Amendment no. 3

Notice Inviting Tender Ref. No.: -PMBI/DRUG/RC-166/2021 **Dated: 16/11/2021**

Subject: - Tender No. PMBI/DRUG/RC-166/2021 dated 30/09/2021 for the supply of drugs/medicines to Pharmaceuticals & Medical Devices Bureau of India (PMBI).

Reference: - Pre-Bid meeting held on 08/10/2021 at 11:00 AM at the premises of PMBI.

Pharmaceuticals & Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for "e-Tender for Supply of Drugs/ Medicines for the year 2021- 2023", vide Notice Inviting Tender No.- PMBI/DRUG/RC-166/2021. 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 in Pre-Bid meeting, the clarifications/ amendments with regard to the tender document and specification of items, have been made as per Annexure-A (of tender clauses) and Annexure-B (in respect of specification and packaging) respectively. 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: -

Annexure- A

S. No.	Tender Clause/ Reference	Query/Suggestion	Clarification/ Amendment
1	Clause No. 2	Bidders have requested to extend the due date of online tender submitting date on CPP portal.	Online tender submitting date has been extended up to 25.11.2021 in Amendment no.2 dated 02.11.2021
2	Clause No. 3.D.(e) & 3.E.	Bidders have requested to consider 02 (two) years market standing certificate Market standing certificate & Manufacturing certificate instead of 03 (three) years.	**Tender condition prevails.** Bidder must submit three years old manufacturing license and have Market Standing Certificate (in India) of last three years of quoted product issued by the concerned Licensing Authority from Drugs Control Department **except for the drugs falling under the category of 'New Drug' as**

			defined by CDSCO (Central Drugs Standard Control Organisation). If permission in Form 46 from DCGI has been obtained, then the 3 years Manufacturing & Market standing clause will be relaxed.
3	Clause No. 3.G.	Bidder asked for clarification that is company having GMP certificate as per revised Schedule M is eligible to participate in the tender.	It is to clarify that company having WHO-GMP certificate is only eligible to participate in the tender i.e., Bidders must have WHO-GMP (WHO-Good Manufacturing Practice) 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.
4	Clause No. 3.I.	Bidder has requested to reduce the turnover from 25 crore.	**Tender condition prevails.**
5	Clause No. 3.T, 3.S. & Annexure X	1) Bidders have asked for how to calculate the value of procurement. 2) Bidders have asked for clarification whether the value of Rs. 10 crores will be calculated for individual products separately or cumulative value of all products quoted. 3) Bidders have asked for clarification for the submission of declaration of local content (Annexure-X) at the time of bid submission or after the award of contract. 4) Bidders have asked for clarification regarding the note of Annexure-X	1) Calculation shall be made in accordance with point no. 6 of Order issued by Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals vide no. 31026/4/2018-Policy dated 01.01.2019. 2) It is to clarify that in Annexure-X, declaration of local content for each quoted product shall be given separately but total amount shall be calculated in cumulative value of all quoted products. 3) It is to clarify that declaration of local content (Annexure-X) shall be submitted at the time of bid submission. 4) It is to clarify that if the cumulative procurement value of all the quoted drugs is below 10 crores, declaration of local content in Annexure-X shall be made on non-judicial stamp paper but if the value is more than 10 crores, then

			declaration of local content in Annexure-X shall be authorised by the statutory auditor or cost auditor of the firm (in case of companies) or from a practicing cost accountant or practicing chartered accountant (in case of suppliers other than companies) giving the percentage of local content as per pt. no. 9.b of DPIIT order no. P-45021/2/2017-PP(BE-II) dated 16.09.2020. 5) All the three notifications have been uploaded with Amendment-3 as Annexure-I, Annexure-II & Annexure-III for reference.
		5) Bidders have requested to make available of all three notifications of DPIIT and DoP mentioned in the tender.	
6	Clause No. 4.M.	Bidder has requested to amend the validity of Rate contract from two years to one year.	**Tender condition prevails** i.e., Validity of Rate Contract: -The rate contract will be applicable for 2(two) year from the date of issuance of LOA. The validity of contract may be extended with mutual consent for some specified period to the maximum of 1(one) year by PMBI, if necessary.
7	Clause No. 15.B & 16.A	**Clause:** "Minimum 50% of the tender quantity may be awarded to the qualified bidder(s) falling under Class I local supplier category, if qualified for award of contract and/or subject to the matching of L1 price for quoted drugs at the discretion of PMBI and remaining 50% of quantity may be awarded to the eligible bidder following the guidelines and respective clauses of DPIIT order no. P-45021/2/2017-PP(BE-II) dated 16.09.2020." **Query:** Bidders have asked to disclose the	The following clause may be read with cases as; **Case-I:** ***If L1 is Class I local supplier***, minimum 50% quantity shall be given to L1 bidder, 25% shall be given to MSEs (if comes within the price band (of L1 + 15%) & qualify) and remaining 25% shall be given to other eligible bidders (if comes within the Margin of Price Preference & qualify). **Case-II:** ***If L1 is Class-II local supplier***, as per PPE-MSE order, initially 25% shall be reserved for MSEs (if comes within the price band (of L1 + 15%) & qualify). Thereafter,

		100% distribution of tender quantity.	preference shall be given to Class-I local supplier to award 50% of tender quantity and at last, if quantity remains balance, 25% quantity shall be given to Class-II L1 bidder following the guidelines and respective clauses of DPIIT and MSME.
8	Clause No. 15.C	**Clause:** However, in case the price quoted by the lowest responsive tenderer (L1) is not reasonable and unacceptable, the price may be negotiated with L1 only as per CVC guidelines and, if it reduces the price to the desirable level, rate contract may be concluded with L1. **To meet the demand, PMBI shall conclude parallel rate contract by counter offering the L1 rate to higher eligible bidders** as per above provision and following the guidelines and respective clauses of DPIIT order no. P45021/2/2017-PP(BE-II) dated 16.09.2020. **Query:** Bidders have asked to clarify that how many higher eligible bidders (L2, L3, L4, etc.) will get counteroffer to match the L1 price.	It is to clarify that as per DPIIT order no. P/45021/2/2017-PP(BE-II) dated 16.09.2020, counteroffer to match the L1 price may be asked from the bidders falling under the clause of "margin of purchase preference"
9	Clause No. 19.D.	Bidder has requested to increase the delivery period from 45 days to 60 days against first order for Products that do not require sterility testing.	**Tender condition prevails.**
10	Clause No. 19.K.	Bidder has requested to amend the shelf life to 18 months for Vitamin category products.	**Tender condition prevails.**

