 18mcg Formoterol Fumarate Dihydrate IP 12mcg	15's	Bidder has requested for amendment in the unit size and pack size as 30's and 30's x 10 respectively	Amendment in the unit size and pack size of drug are hereby authorized as follows: Unit Size: 30's Pack size: 30's x 1 x 10
12	Annexure - XII Clause 18 (M)	565	Tiotropium Bromide 18mcg, Formoterol Fumarate Dihydrate 12mcg and Ciclesonide 400mcg Rotacaps	Each capsule contains: Tiotropium (as Tiotropium Bromide Monohydrate IP) 18 mcg Formoterol Fumarate Dihydrate IP 12mcg Ciclesonide IP 400 mcg	15's	Bidder has requested for amendment in the unit size and pack size as 30's and 30's x 10 respectively	Amendment in the unit size and pack size of drug are hereby authorized as follows: Unit Size: 30's Pack size: 30's x 1 x 10
13	Annexure - XII Clause 18 (M)	599	Pregabalin Tablets 75 mg	Each film coated tablet contains: Pregabalin IP 75 mg	10's	Bidder has requested to accept the drug/ medicine in Capsule form.	<u>No change</u> <i>Tender condition prevails</i>
14	Annexure - XII Clause 18 (M)	626	Ketoconazole Shampoo 2% w/v	Ketoconazole Shampoo 2% W/V	100 ml Bottle	Bidder has requested for amendment in the detailed specification as: Ketoconazole Shampoo BP Composition: Ketoconazole IP 2% w/v Shampoo base q.s. Approved colour used	Amendment in the detailed specification is hereby authorized as follows: Composition: Ketoconazole IP 2% w/v Shampoo base q.s.
15	Annexure - XII Clause 18 (M)	670	Glucosamine 750mg, Diacerein 50mg and Methylsulfonylmethane 250mg Tablets	Each film-coated tablet contains: Glucosamine Sulphate Potassium Chloride 750 mg Diacerein 50 mg Methylsulfonylmethane 250mg	10's	Bidder has requested for amendment in the unit size as 15's	<u>No change</u> <i>Tender condition prevails</i>

16	Annexure - XII Clause 18 (M)	671	Glucosamine 500mg and Diacerein 50mg Tablets	Each film-coated tablet contains: Glucosamine Sulphate Potassium Chloride 500 mg Diacerein 50 mg	10's	Bidder has requested for amendment in the detailed specification and pack size as: Glucosamine Sulphate Potassium Chloride 750mg	Amendment in the pack size is hereby authorized as: 10's x 1 x 10
17	Annexure - XII Clause 18 (M)	926	Ketoconazole Cream 2% w/w	Each gm contains: Ketoconazole 20mg	15g Lami-tube	Bidder has requested for amendment in the detailed specification as: Ketoconazole Cream BP Composition: Ketoconazole IP 2% w/v Cream base q.s.	Amendment in the detailed specification is hereby authorized as follows: Composition: Ketoconazole IP 2% w/w Cream base q.s.
18	Annexure - XII Clause 18 (M)	974	Natural Micronized Progesterone Capsules 100mg	Each soft gelatin capsule contains Progesterone 100mg (Natural, Micronized)	10's	Bidder has requested to accept Capsule/ Tablet form of drug	No change <i>Tender condition prevails.</i>
19	Annexure - XII Clause 18 (M)	987	Nitrofurantoin Tablets I.P 100mg	Each uncoated tablet contains: Nitrofurantoin IP 100 mg	10's	Bidder has requested to accept Film-coated sustained release form instead of uncoated tablet in the detailed specification.	No change <i>Tender condition prevails.</i>
20	Annexure - XII Clause 18 (M)	997	Paclitaxel Injection IP 100mg (6mg/ml)	Each ml contains: Paclitaxel IP 6mg	Vial	Bidder has requested to amend the unit size as: Paclitaxel 100mg/ 16.7ml	Amendment in the name and detailed specification are hereby authorized as follows: Name: Paclitaxel Injection IP 100mg Detailed specifications: Each vial contains: Paclitaxel 100mg
21	Annexure - XII Clause 18 (M)	1098	Metformin Hydrochloride 500mg (Sustained Release) and Voglibose 0.2mg Tablets	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (Sustained Release) Voglibose IP 0.2mg	10's	Bidder has requested to accept uncoated form instead of uncoated bilayered form in the detailed specifications.	No change <i>Tender condition prevails.</i>
22	Annexure - XII Clause 18 (M)	1114	Moxifloxacin Hydrochloride Eye Drops IP 0.5% w/v	Each ml contains Moxifloxacin Hydrochloride IP equivalent to Moxifloxacin IP 5 mg	5 ml	Bidder has requested to amend the detailed specifications as Moxifloxacin Hydrochloride IP equivalent to Moxifloxacin IP 5mg/ 0.5% w/v	Amendment in the detailed specification is hereby authorized as follows: Contains: Moxifloxacin Hydrochloride IP equivalent to Moxifloxacin IP 0.5% w/v

