

PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(Set up under the Department of Pharmaceuticals, Govt. of India)

8th & 9th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

Amendment no. 2

No.: PMBI/DRUG/RC-204/2022

Dated: 19/10/2022

Subject: - Tender No. PMBI/DRUG/RC-204/2022 dated 29/09/2022 for supply of drug/medicine to Pharmaceutical and Medical Devices Bureau of India (PMBI).

Reference: - i. All queries of Pre-Bid meeting held on 11/10/2022 at 15:00 Hours in the premises of PMBI.
ii. Bidders query received through mails.

Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for “e- Tender for Supply of Drugs/Generic Medicines for the year 2022- 2024”, vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-192/2022. 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.

After considering the suggestions/ queries received from the prospective bidders, the clarifications/ amendments regarding the specification, packing and dates in tender document have been made as per Part-A, Part-B and Part-C. All other technical specifications, terms, and conditions along with the tender schedule as mentioned in tender document shall remain unchanged.

The following amendment in Tender Document is hereby authorized: -

Part- A

Sl. No.	Tender Clause/Reference	Query/Suggestion	Clarification/ Amendment
1	Clause no. 4. A. GENERAL CONDITIONS at page 12 of the tender document.	Representative of one of the prospective bidders has mentioned that DC-1667 and 1964 are imported item and the lead time taken from manufacturing to importing is minimum 9 months. They had further mentioned that above timeline challenges and offering of generic pack along with customized packing as per PMBI is not possible. They have requested to allow them to supply the drugs in normal trade pack/market pack. They had also requested to exempt Local content clause for aforementioned items.	Tender condition prevails.

Part- B: -**I: The following Amendment in Specification is hereby authorized: -**

Sl. No.	Tender Clause/ Reference	Sl. No. in the tender document	Drug Code	Generic Name of the Drug	Composition of the Drug in tender	Unit Size	Bidders Query	Amendment
1	Annexure -XII Clause 18 (M)	8	DC-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 request to change strength of the drug	Tender specification prevails.
2	Annexure -XII Clause 18 (M)	40	DC-1897	Quinine Sulphate Tablets IP 600 mg	Each Sugar-coated tablet Contains: Quinine Sulphate IP 600 mg	10's	Bidder has request to dosage form as film coated tablets against sugar-coated tablets	The dosage form is here by amended as film-coated tablets as against sugar-coated tablets in the tender.
3	Annexure -XII Clause 18 (M)	87	DC-2296	Dabigatran Etxilate Mesilate Capsules 75 mg	Each hard gelatin capsule contains: Dabigatran Etxilate Mesylate 86.48 mg equivalent to Dabigatran Etxilate 75mg	10's	Bidder has requested to amend hard gelatin capsule to hard cellulose capsule.	'Hard cellulose capsule' will also be considered
4	Annexure -XII Clause 18 (M)	148	DC-2271	Vitamin D3 60000 IU Oral Disintegrating Strips	Each orally disintegrating strip contains Vitamin D3 (Cholecalciferol) IP 60000 IU	1's in mono carton	Bidder has request to amend dosage form to Tablet / capsule	Tender specification prevails.
5	Annexure -XII Clause 18 (M)	152	DC-2275	Pregabalin 75mg and Duloxetine (Delayed Release) 20mg Capsules	Each hard gelatin capsule contains Pregabalin IP 75 mg Duloxetine Hydrochloride IP equivalent to Duloxetine 20 mg (As delayed release pellets)	10's	Bidder has request to amend packing type	Tender specification prevails.
6	Annexure -XII Clause 18 (M)	170	DC-2293	Bosentan 62.5mg Tablets	Each film coated tablet contains Bosentan Monohydrate equivalent to Bosentan 8 mg	10's	Bidder has request to clarify strength in the specification	The Composition of the Drug in tender is here by amended as "Each film coated tablet contains Bosentan Monohydrate