11	Clause No. 19.N.	Bidder has requested to consider the Pandemic (like COVID-19) under Force Majeure events.	**Tender condition prevails** for now but will be considered as per Government notification issued at times.
12	Annexure-X	Bidders have asked to clarify the column no. 4 i.e., Details of Location(s) at which value addition is made.	It is to clarify that the bidders have to provide the details of their manufacturing premises at which value addition of local content is made.
13	Clause no. 18 (M), Annexure XII & XIII and BOQ	Bidders have requested to consider the product permission in Sustained Release or Prolonged release or Extended Release or Controlled Release as all these terms are same.	With reference to Indian Pharmacopoeia, Prolonged release tablets are also known as Sustained release tablets or Controlled release tablets or Extended-release tablets and therefore, product permission in alternate forms may be accepted in comply to the monograph of IP.
14	Clause no. 18 (M), Annexure XII & XIII and BOQ	Bidders have requested to clarify the secondary pack of oral liquids with mono-carton.	It is to clarify that the secondary pack of oral liquids with mono-carton shall be supplied as per tender requirement.
15	Clause no. 18 (M), Annexure XII & XIII and BOQ	Bidders have asked for requirement of dropper with oral drops.	It is to clarify that dropper shall be provided with the drop's formulation as per market standard.

Annexure- B

Part-1

S.No.	Tender Clause/ Reference	Item Code	Generic Name with detailed specification and Unit Size of the Item	Clarification/ Amendment
1	Clause no. 18 (M), Annexure XII & XIII and BOQ	72	Azithromycin Tablets IP 500 mg Unit Size- 3's **Secondary Pack- 5's X 10**	The following amendment in Secondary Pack is hereby authorised as: Unit Size- 3's **Secondary Pack- 3's X 10**

2	Clause no. 18 (M), Annexure XII & XIII and BOQ	194	Hyoscine Butylbromide Tablets IP 10 mg Each **sugar coated** tablet contains: Hyoscine Butylbromide IP 10 mg	The following amendment in Detailed Specification is hereby authorised as: Each **Uncoated tablet** contains: Hyoscine Butylbromide IP 10 mg
3	Clause no. 18 (M), Annexure XII & XIII and BOQ	198	Dried Aluminium Hydroxide 250mg, Magnesium Hydroxide 250mg, **Simethicone 50mg** per 5ml Suspension Each 5ml contains: Dried Aluminium Hydroxide 250mg Magnesium Hydroxide 250mg Activated Methyl Polysiloxane 50mg	The following amendment in Generic name and Detailed Specification is hereby authorised as: Dried Aluminium Hydroxide 250mg, Magnesium Hydroxide 250mg and **Activated Dimethicone 50mg** per 5ml Suspension Each 5ml contains: Activated Dimethicone 50mg Dried Aluminium Hydroxide 250mg Magnesium Hydroxide 250mg
4	Clause no. 18 (M), Annexure XII & XIII and BOQ	225	Syrup of Iron and Folic Acid in a flavoured Base	The following detailed specification has been added as: Each 5 ml contains: Ferrous Ascorbate eq. to Elemental Iron 30 mg Folic Acid 0.5 mg In a flavoured syrupy base
5	Clause no. 18 (M), Annexure XII & XIII and BOQ	227	Polyvitamin Tablets NFI (Prophylactic) Each film-coated tablet contains: Vitamin A 2500 IU Vitamin D3 200IU Vitamin B1 2mg Vitamin B6 0.5mg **Vitamin B12 2mg** Niacinamide 25mg Calcium Pantothenate 1mg Vitamin C 50mg Folic Acid 0.2mg	The following amendment in Detailed Specification is hereby authorised as: Each film-coated tablet contains: Vitamin A 2500 IU Vitamin D3 200 IU Vitamin B1 2 mg Vitamin B6 0.5 mg **Vitamin B2 2 mg** Niacinamide 25 mg Calcium Pantothenate 1 mg Vitamin C 50 mg Folic Acid 0.2 mg

6	Clause no. 18 (M), Annexure XII & XIII and BOQ	235	Budesonide Respules 0.5 mg per ml Each 2 ml respulse contains: Budesonide : 1 mg	The following amendment in Generic Name is hereby authorised as: **Budesonide Nebuliser Suspension (1mg/2ml)** Each 2ml respule contains: Budesonide 1 mg
7	Clause no. 18 (M), Annexure XII & XIII and BOQ	250	Montelukast Sodium Tablets IP 5mg Each **film coated** tablet contains: Montelukast Sodium IP eq. to Montelukast 5mg	The following amendment in Detailed Specification is hereby authorised as: Each **Uncoated** tablet contains: Montelukast Sodium IP eq. to Montelukast 5mg
8	Clause no. 18 (M), Annexure XII & XIII and BOQ	270	Clopidogrel 75mg and Aspirin 75mg Tablets IP Each **film-coated** tablet contains: Clopidogrel Bisulphate IP equivalent to Clopidogrel 75mg Aspirin 75mg	The following amendment in Detailed Specification is hereby authorised as: Each **Uncoated bilayer tablet** contains: Clopidogrel Bisulphate IP equivalent to Clopidogrel 75mg Aspirin 75mg
9	Clause no. 18 (M), Annexure XII & XIII and BOQ	277	Enoxaparin Injection IP 60 mg per 0.6 ml Each pre-filled syringe contains: Enoxaparin sodium IP 60 mg equivalent to 6,000 IU anti-Xa activity.	The following amendment in Detailed Specification is hereby authorised as: Each prefilled syringe contains: Enoxaparin sodium IP 60mg water for injection IP q.s.
10	Clause no. 18 (M), Annexure XII & XIII and BOQ	316	Betahistine Tablets IP 8 mg Each **ncoated** tablet contains: Betahistine Hydrochloride IP 8mg	The following amendment in Detailed Specification is hereby authorised as: Each **Uncoated** tablet contains: Betahistine Hydrochloride IP 8mg
11	Clause no. 18 (M), Annexure XII & XIII and BOQ	317	Carbamazepine Tablets IP 100 mg Each uncoated tablet contains: **Carbimazole IP 100mg**	The following amendment in Detailed Specification is hereby authorised as: Each uncoated tablet contains: **Carbamazepine IP 100mg**