23	Annexure - XII Clause 18 (M)	1544	Coenzyme Q10 100mg, Lycopene 4000mcg, Selenium 70mcg and Omega-3 Fatty Acids (EPA 90mg and DHA 60mg) Capsules	Each soft gelatine capsule contains: Coenzyme Q10 (Ubidecarenone) 100 mg Ecosapentanoic Acid (EPA) 90 mg Docosahexaenoic Acid (DHA) 60 mg Lycopene (as 100%) 4000mcg Selenium (as Selenium Dioxide Monohydrate) 70mcg	10's	Bidder has requested to amend the packaging type and packaging standard as PVC blister. Also, bidder has requested to amend the pack size as: 10 x 1 x 10 (with monocarton)	Amendment in the packaging standard and unit size is hereby authorized as follows: Packaging type and packaging standard as: PVC blister Unit size: 10's in monocarton
24	Annexure - XII Clause 18 (M)	1665	Indacaterol 110mcg and Glycopyrronium 50mcg Inhalation Powder, Hard Capsules	Each capsule contains: Indacaterol maleate 143 mcg e.q to Indacaterol 110 mcg Glycopyrronium Bromide 63 mcg e.q to Glycopyrronium 50 mcg	30 capsules and 1 inhaler in monocarton	Bidder has requested for amendment in the unit size as: 30 capsules & 1 inhalation device in mono pack (Pin puncture device for rotacap) of polymed material/ Acrylonitrile butadiene/ Styrene Polymer/ Polycarbonate/ Acetal Resin/ Polyacetal copolymer (which reduces less deposition of drug in the device)	Amendment in the pack size is hereby authorized as follows: 30's Capsules & 1 inhalation device made of Polymed Material/ Acrylonitrile Butadiene/ Styrene Polymer/ Polycarbonate/ Acetal Resin/ Polyacetal copolymer in monocarton.
25	Annexure - XII Clause 18 (M)	2054	Mecobalamin 1500 mcg, Alpha Lipoic Acid 100mg, Inositol 100mg, Folic Acid 1.5mg, Chromium Picolinate 200mcg, Selenium Dioxide 55mcg and Benfotiamine 150 mg Soft gel Capsule	Each Soft gelatin Capsule contains: Mecobalamin IP 1500mcg Alfa Lipoic Acid 100mg Inositol 100mg Folic Acid IP 1.5mg Chromium Picolinate 200mcg Selenium Dioxide 55mcg Benfotiamine 150mg	10's	Bidder has requested for clarification in the pack size.	Amendment in the pack size is hereby authorized as follows: 10's x 1 x 10
26	Annexure - XII Clause 18 (M)	2109	Glucosamine Tablets USP 500mg	Each film coated tablet contains: Glucosamine Sulphate Potassium Chloride USP 500mg equivalent to Glucosamine base 296mg	30's in Bottle	Bidder has requested clarification in the pack size.	Amendment in the unit size pack size is hereby authorized as: Unit Size: 30's in HDPE Bottle Pack size: 30's x 1 x 10
27	Annexure - XII Clause 18 (M)	2111	Isotretinoin Capsules IP 10mg	Each soft gelatin capsule contains: Isotretinoin 10mg	10's	Bidder has requested to amend the packaging type and packaging standard as PVC blister. Also, bidder has requested to amend the pack size as: 10 x 1 x 10 (with monocarton and insert)	Amendment in the packaging standard and unit size is hereby authorized as follows: Detailed specification:

							Each soft gelatin capsule contains: Isotretinoin IP 10mg Packaging type and packaging standard as: PVC blister Unit size: 10's in monocarton Note: DC-2111 shall be provided with insert as per CDSCO guidelines.
28	Annexure - XII Clause 18 (M)	2132	Pregabalin (Sustained release) 75mg and Methylcobalamin 1500mcg Tablets	Each uncoated bilayered tablet contains: Pregabalin IP 75mg (as sustained-release form) Methylcobalamin IP 1500mcg	10's	Bidder has requested to accept film-coated form instead uncoated bi-layered form in detailed specifications:	No change <i>Tender condition prevails.</i>
29	Annexure - XII Clause 18 (M)	2149	Bacillus Mesentericus-2M, Clostridium Botulinum Toxin Type A-4M, Lactobacillus Sporogenes-100M, Streptococcus Faecalis-60M Capsules	Each Capsule Contains: Bacillus Mesentericus-2M, Clostridium Botulinum Toxin Type A-4M, Lactobacillus Sporogenes100M, Streptococcus Faecalis 60M	10's	Bidder has requested for amendment in the detailed specification as: Each Capsule Contains: Streptococcus Faecalis T-110 JPC 60 million Clostridium Butyricum TO-A 4 million Bacillus Mesentricus TO-A JPC 2 million Lactic Acid Bacillus 100 million (Lactobacillus Sporogenes)	The following amendment in detailed specification are hereby authorized: Pre & Pro-Biotic Capsules (Bacillus Mesentericus- 2M, Clostridium Butyricum-4M, Lactobacillus Sporogenes-100M, Streptococcus Faecalis-60M)
30	Annexure - XII Clause 18 (M)	2175	Iron Sucrose Injection USP	Each ml contains ferric hydroxide complex with sucrose equivalent to elemental iron 20 mg	1's	Bidder has requested for amendment in the pack size.	Amendment in the pack size is hereby authorized as follows: 1's x 10 in monocarton
31	Annexure - XII Clause 18 (M)	2211	Perindopril Erbumine 4mg and Indapamide 1.25mg Tablets	Each film coted tablet Contain Perindopril Erbumine 4mg and Indapamide 1.25mg	10's	Bidder has requested to amend the detailed specification and pack size as: Each uncoated tablet contains: Pack size as: 10's x 6	No change <i>Tender condition prevails.</i>
32	Annexure - XII Clause 18 (M)	2218	Sacubitril and Valsartan Tablets 200mg	Each film coated tablet contains: Sacubitril 97mg Valsartan (as Sodium salt complex) 103mg	7's	Bidder has requested for amendment in the detailed specifications as: Each film coated tablet contains: Sacubitril 97mg	No change <i>Tender condition prevails.</i>