								equivalent to Bosentan 62.5 mg"
7	Annexure -XII Clause 18 (M)	172	DC-2295	Brivaracetam 50mg Tablets	Each film coated tablet contains Brivaracetam 8 mg	10's	Bidder has request to clarify strength in the specification	The Composition of the Drug in tender is here by amended as "Each film coated tablet contains Brivaracetam 50 mg"
8	Annexure -XII Clause 18 (M)	173	DC-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 hard 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 hard gelatin capsule to soft gelatin capsule.	The amendment is hereby authorized as below: - a. The dosage form is amended as Soft Gelatin capsule as against hard gelatin capsule in the tender.
9	Annexure -XII Clause 18 (M)	185	DC-2308	Dexlansoprazole MR capsules 60mg	Each HPMC capsule contains Dexlansoprazole 60mg (as modified release pellets)	10's	Bidder has request to change the dosage form from HPMC capsule to Hard gelatin capsule	Tender specification prevails.
10	Annexure -XII Clause 18 (M)	205	DC-2328	Methylcobalamin 1500 mcg, Vitamin B6 (Pyridoxine) 5mg Benfotiamine 50 mg Alpha Lipoic Acid 200 mg Folic Acid 5mg Biotin 5 mg Capsule	Each capsule contains Methylcobalamin 1500 mcg Vitamin B6 (Pyridoxine) 5 mg Benfotiamine 50mg Alpha Lipoic Acid 200mg Folic Acid 5mg Biotin 5 mg	10's	Bidder has request to change the dosage form to soft gelatin capsule	The dosage form is here by amended as Soft Gelatin capsule as against hard gelatin capsule in the tender.

11	Annexure -XII Clause 18 (M)	240	DC-2363	Sitagliptin 100mg and Metformin 1000mg Extended Release Tablets	Each Film coated bi-layered tablet contains Sitagliptin Phosphate IP equivalent To Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (as an extended release form)	10's	Bidder has request to change the dosage form from Film coated bi-layered to Film coated	Tender specification prevails.
12	Annexure -XII Clause 18 (M)	241	DC-2364	Sitagliptin 50 mg and Metformin 500mg Extended Release Tablets	Each Film coated bi-layered tablet contains Sitagliptin Phosphate IP equivalent To Sitagliptin 50 mg Metformin Hydrochloride IP 500 mg (as an extended release form)	10's	Bidder has request to change the dosage form from Film coated bi-layered to Film coated	Tender specification prevails.
13	Annexure -XII Clause 18 (M)	248	DC-2371	Nebivolol 2.5mg and Cilnidipine 10mg Tablets	Each Film coated bi-layered tablet contains Nebivolol Hydrochloride IP equivalent To Nebivolol 2.5mg Cilnidipine IP 10 mg	10's	Bidder has request to change the dosage form from Film coated bi-layered to Film coated	Tender specification prevails.

Part- II: The following Amendment in pack size is hereby authorized: -

S. no.	Sl. No. in the tender document	Drug Code	Tender Clause/ Reference	Generic Name of the Drug	Unit Size	Amendment in Unit size / Pack Size
1	30	DC-1794	Annexure -XII Clause 18 (M)	Salbutamol Rotacaps 200mcg	30's in Mono Pack	1 X 30's X 10
2	71	DC-2020	Annexure -XII Clause 18 (M)	Desmopressin Tablets 0.1 mg	15's in bottle	1 X 15's X 10
3	75	DC-2031	Annexure -XII Clause 18 (M)	Sofosbuvir 400mg and Velpatasvir 100mg Tablets	28's Bottle	1 X 28's X 10
4	87	DC-2098	Annexure -XII Clause 18 (M)	Dabigatran Etxilate Mesilate Capsules 75 mg	10's	1 X 10's X 10
5	92	DC-2144	Annexure -XII Clause 18 (M)	Pyridostigmine Bromide Tablets IP 60mg	10's	1 X 10's X 10
6	93	DC-2146	Annexure -XII Clause 18 (M)	Combi kit of Tablet A : Eplerenone Tablet 25mg Tablet B : Torsemide Tablet IP 10mg	Combi kit of 20 tablets in Mono carton	1 X KIT X 10
7	94	DC-2150	Annexure -XII Clause 18 (M)	Beclomethasone Dipropionate IP 200mcg Inhaler	200 MDI	1 X 1 X 10