12	Clause no. 18 (M), Annexure XII & XIII and BOQ	387	Terbinafine Tablets IP 250mg Unit Size- 7's Secondary Pack- **10's X 10**	The following amendment in Secondary Pack is hereby authorised as: Unit Size- 7's **Secondary Pack- 7's X 10**
13	Clause no. 18 (M), Annexure XII & XIII and BOQ	396	Liposomal Amphotericin B Injection 50 mg per Vial Each Vial contains: **AMPHOTERICIN B 50 mg**	The following amendment in Detailed Specification is hereby authorised as: Each Vial contains: **Liposomal** Amphotericin B 50 mg
14	Clause no. 18 (M), Annexure XII & XIII and BOQ	407	Ivermectin Tablets 12 mg Each uncoated dispersible tablet contains: Ivermectin 12mg	The following amendment in Generic Name is hereby authorised as: **Ivermectin Dispersible Tablets 12 mg** Each uncoated dispersible tablet contains: Ivermectin 12mg
15	Clause no. 18 (M), Annexure XII & XIII and BOQ	417	Telmisartan 40mg and Amlodipine 5mg Tablets IP Each **uncoated bilayer** tablet contains: Telmisartan IP 40mg Amlodipine Besilate IP equivalent to Amlodipine 5mg	The following amendment in Detailed Specification is hereby authorised as: Each **uncoated tablet** contains: Telmisartan IP 40mg Amlodipine Besilate IP equivalent to Amlodipine 5mg
16	Clause no. 18 (M), Annexure XII & XIII and BOQ	471	Oxetacaine, Aluminium Hydroxide and Magnesium Hydroxide Gel Each 5ml contains: Oxetacaine 10 mg Aluminium Hydroxide 0.291 g, Magnesium Hydroxide 98 mg	The following amendment in Generic Name is hereby authorised as: **Oxetacaine, Aluminium Hydroxide and Magnesium Hydroxide Suspension**

17	Clause no. 18 (M), Annexure XII & XIII and BOQ	487	Dicyclomine Hydrochloride 10mg and **Dimethicone** 40mg Suspension Each 5ml contains: Dicyclomine Hydrochloride IP 10mg **Simethicone IP 40mg**	The following amendment in Generic Name & Detailed Specification is hereby authorised as: **Dicyclomine Hydrochloride 10mg and Activated Dimethicone 40mg per 5 ml Suspension** Each 5ml contains: Dicyclomine Hydrochloride IP 10mg **Activated Dimethicone IP 40mg**
18	Clause no. 18 (M), Annexure XII & XIII and BOQ	537	Ambroxol Hydrochloride and Levosalbutamol Sulphate Syrup Each 5ml contains: Ambroxol Hydrochloride 15 mg Salbutamol Sulphate equivalent to **Salbutamol 1 mg**	The following amendment in Detailed Specification is hereby authorised as: Each 5ml contains: Ambroxol Hydrochloride 15 mg Levosalbutamol Sulphate equivalent to **Levosalbutamol 1 mg**
19	Clause no. 18 (M), Annexure XII & XIII and BOQ	558	Fluticasone 50mcg and Azelastine 140mcg Nasal Spray Each Spray delivers: **Fluticasone Furoate 27.5 mcg** Azelastine Hydrochloride 140 mcg	The following amendment in Generic Name & Detailed Specification is hereby authorised as: **Fluticasone Propionate 50mcg and Azelastine Hydrochloride 140mcg Nasal Spray** Each Spray delivers: **Fluticasone Propionate 50 mcg** Azelastine Hydrochloride 140 mcg
20	Clause no. 18 (M), Annexure XII & XIII and BOQ	595	Thiamine 100mg, Pyridoxine Hydrochloride 50mg and Cyanocobalamin 1000mcg Injection **Each 2 ml ampoule contains**: Mecobalamin IP 1000 mcg **Pyridoxine HCl IP 50 mg** Thiamine 100 mg **Unit Size- 2 ml**	The following amendment in Generic name, Detailed Specification & Unit size is hereby authorised as: **(i) Thiamine 100mg, Pyridoxine Hydrochloride 100mg and Cyanocobalamin 1000mcg per 3 ml Injection** (ii) **Each 3 ml ampoule contains**: Thiamine (B1) 100 mg **Pyridoxine HCl (B6) 100 mg** Cyanocobalamin (B12) 1000 mcg

				(iii) **Unit Size- 3 ml**
21	Clause no. 18 (M), Annexure XII & XIII and BOQ	683	Rabeprazole Sodium 20mg and Itopiride Hydrochloride 150mg Capsules Each hard gelatin capsule contains: Rabeprazole Sodium 20mg (as enteric coated pellets) Itopride Hydrochloride 150mg (as sustained-release pellets)	The following amendment in Generic Name & Detailed Specification is hereby authorised as: **Rabeprazole Sodium (Gastro-resistant) 20mg and Itopride Hydrochloride Prolonged release 150mg Capsules IP** Each hard gelatin capsule contains: Rabeprazole Sodium IP 20mg (as enteric coated pellets) Itopride Hydrochloride IP 150mg (as prolonged-release pellets)
22	Clause no. 18 (M), Annexure XII & XIII and BOQ	687	Lactulose 10gm per 15ml Each 15ml contains: Lactulose solution equivalent to Lactulose 10gm palatable base q.s	The following amendment in detailed specification is hereby authorised as: Each 15ml contains: **Lactulose Concentrate equivalent to Lactulose 10gm** In a flavoured syrupy base.
23	Clause no. 18 (M), Annexure XII & XIII and BOQ	769	Acetylsalicylic Acid (Aspirin) Tablets IP 325mg Each gastro-resistant tablet contains: Aspirin 325mg	The following amendment in Generic name is hereby authorised as: **Acetylsalicylic Acid (Aspirin) Gastro-resistant Tablets IP 325mg**
24	Clause no. 18 (M), Annexure XII & XIII and BOQ	885	Ethinylestradiol 0.05mg and Levonorgestrel 0.25mg Tablets IP Unit Size- 21's Secondary Pack- 21's X 10	The following amendment in Secondary Pack is hereby authorised as: Unit Size- 21's **Secondary Pack- 21's x 1 x 10**