						Valsartan 103mg	
33	Annexure - XII Clause 18 (M)	2286	Adapalene 1% w/w and Benzoyl Peroxide 2.5% w/w Gel 15 gm	Each tube contains Adapalene 1% w/w (as microspheres) Hydrous Benzoyl Peroxide 2.5% w/w Gel base q.s.	15gm Lami Tube	Bidder has requested for clarification in the name and detailed specification	Amendment in the name and detailed specification of drug are hereby authorized as follows: Name: Adapalene 0.1% w/w and Benzoyl Peroxide 2.5% w/w Gel 15 gm Detailed specification: Each tube contains: Adapalene 0.1% w/w (as microspheres) Hydrous Benzoyl Peroxide 2.5% w/w Gel base q.s.
34	Annexure - XII Clause 18 (M)	2295	Brivaracetam 50mg Tablets	Each film coated tablet contains Brivaracetam 50 mg	10's	Bidder has requested for clarification in the pack size.	Amendment in the pack size is hereby authorized as follows: 10's x 1 x 10
35	Annexure - XII Clause 18 (M)	2296	Calcitriol 0.25 mcg, Calcium Carbonate 500 Mg, Vitamin K27 45 mcg, Methylcobalamin 1500 mcg, Zinc 7.5 mg, Magnesium 50 mg and L-Methylfolate - 800 mcg capsule	Each soft gelatin capsule contains: Calcitriol 0.25 mcg Calcium Carbonate 500 Mg Vitamin K27 45 Mcg Methylcobalamin 1500 Mcg Zinc 7.5 Mg Magnesium 50 Mg L- Methylfolate -800 Mcg Appropriate Overages may be added to compensate loss on storage during the shelf life	10's	Bidder has requested to amend the packaging type/ packaging standard as PVC blister and detailed specification as: Calcitriol 0.25 mcg, Calcium Carbonate 1250 Mg, Vitamin K27 45 mcg, Methylcobalamin 1500 mcg, Zinc 7.5 mg, Magnesium 50 mg and L- Methylfolate - 800 mcg capsule Also, bidder has requested to amend the pack size as: 10 x 1 x 10 (with monocarton)	No change <i>Tender condition prevails</i> in detailed specification. However, Amendment in the packaging standard and unit size is hereby authorized as follows: Packaging type and packaging standard as: PVC blister Unit size: 10's in monocarton
36	Annexure - XII Clause 18 (M)	2314	Flurbiprofen 0.03% w/v Eye Drop 5 ml	Each 5 ml contains: Furbiprofen Sodium IP 0.03% w/v Preservative 0.04% w/v Buffered vehicle q.s.	5 ml Drop bottle in Mono carton	Bidder has requested to amend the packaging specification as: LDPE-BFS vial of 5ml in Mono-carton and screw cap	Amendment in the unit size and packaging specification is hereby authorized as: Unit size: LDPE vial with screw cap in monocarton.

37	Annexure - XII Clause 18 (M)	2400	Caffeine (30mg) + Diphenhydramine (25mg) + Paracetamol (500mg) + Phenylephrine (5mg) Tablets	Each Film coated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg Diphenhydramine Hydrochloride IP 25mg Caffeine (Anhydrous) IP 30mg	10's	Bidder has requested for amendment in the detailed specification as: Each uncoated tablet contains: Each Film coated tablet contains: Paracetamol IP 325mg Phenylephrine Hydrochloride IP 5mg Diphenhydramine Hydrochloride IP 25mg Caffeine (Anhydrous) IP 30mg	No change <i>Tender condition prevails</i>
38	Annexure - XII Clause 18 (M)	2506	Benzoic acid 6% w/w and Salicylic acid 3% w/w IP Ointment	Composition: Benzoic Acid 6% w/w Salicylic Acid 3% w/w	15g in monocarton	Bidder has requested for amendment in the detailed specification as: Compound Benzoic Acid Ointment IP Composition: Benzoic Acid IP 6% w/w Salicylic Acid IP 3% w/w Ointment base q.s.	Amendment in the name and detailed specification is hereby authorized as follows: Name: Compound Benzoic Acid Ointment IP Detailed specification: Benzoic Acid IP 6% w/w Salicylic Acid IP 3% w/w Suitable Ointment base q.s.
39	Annexure - XII Clause 18 (M)	2655	Vildagliptin 50mg and Metformin Hydrochloride (sustained release) 1000mg Tablets	Each uncoated bilayered tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg (As Sustained release)	15's	Bidder has requested for amendment in the detailed specification, unit size and pack size as 10's instead of 15's	Amendment in the unit size and pack size is hereby authorized as follows: Unit Size: 10's Pack size: 10's x 1 x 10
40	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)	15's	Bidder has requested for amendment in the detailed specification, unit size and pack size as 10's instead of 15's	Amendment in the unit size and pack size is hereby authorized as follows: Unit Size: 10's Pack size: 10's x 1 x 10

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 17/04/2025 and this Amendment No.2 dated 29/04/2025

Sd-/
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For & on behalf of PMBI
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