8	95	DC-2151	Annexure -XII Clause 18 (M)	Beclomethasone Dipropionate IP 100mcg Inhaler	200 MDI	1 X 1 X 10
9	106	DC-2173	Annexure -XII Clause 18 (M)	Ibendronic Acid Tablets 150mg	10's	1 X 10's X 10
10	111	DC-2191	Annexure -XII Clause 18 (M)	Progesterone 100mg/2ml Injection IP	2ml Ampoule in Mono blister	1 X 1 X 10
11	113	DC-2194	Annexure -XII Clause 18 (M)	Remogliflozin Etabonate 100mg and Metformin Hydrochloride 1000mg Tablets	10's	1 X 10's X 10
12	117	DC-2200	Annexure -XII Clause 18 (M)	Selegiline Hydrochloride 5mg Tablets	10's	1 X 10's X 10
13	118	DC-2205	Annexure -XII Clause 18 (M)	Verapamil Hydrochloride Prolonged Release 120mg Tablet IP	15's	1 X 15's X 10
14	119	DC-2209	Annexure -XII Clause 18 (M)	Ziprasidone 20mg Capsules	10's	1 X 10's X 10
15	120	DC-2212	Annexure -XII Clause 18 (M)	Micronized Purified flavonoid Fraction Tablets (MPFF Diosmin 450mg and Hesperidin 50mg Tablets)	10's	1 X 10's X 10
16	121	DC-2213	Annexure -XII Clause 18 (M)	Ziprasidone 40mg Capsules	10's	1 X 10's X 10
17	122	DC-2218	Annexure -XII Clause 18 (M)	Sacubitril and Valsartan Tablets 200mg	7's	1 X 7's X 10
18	126	DC-2249	Annexure -XII Clause 18 (M)	Abacavir 600mg Dolutegravir 50mg and Lamivudine 300mg Tablet	30's Bottle	1 X 30's X 10
19	127	DC-2250	Annexure -XII Clause 18 (M)	Abacavir 600mg and Lamivudine 300mg Tablets	30's Bottle	1 X 30's X 10
20	130	DC-2253	Annexure -XII Clause 18 (M)	Bisacodyl Suppository 5mg	5's	1 X 5's X 10
21	132	DC-2255	Annexure - XII Clause 18 (M)	Colchicine Tablet 0.5mg	10's	1 X 10's X 10
22	142	DC-2265	Annexure -XII Clause 18 (M)	Multivitamin Syrup Chocolate Flavour	200ml Bottle	1 X 1 X 10
23	143	DC-2266	Annexure -XII Clause 18 (M)	Nicotine 2mg Oral Disintegrating Strips	12's in mono carton	1 X 12's X 10
24	144	DC-2267	Annexure -XII Clause 18 (M)	Nicotine Oral Disintegrating Strips 4mg	12's in mono carton	1 X 12's X 10
25	145	DC-2268	Annexure -XII Clause 18 (M)	Ondansetron 4mg Oral Disintegrating Strips	12's in mono carton	1 X 12's X 10
26	146	DC-2269	Annexure -XII Clause 18 (M)	Ondansetron 8mg Oral Disintegrating Strips	12's in mono carton	1 X 12's X 10