25	Clause no. 18 (M), Annexure XII & XIII and BOQ	1307	Ethinylestradiol 0.03mg and Desogestrel 0.15mg Tablets Unit Size- 21's Secondary Pack- 21's X 10	The following amendment in Secondary Pack is hereby authorised as: Unit Size- 21's **Secondary Pack- 21's x 1 x 10**
26	Clause no. 18 (M), Annexure XII & XIII and BOQ	1308	Ethinylestradiol 0.03mg and Levonorgestrel 0.15mg Tablets IP Unit Size- 21's Secondary Pack- 21's X 10	The following amendment in Secondary Pack is hereby authorised as: Unit Size- 21's **Secondary Pack- 21's x 1 x 10**
27	Clause no. 18 (M), Annexure XII & XIII and BOQ	1485	Mesalazine Prolonged release Tablets IP 1200 mg Each gastro-resistant prolonged release tablet contains: Mesalazine 1200 mg (Prolonged Release)	The following amendment in Detailed Specification is hereby authorised as: Each enteric coated tablet contains: Mesalazine 1200 mg (as Prolonged Release)
28	Clause no. 18 (M), Annexure XII & XIII and BOQ	1490	Acebrophylline Sustained Release Tablets 200 mg Each **uncoated sustained release** tablet contains: Acebrophylline 200 mg	The following amendment in Detailed Specification is hereby authorised as: Each **Film-coated sustained release** tablet contains: Acebrophylline 200 mg
29	Clause no. 18 (M), Annexure XII & XIII and BOQ	1495	Aceclofenac 100mg , Paracetamol 325mg and **Tizanidine 10mg** Tablets Each film coated tablet contains: Aceclofenac 100 mg Paracetamol 325mg Tizanidine Hydrochloride equivalent to Tizanidine 2mg	The following amendment in Generic Name is hereby authorised as: Aceclofenac 100mg , Paracetamol 325mg and **Tizanidine 2mg** Tablets Each film coated tablet contains: Aceclofenac 100 mg Paracetamol 325mg Tizanidine Hydrochloride equivalent to Tizanidine 2mg

30	Clause no. 18 (M), Annexure XII & XIII and BOQ	1581	Clopidogrel 75mg and Aspirin 150mg Capsules Each hard gelatin capsule contains: Clopidrogrel Bisulphate equivalent to Clopidrogrel 150mg Aspirin IP 75mg (as gastro-resistant)	The following amendment in Detailed Specification is hereby authorised as: Each hard gelatin capsule contains: Clopidrogrel Bisulphate equivalent to **Clopidrogrel 75mg** **Aspirin 150mg** (as gastro-resistant)
31	Clause no. 18 (M), Annexure XII & XIII and BOQ	1605	Dosulepin (or Dothiepin) Tablets 25 mg Each film coated tablet contains: Dosulepin Hydrochloride **55 mg** (Formely Dothiapine Hydrochloride)	The following amendment in Detailed Specification is hereby authorised as: Each film coated tablet contains: Dosulepin Hydrochloride **25 mg** (Formerly Dothiepine Hydrochloride)
32	Clause no. 18 (M), Annexure XII & XIII and BOQ	1654	Guaifenesin 100 mg, Dextromethorphan 10 mg and Phenylephrine 2.5 mg Syrup Each 5 ml contains: Guaifenesin IP 100 mg Dextromethorphan IP 10 mg **Phenylephrine IP 25 mg**	The following amendment in Detailed Specification is hereby authorised as: Each 5 ml contains: Guaifenesin IP 100 mg Dextromethorphan IP 10 mg **Phenylephrine IP 2.5 mg**
33	Clause no. 18 (M), Annexure XII & XIII and BOQ	1733	Omeprazole 20mg and Domperidone 30mg (Sustained Release) Capsules Each Capsule contains: Omeprazole 20 mg (as enteric coated pellets) Domperidone 30 mg (as sustained release pellets)	The following amendment in Generic name is hereby authorised as: **Omeprazole Gastro-resistant 20mg and Domperidone Sustained Release 30mg Capsules**
34	Clause no. 18 (M), Annexure XII & XIII and BOQ	1737	Oxaceprol Capsules 200mg Each Capsule contains: Oxaceprol Capsules 200mg	The following amendment in Detailed Specification is hereby authorised as: Each hard gelatin capsule contains: Oxaceprol 200mg

35	Clause no. 18 (M), Annexure XII & XIII and BOQ	1739	Pancreatin Capsule 10000 mg Each capsule contains: Pancreatin 10000 mg	The following amendment in Generic name and Detailed Specification is hereby authorised as: **Pancreatin Capsules 10000** Each hard gelatin capsule contains: Pancreatin Minimicrospheres eq. to Pancreatin IP 150 mg Declared enzymes activity per capsule: Amylase 8000 units Lipase 10,000 units Protease 600 units
36	Clause no. 18 (M), Annexure XII & XIII and BOQ	1740	Pancreatin Capsule 25000 mg Each capsule contains: Pancreatin 25000 mg	The following amendment in Generic name and Detailed Specification is hereby authorised as: **Pancreatin Capsules 25000** Each hard gelatin capsule contains: Pancreatin Minimicrospheres eq. to Pancreatin IP 300 mg Declared enzymes activity per capsule: Amylase 18,000 units Lipase 25,000 units Protease 1,000 units
37	Clause no. 18 (M), Annexure XII & XIII and BOQ	1822	Tiotropium Powder for Inhalation IP 18mcg Each actuation delivers: Tiotropium Bromide Monohydrate IP equivalent to Tiotropium 18 mcg Unit Size- 1's Secondary Pack- 1's X 10	The following amendment in Generic name, Detailed specification, Unit Size and Secondary Pack is hereby authorised as: **(i) Tiotropium Powder for Inhalation IP 18mcg Rotacaps** **(ii) Each capsule contains:** Tiotropium Bromide Monohydrate IP equivalent to Tiotropium 18mcg **(iii) Unit Size- 15's in Monocarton** **(iv) Secondary Pack- 15's x 1 x 10**

Part-2

S.No.	Tender Clause/ Reference	Item Code	Generic Name with detailed specification and Unit Size of the Item	Packaging Type	Amendment
1	Clause no. 20 (B) & Annexure XIII	54	Cefixime Tablets IP 100 mg	Alu-Alu	Strip
2	Clause no. 20 (B) & Annexure XIII	105	Roxithromycin Tablets IP 150 mg	Blister	Alu-Alu
3	Clause no. 20 (B) & Annexure XIII	212	Pantoprazole Gastro Resistant Tablets IP 40 mg	Alu-Alu	Strip
4	Clause no. 20 (B) & Annexure XIII	250	Montelukast Sodium Tablets IP 5mg	Strip	Alu-Alu
5	Clause no. 20 (B) & Annexure XIII	360	Mifepristone Tablets IP 200 mg	Alu-Alu	Blister
6	Clause no. 20 (B) & Annexure XIII	1012	Piracetam Tablets 400mg	Blister (Amber PVC)	Alu-Alu
7	Clause no. 20 (B) & Annexure XIII	1099	Metformin Hydrochloride 500mg and Voglibose 0.3mg Tablets	Blister	Strip
8	Clause no. 20 (B) & Annexure XIII	1488	Acarbose Tablets IP 25 mg	Blister	Strip
9	Clause no. 20 (B) & Annexure XIII	1512	Apremilast Tablets 10mg	Blister	Alu-Alu
10	Clause no. 20 (B) & Annexure XIII	1513	Apremilast Tablets 20mg	Blister	Alu-Alu
11	Clause no. 20 (B) & Annexure XIII	1514	Apremilast Tablets 30 mg	Blister	Alu-Alu
12	Clause no. 20 (B) & Annexure XIII	1519	Azilsartan Medoxomil 40mg and Chlorthalidone 12.5mg Tablets	Blister	Alu-Alu
13	Clause no. 20 (B) & Annexure XIII	1525	Betahistine Tablets IP 16 mg	Alu-Alu	Strip

14	Clause no. 20 (B) & Annexure XIII	1622	Ferrous Ascorbate 100mg, Folic Acid 1.5mg and Zinc Sulphate 22.5mg Tablets	Alu-Alu	Strip
15	Clause no. 20 (B) & Annexure XIII	1683	Levocetirizine Dihydrochloride Tablets IP 10mg	Alu-Alu	Blister
16	Clause no. 20 (B) & Annexure XIII	1737	Oxaceprol Capsules 200mg	Strip	Alu-Alu

Part-3

The following items is hereby deleted from the Annexure- XII, Annexure XIII of the tender document and BOQ. Details are as below: -

S. No.	Item Code	Generic Name of the Item	Unit Size
1	1590	Dabigatran Etexilate Mesilate Capsules 110 mg	10's
2	1591	Dabigatran Etexilate Mesilate Capsules 150 mg	10's
3	1698	Liquid Paraffin 3.75ml and Milk of Magnesia 11.25ml Emulsion per 15ml	200 ml

Enclosure – Annexure-I, Annexure-II & Annexure-III

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 18/10/2021, Amendment no. 2 dated 02/11/2021 and Amendment no. 3 dated 16/11/2021.

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

ANNEXURE-I

No. P-45021/2/2017-PP (BE-II)
Government of India
Ministry of Commerce and Industry
Department for Promotion of Industry and Internal Trade
(Public Procurement Section)

Udyog Bhawan, New Delhi
Dated: 16th September, 2020

To

All Central Ministries/Departments/CPSUs/All concerned

ORDER

Subject: Public Procurement (Preference to Make in India), Order 2017– Revision; regarding.

Department for Promotion of Industry and Internal Trade, in partial modification [Paras 2, 3, 5, 10 & 13] of Order No.P-45021/2/2017-B.E.-II dated 15.6.2017 as amended by Order No.P-45021/2/2017-B.E.-II dated 28.05.2018, Order No.P-45021/2/2017-B.E.-II dated 29.05.2019 and Order No.P-45021/2/2017-B.E.-II dated 04.06.2020, hereby issues the revised 'Public Procurement (Preference to Make in India), Order 2017" dated 16.09.2020 effective with immediate effect.

Whereas it is the policy of the Government of India to encourage 'Make in India' and promote manufacturing and production of goods and services in India with a view to enhancing income and employment, and

Whereas procurement by the Government is substantial in amount and can contribute towards this policy objective, and

Whereas local content can be increased through partnerships, cooperation with local companies, establishing production units in India or Joint Ventures (JV) with Indian suppliers, increasing the participation of local employees in services and training them,

Now therefore the following Order is issued:

1. This Order is issued pursuant to Rule 153 (iii) of the General Financial Rules 2017.

2. **Definitions**: For the purposes of this Order:

   'Local content' means the amount of value added in India which shall, unless otherwise prescribed by the Nodal Ministry, be the total value of the item procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent.

   'Class-I local supplier' means a supplier or service provider, whose goods, services or works offered for procurement, meets the minimum local content as prescribed for 'Class-I local supplier' under this Order.

.....Contd. p/2

'Class-II local supplier' means a supplier or service provider, whose goods, services or works offered for procurement, meets the minimum local content as prescribed for 'Class-II local supplier' but less than that prescribed for 'Class-I local supplier' under this Order.

'Non - Local supplier' means a supplier or service provider, whose goods, services or works offered for procurement, has local content less than that prescribed for 'Class-II local supplier' under this Order.

'L1' means the lowest tender or lowest bid or the lowest quotation received in a tender, bidding process or other procurement solicitation as adjudged in the evaluation process as per the tender or other procurement solicitation.

'Margin of purchase preference' means the maximum extent to which the price quoted by a "Class-I local supplier" may be above the L1 for the purpose of purchase preference.

'Nodal Ministry' means the Ministry or Department identified pursuant to this order in respect of a particular item of goods or services or works.

'Procuring entity' means a Ministry or department or attached or subordinate office of, or autonomous body controlled by, the Government of India and includes Government companies as defined in the Companies Act.

'Works' means all works as per Rule 130 of GFR- 2017, and will also include *'turnkey works'*.

3. Eligibility of 'Class-I local supplier'/ 'Class-II local supplier'/ 'Non-local suppliers' for different types of procurement

(a) In procurement of all goods, services or works in respect of which the Nodal Ministry / Department has communicated that there is sufficient local capacity and local competition, only 'Class-I local supplier', as defined under the Order, shall be eligible to bid irrespective of purchase value.