27	147	DC-2270	Annexure -XII Clause 18 (M)	Sildenafil 50mg Oral Disintegrating Strips	5's in mono carton	The amendment is hereby authorized as below: - Unit size: 5 sachets in mono carton Pack size shall be read as: 1 X 5's X 10
28	148	DC-2271	Annexure -XII Clause 18 (M)	Vitamin D3 60000 IU Oral Disintegrating Strips	10's in mono carton	The amendment is hereby authorized as below: - Unit Size: 10 sachets in mono carton Pack size shall be read as: 1 X 10's X 10
29	149	DC-2272	Annexure -XII Clause 18 (M)	Dapagliflozin 5mg and Sitagliptin 50mg Tablets	10's	1 X 10's X 10
30	151	DC-2274	Annexure -XII Clause 18 (M)	Pregabalin 75mg and Duloxetine (Delayed Release) 30mg Capsules	10's	1 X 10's X 10
31	155	DC-2278	Annexure -XII Clause 18 (M)	Vitamin C Effervescent Tablets	10's	1 X 10's X 10
32	156	DC-2279	Annexure -XII Clause 18 (M)	Nandrolone Decanoate Injection IP 50mg/ml	1ml Ampoule in mono carton	1 X 1 X 10
33	158	DC-2281	Annexure -XII Clause 18 (M)	Vitamin A, Vitamin C, Vitamin D and Zinc tablets	10's	1 X 10's X 10
34	163	DC-2286	Annexure -XII Clause 18 (M)	Adapalene 1% w/w and Benzoyl Peroxide 2.5% w/w Gel 15 gm	15gm Lamitube	1 X 1 X 10
35	166	DC-2289	Annexure -XII Clause 18 (M)	Armodafinil 150mg Tablets	10's	1 X 10's X 10
36	173	DC-2296	Annexure -XII Clause 18 (M)	Calcitriol 0.25 mcg, Calcium Carbonate 500 Mg, Vitamin K2 45 mcg, Methylcobalamin 1500 mcg, Zinc 7.5 mg, Magnesium 50 mg and L- Methylfolate - 800 mcg capsule	10's	1 X 10's X 10
37	174	DC-2297	Annexure -XII Clause 18 (M)	Calcium (Calcium Carbonate): 1250 Mg Vitamin D3: 2000 IU Mecobalamin (Vitamin B12): 1500 Mcg L-Methylfolate Calcium (Vitamin B9): 1 Mg Pyridoxal-5-Phosphate (Vitamin B6): 20 Mg, Tablets	10's	1 X 10's X 10
38	176	DC-2299	Annexure -XII Clause 18 (M)	Nadifloxacin 1% w/w and Clobetasol Propionate 0.05% 10 gm skin cream	10gm Lamitube	1 X 1 X 10
39	178	DC-2301	Annexure - XII Clause 18 (M)	Dapoxetine 30mg Tablets	4's	1 X 4's X 10
40	181	DC-2304	Annexure -XII Clause 18 (M)	Desvenlafaxine 50 mg and Clonazepam 0.5mg Tablets	10's	1 X 10's X 10

41	187	DC-2310	Annexure -XII Clause 18 (M)	Donepezil 5mg and Memantine 5mg Tablets	10's	1 X 10's X 10
42	190	DC-2313	Annexure -XII Clause 18 (M)	Etizolam 0.5 mg and Propranolol Hydrochloride 40mg Tablets	10's	1 X 10's X 10
43	193	DC-2316	Annexure -XII Clause 18 (M)	Flupentixole 0.5 mg and Nortriptyline 10 mg tablets	10's	1 X 10's X 10
44	195	DC-2318	Annexure -XII Clause 18 (M)	Tannic Acid Glycerin, Potassium Iodide, Iodine, Menthol & Thymol Mouth Paint	20ml Bottle in Mono carton	1 X 1 X 10
45	196	DC-2319	Annexure -XII Clause 18 (M)	Ketorolac (0.5% W/V) and Moxifloxacin (0.5% W/V) Eye Drops	5ml Drop bottle in Mono carton	1 X 1 X 10
46	197	DC-2320	Annexure -XII Clause 18 (M)	Lactic Acid 1.2% W/V Intimate Hygiene Wash	90ml in Mono carton	1 X 1 X 10
47	198	DC-2321	Annexure -XII Clause 18 (M)	Lapatinib Tablets IP 250Mg tablet	30's Bottle	1 X 30's X 10
48	201	DC-2324	Annexure -XII Clause 18 (M)	L-Methylfoate, Vit K2, Methylcobalamin, Pyridoxal 5, Phosphate, Lycopene, Calcium Citrate	10's	1 X 10's X 10
49	203	DC-2326	Annexure -XII Clause 18 (M)	Lutein, Astaxanthin, Zeaxanthin, Omega 3 Fatty Acid Capsule	10's	1 X 10's X 10
50	204	DC-2327	Annexure -XII Clause 18 (M)	Omega 3 Fatty Acid 500 mg EPA 150 mg DHA 100 mg Bilberry Extract 50 mg Lutein 20% & Zeaxanthin 4%- 25 mg Beta carotene 4.8 mg Vitamin D3 10 mcg Capsules	30's Bottle	1 X 30's X 10
51	205	DC-2328	Annexure -XII Clause 18 (M)	Methylcobalamin 1500 mcg, Vitamin B6 (Pyridoxine) 5mg Benfotiamine 50 mg Alpha Lipoic Acid 200 mg Folic Acid 5 mg Biotin 5mg Capsule	10's	1 X 10's X 10
52	206	DC-2329	Annexure -XII Clause 18 (M)	Midazolam 0.5mg Nasal Spray	5ml bottle with nasal atomizer in Mono carton	1 X 1 X 10
53	208	DC-2331	Annexure -XII Clause 18 (M)	Nadifloxacin 1% w/w cream	10gm Lamitube	1 X 1 X 10
54	209	DC-2332	Annexure -XII Clause 18 (M)	Nicoumalone (Acenocoumarol) 2mg Tablets	10's	1 X 10's X 10
55	211	DC-2334	Annexure -XII Clause 18 (M)	Nitazoxanide 500mg Tablets	10's	1 X 10's X 10
56	212	DC-2335	Annexure -XII Clause 18 (M)	Obeticholic Acid 10mg Tablets	10's	1 X 10's X 10