(b) Only 'Class-I local supplier' and 'Class-II local supplier', as defined under the Order, shall be eligible to bid in procurements undertaken by procuring entities, except when Global tender enquiry has been issued. In global tender enquiries, 'Non-local suppliers' shall also be eligible to bid along with 'Class-I local suppliers' and 'Class-II local suppliers'. In procurement of all goods, services or works, not covered by sub-para 3(a) above, and with estimated value of purchases less than Rs. 200 Crore, in accordance with Rule 161(iv) of GFR, 2017, Global tender enquiry shall not be issued except with the approval of competent authority as designated by Department of Expenditure.

(c) For the purpose of this Order, works includes Engineering, Procurement and Construction (EPC) contracts and services include System Integrator (SI) contracts.

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3A. Purchase Preference

(a) Subject to the provisions of this Order and to any specific instructions issued by the Nodal Ministry or in pursuance of this Order, purchase preference shall be given to 'Class-I local supplier' in procurements undertaken by procuring entities in the manner specified here under.

(b) In the procurements of goods or works, which are covered by para 3(b) above and which are divisible in nature, the 'Class-I local supplier' shall get purchase preference over 'Class-II local supplier' as well as 'Non-local supplier', as per following procedure:

i. Among all qualified bids, the lowest bid will be termed as L1. If L1 is 'Class-I local supplier', the contract for full quantity will be awarded to L1.

ii. If L1 bid is not a 'Class-I local supplier', 50% of the order quantity shall be awarded to L1. Thereafter, the lowest bidder among the 'Class-I local supplier' will be invited to match the L1 price for the remaining 50% quantity subject to the Class-I local supplier's quoted price falling within the margin of purchase preference, and contract for that quantity shall be awarded to such 'Class-I local supplier' subject to matching the L1 price. In case such lowest eligible 'Class-I local supplier' fails to match the L1 price or accepts less than the offered quantity, the next higher 'Class-I local supplier' within the margin of purchase preference shall be invited to match the L1 price for remaining quantity and so on, and contract shall be awarded accordingly. In case some quantity is still left uncovered on Class-I local suppliers, then such balance quantity may also be ordered on the L1 bidder.

(c) In the procurements of goods or works, which are covered by para 3(b) above and which are not divisible in nature, and in procurement of services where the bid is evaluated on price alone, the 'Class-I local supplier' shall get purchase preference over 'Class-II local supplier' as well as 'Non-local supplier', as per following procedure:

i. Among all qualified bids, the lowest bid will be termed as L1. If L1 is 'Class-I local supplier', the contract will be awarded to L1.

ii. If L1 is not 'Class-I local supplier', the lowest bidder among the 'Class-I local supplier', will be invited to match the L1 price subject to Class-I local supplier's quoted price falling within the margin of purchase preference, and the contract shall be awarded to such 'Class-I local supplier' subject to matching the L1 price.

iii. In case such lowest eligible 'Class-I local supplier' fails to match the L1 price, the 'Class-I local supplier' with the next higher bid within the margin of purchase preference shall be invited to match the L1 price and so on and contract shall be awarded accordingly. In case none of the 'Class-I local supplier' within the margin of purchase preference matches the L1 price, the contract may be awarded to the L1 bidder.

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(d) "Class-II local supplier" will not get purchase preference in any procurement, undertaken by procuring entities.

3B. Applicability in tenders where contract is to be awarded to multiple bidders - In tenders where contract is awarded to multiple bidders subject to matching of L1 rates or otherwise, the 'Class-I local supplier' shall get purchase preference over 'Class-II local supplier' as well as 'Non-local supplier', as per following procedure:

a) In case there is sufficient local capacity and competition for the item to be procured, as notified by the nodal Ministry, only Class I local suppliers shall be eligible to bid. As such, the multiple suppliers, who would be awarded the contract, should be all and only 'Class I Local suppliers'.

b) In other cases, 'Class II local suppliers' and 'Non local suppliers' may also participate in the bidding process along with 'Class I Local suppliers' as per provisions of this Order.

c) If 'Class I Local suppliers' qualify for award of contract for at least 50% of the tendered quantity in any tender, the contract may be awarded to all the qualified bidders as per award criteria stipulated in the bid documents. However, in case 'Class I Local suppliers' do not qualify for award of contract for at least 50% of the tendered quantity, purchase preference should be given to the 'Class I local supplier' over 'Class II local suppliers'/ 'Non local suppliers' provided that their quoted rate falls within 20% margin of purchase preference of the highest quoted bidder considered for award of contract so as to ensure that the 'Class I Local suppliers' taken in totality are considered for award of contract for at least 50% of the tendered quantity.

d) First purchase preference has to be given to the lowest quoting 'Class-I local supplier', whose quoted rates fall within 20% margin of purchase preference, subject to its meeting the prescribed criteria for award of contract as also the constraint of maximum quantity that can be sourced from any single supplier. If the lowest quoting 'Class-I local supplier', does not qualify for purchase preference because of aforesaid constraints or does not accept the offered quantity, an opportunity may be given to next higher 'Class-I local supplier', falling within 20% margin of purchase preference, and so on.

e) To avoid any ambiguity during bid evaluation process, the procuring entities may stipulate its own tender specific criteria for award of contract amongst different bidders including the procedure for purchase preference to 'Class-I local supplier' within the broad policy guidelines stipulated in sub-paras above.

4. **Exemption of small purchases**: Notwithstanding anything contained in paragraph 3, procurements where the estimated value to be procured is less than Rs. 5 lakhs shall be exempt from this Order. However, it shall be ensured by procuring entities that procurement is not split for the purpose of avoiding the provisions of this Order.

5. **Minimum local content**: The 'local content' requirement to categorize a supplier as 'Class-I local supplier' is minimum 50%. For 'Class-II local supplier', the 'local content' requirement is minimum 20%. Nodal Ministry/ Department may prescribe only a higher

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percentage of minimum local content requirement to categorize a supplier as 'Class-I local supplier'/ 'Class-II local supplier'. For the items, for which Nodal Ministry/ Department has not prescribed higher minimum local content notification under the Order, it shall be 50% and 20% for 'Class-I local supplier'/ 'Class-II local supplier' respectively.

6. **Margin of Purchase Preference**: The margin of purchase preference shall be 20%.

7. **Requirement for specification in advance**: The minimum local content, the margin of purchase preference and the procedure for preference to Make in India shall be specified in the notice inviting tenders or other form of procurement solicitation and shall not be varied during a particular procurement transaction.

8. **Government E-marketplace**: In respect of procurement through the Government E-marketplace (GeM) shall, as far as possible, specifically mark the items which meet the minimum local content while registering the item for display, and shall, wherever feasible, make provision for automated comparison with purchase preference and without purchase preference and for obtaining consent of the local supplier in those cases where purchase preference is to be exercised.

9. **Verification of local content**:

   a. The 'Class-I local supplier'/ 'Class-II local supplier' at the time of tender, bidding or solicitation shall be required to indicate percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local supplier'/ 'Class-II local supplier', as the case may be. They shall also give details of the location(s) at which the local value addition is made.

   b. In cases of procurement for a value in excess of Rs. 10 crores, the 'Class-I local supplier'/ 'Class-II local supplier' shall be required to provide a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content.

   c. Decisions on complaints relating to implementation of this Order shall be taken by the competent authority which is empowered to look into procurement-related complaints relating to the procuring entity.

   d. Nodal Ministries may constitute committees with internal and external experts for independent verification of self-declarations and auditor's/ accountant's certificates on random basis and in the case of complaints.

   e. Nodal Ministries and procuring entities may prescribe fees for such complaints.

   f. False declarations will be in breach of the Code of Integrity under Rule 175(1)(i)(h) of the General Financial Rules for which a bidder or its successors can be debarred for up to two years as per Rule 151 (iii) of the General Financial Rules along with such other actions as may be permissible under law.

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g. A supplier who has been debarred by any procuring entity for violation of this Order shall not be eligible for preference under this Order for procurement by any other procuring entity for the duration of the debarment. The debarment for such other procuring entities shall take effect prospectively from the date on which it comes to the notice of other procurement entities, in the manner prescribed under paragraph 9h below.

h. The Department of Expenditure shall issue suitable instructions for the effective and smooth operation of this process, so that:

   i. The fact and duration of debarment for violation of this Order by any procuring entity are promptly brought to the notice of the Member-Convenor of the Standing Committee and the Department of Expenditure through the concerned Ministry /Department or in some other manner;

   ii. on a periodical basis such cases are consolidated and a centralized list or decentralized lists of such suppliers with the period of debarment is maintained and displayed on website(s);

   iii. in respect of procuring entities other than the one which has carried out the debarment, the debarment takes effect prospectively from the date of uploading on the website(s) in the such a manner that ongoing procurements are not disrupted.

10. **Specifications in Tenders and other procurement solicitations**:

a. Every procuring entity shall ensure that the eligibility conditions in respect of previous experience fixed in any tender or solicitation do not require proof of supply in other countries or proof of exports.

b. Procuring entities shall endeavour to see that eligibility conditions, including on matters like turnover, production capability and financial strength do not result in unreasonable exclusion of 'Class-I local supplier'/ 'Class-II local supplier' who would otherwise be eligible, beyond what is essential for ensuring quality or creditworthiness of the supplier.

c. Procuring entities shall, within 2 months of the issue of this Order review all existing eligibility norms and conditions with reference to sub-paragraphs 'a' and 'b' above.

d. Reciprocity Clause

   i. When a Nodal Ministry/Department identifies that Indian suppliers of an item are not allowed to participate and/ or compete in procurement by any foreign government, due to restrictive tender conditions which have direct or indirect effect of barring Indian companies such as registration in the procuring country, execution of projects of specific value in the procuring country etc., it shall provide such details to all its procuring entities including CMDs/CEOs of PSEs/PSUs, State Governments and other procurement agencies under their administrative control and GeM for appropriate reciprocal action.

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ii. Entities of countries which have been identified by the nodal Ministry/Department as not allowing Indian companies to participate in their Government procurement for any item related to that nodal Ministry shall not be allowed to participate in Government procurement in India for all items related to that nodal Ministry/ Department, except for the list of items published by the Ministry/ Department permitting their participation.

iii. The stipulation in (ii) above shall be part of all tenders invited by the Central Government procuring entities stated in (i) above. All purchases on GeM shall also necessarily have the above provisions for items identified by nodal Ministry/ Department.

iv. State Governments should be encouraged to incorporate similar provisions in their respective tenders.

v. The term 'entity' of a country shall have the same meaning as under the FDI Policy of DPIIT as amended from time to time.

e. Specifying foreign certifications/ unreasonable technical specifications/ brands/ models in the bid document is restrictive and discriminatory practice against local suppliers. If foreign certification is required to be stipulated because of non-availability of Indian Standards and/or for any other reason, the same shall be done only after written approval of Secretary of the Department concerned or any other Authority having been designated such power by the Secretary of the Department concerned.

f. "All administrative Ministries/Departments whose procurement exceeds *Rs.* 1000 Crore per annum shall notify/ update their procurement projections every year, including those of the PSEs/PSUs, for the next 5 years on their respective website."

10A. Action for non-compliance of the Provisions of the Order: In case restrictive or discriminatory conditions against domestic suppliers are included in bid documents, an inquiry shall be conducted by the Administrative Department undertaking the procurement (including procurement by any entity under its administrative control) to fix responsibility for the same. Thereafter, appropriate action, administrative or otherwise, shall be taken against erring officials of procurement entities under relevant provisions. Intimation on all such actions shall be sent to the Standing Committee.

11. **Assessment of supply base by Nodal Ministries**: The Nodal Ministry shall keep in view the domestic manufacturing / supply base and assess the available capacity and the extent of local competition while identifying items and prescribing the higher minimum local content or the manner of its calculation, with a view to avoiding cost increase from the operation of this Order.

12. **Increase in minimum local content**: The Nodal Ministry may annually review the local content requirements with a view to increasing them, subject to availability of sufficient local competition with adequate quality.

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13. **Manufacture under license/ technology collaboration agreements with phased indigenization**: While notifying the minimum local content, Nodal Ministries may make special provisions for exempting suppliers from meeting the stipulated local content if the product is being manufactured in India under a license from a foreign manufacturer who holds intellectual property rights and where there is a technology collaboration agreement / transfer of technology agreement for indigenous manufacture of a product developed abroad with clear phasing of increase in local content.