57	214	DC-2337	Annexure - XII Clause 18 (M)	Olopatadine Hydrochloride 0.4% w/v and Ketorolac 0.1 % w/v Ophthalmic Solution	5ml Drop bottle in Mono carton	1 X 1 X 10
58	216	DC-2339	Annexure - XII Clause 18 (M)	Polyethylene Glycol 400- 0.4% w/v and Propylene Glycol 0.3% w/v Ophthalmic solution	10ml Drop bottle in Mono carton	1 X 1 X 10
59	217	DC-2340	Annexure - XII Clause 18 (M)	Pomalidomide 2 mg Capsule	21's in bottle	1 X 21's X 10
60	233	DC-2356	Annexure - XII Clause 18 (M)	Valacyclovir Tablets 500 mg	3's in Mono carton	1 X 3's X 10
61	237	DC-2360	Annexure - XII Clause 18 (M)	Vildagliptin 100mg Extended-Release Tablet	10's	1 X 10's X 10
62	238	DC-2361	Annexure - XII Clause 18 (M)	Zonisamide 50mg Capsule	10's	1 X 10's X 10
63	241	DC-2364	Annexure - XII Clause 18 (M)	Sitagliptin 50 mg and Metformin 500mg Extended-Release Tablets	10's	1 X 10's X 10
64	242	DC-2365	Annexure - XII Clause 18 (M)	Ketoconazole 2 % w/v Shampoo pouch, 30 ml	30ml Pouch	1 X 1 X 10
65	243	DC-2366	Annexure - XII Clause 18 (M)	Melatonin 5mg Tablets	15's	1 X 15's X 10
66	246	DC-2369	Annexure - XII Clause 18 (M)	Cilnidipine 10 mg and Olmesartan Medoxomil 40 mg Tablets	10's	1 X 10's X 10
67	247	DC-2370	Annexure - XII Clause 18 (M)	Nebivolol 5mg and Cilnidipine 10mg Tablets	10's	1 X 10's X 10

Part-C

It is hereby to inform all the prospective bidders(s) that PMBI has extended the last date of submission of online bid (COVER-A) against subject tender vide no. PMBI/DRUGS/RC-204/2022 dated 29.09.2022 vide Amendment no. 1 dated 17/10/2022. Where in the column containing existing schedule has typographical error in critical dates. Hence bidders are requested to consider the existing schedule as per tender document (published) and the extension in the last date of submission of online bid as per Amendment no. 1 dated 17/10/2022. This may be seen as under: -

Sl. No.	Details	Existing Scheduled	Amended Schedule
1	Last date and time for submission of Online Bid i.e., Bid Submission End Date and time.	On 25.10.2022 (Tuesday) up to 17.00 Hours	On 09/11/2022 till 17:00 hours
2	Last Date and time for submission of EMD and Original Required Documents as per ANNEXURE I (Check List) in physical Form and samples in office of Pharmaceuticals &	On 28.10.2022 (Friday) at 15.00 hours	On 11/11/2022 till 15:00 hours

	Medical Devices Bureau of India, 8th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi 110055		
3	Date and Time of opening of Technical Bid	On 28.10.2022 (Friday) by 16.00 hours	On 11/11/2022 at 16:00 hours

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 17/10/2022 & Amendment no. 2 dated 19/10/2022.

Sd/-
DGM (Procurement & Quality)
For & on behalf of PMBI
PH: 011-49431811