13A. In procurement of all goods, services or works in respect of which there is substantial quantity of public procurement and for which the nodal ministry has not notified that there is sufficient local capacity and local competition, the concerned nodal ministry shall notify an upper threshold value of procurement beyond which foreign companies shall enter into a joint venture with an Indian company to participate in the tender. Procuring entities, while procuring such items beyond the notified threshold value, shall prescribe in their respective tenders that foreign companies may enter into a joint venture with an Indian company to participate in the tender. The procuring Ministries/Departments shall also make special provisions for exempting such joint ventures from meeting the stipulated minimum local content requirement, which shall be increased in a phased manner.

14. **Powers to grant exemption and to reduce minimum local content**: The administrative Department undertaking the procurement (including procurement by any entity under its administrative control), with the approval of their Minister-in-charge, may by written order, for reasons to be recorded in writing,

    a. reduce the minimum local content below the prescribed level; or
    b. reduce the margin of purchase preference below 20%; or
    c. exempt any particular item or supplying entities from the operation of this Order or any part of the Order.

    A copy of every such order shall be provided to the Standing Committee and concerned Nodal Ministry / Department. The Nodal Ministry / Department concerned will continue to have the power to vary its notification on Minimum Local Content.

15. **Directions to Government companies**: In respect of Government companies and other procuring entities not governed by the General Financial Rules, the administrative Ministry or Department shall issue policy directions requiring compliance with this Order.

16. **Standing Committee**: A standing committee is hereby constituted with the following membership:

    Secretary, Department for Promotion of Industry and Internal Trade—Chairman
    Secretary, Commerce—Member
    Secretary, Ministry of Electronics and Information Technology—Member
    Joint Secretary (Public Procurement), Department of Expenditure—Member
    Joint Secretary (DPIIT)—Member-Convenor

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The Secretary of the Department concerned with a particular item shall be a member in respect of issues relating to such item. The Chairman of the Committee may co-opt technical experts as relevant to any issue or class of issues under its consideration.

17. **Functions of the Standing Committee**: The Standing Committee shall meet as often as necessary, but not less than once in six months. The Committee

a. shall oversee the implementation of this order and issues arising therefrom, and make recommendations to Nodal Ministries and procuring entities.
b. shall annually assess and periodically monitor compliance with this Order
c. shall identify Nodal Ministries and the allocation of items among them for issue of notifications on minimum local content
d. may require furnishing of details or returns regarding compliance with this Order and related matters
e. may, during the annual review or otherwise, assess issues, if any, where it is felt that the manner of implementation of the order results in any restrictive practices, cartelization or increase in public expenditure and suggest remedial measures
f. may examine cases covered by paragraph 13 above relating to manufacture under license/ technology transfer agreements with a view to satisfying itself that adequate mechanisms exist for enforcement of such agreements and for attaining the underlying objective of progressive indigenization
g. may consider any other issue relating to this Order which may arise.

18. **Removal of difficulties**: Ministries /Departments and the Boards of Directors of Government companies may issue such clarifications and instructions as may be necessary for the removal of any difficulties arising in the implementation of this Order.

19. **Ministries having existing policies**: Where any Ministry or Department has its own policy for preference to local content approved by the Cabinet after 1st January 2015, such policies will prevail over the provisions of this Order. All other existing orders on preference to local content shall be reviewed by the Nodal Ministries and revised as needed to conform to this Order, within two months of the issue of this Order.

20. **Transitional provision**: This Order shall not apply to any tender or procurement for which notice inviting tender or other form of procurement solicitation has been issued before the issue of this Order.

(Rajesh Gupta)
Director
Tel: 23063211
rajesh.gupta66@gov.in

ANNEXURE-II

F.No.31026/65/2020-MD
Ministry of Chemicals & Fertilizers
Government of India
Department of Pharmaceuticals

Dated 30th December, 2020
Shastri Bhawan, New Delhi

Subject: Guidelines for implementing the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017 - revision, related to procurement of Goods & Services in Pharmaceutical Formulations - reg.

Whereas Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153(iii) of the General Financial Rules 2017, has issued Public Procurement (Preference to Make in India) Order (PPO), 2017 vide no. P 4502/2/2017-B.E.-II dated 15.06.2017, which is partially modified by Order no. P-45021/2/2017-PP (BE-II) dated 28.05.2018, Order no. P-45021/2/2017-PP (BE-II) dated 29.05.2019, Order no. P-45021/2/2017-PP (BE-II) dated 04.06.2020 and Order no. P-45021/2/2017-PP (BE-II) dated 16.09.2020.

Whereas it is the policy of the Government of India to encourage 'Make in India' and promote manufacturing and production of goods and services in India with a view to enhancing income and employment, and

Whereas DPIIT, in order to facilitate the implementation of the PPO, 2017, vide D.O. No. P-45021/2/2017-BE-II dated 14.08.2017 has identified Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions of the PPO, 2017 relating to goods & services related to Pharmaceuticals Sector.

Now, therefore, Department of Pharmaceuticals (DoP), in supersession of the guidelines issued earlier by DoP vide F.No. 31026/4/2018-Policy dated 01.01.2019, F.No. 31026/4/2018-Policy dated 14.01.2019 and F.No. 31026/4/2018-Policy dated 25.02.2019, issues the following guidelines for implementation of the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017, as revised by DPIIT on 16.09.2020, with respect to public procurement of Goods & Services in Pharmaceutical Formulations:-

1. **Local Content:** 'Local content' means the amount of value added in India which shall be the total value of the item procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent.

2. **Formulation**: 'Formulation', as defined in the Drugs (Price Control) Order, 2013, means a medicine processed out of or containing one or more drugs with or without use of any

pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include:

i. any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;
ii. any medicine included in the Homeopathic system of medicine; and
iii. any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.

3. In exercise of provisions of Para 5 of Public Procurement (Preference to Make in India) Order, 2017 revision dated 16.09.2020 of DPIIT, the minimum local content for Pharmaceutical Formulations are fixed as under:

i. **Class-I Local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content equal to or more than 80%.
ii. **Class-II local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content more than 50% but less than 80%.
iii. **Non–Local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content less than or equal to 50%.

4. Verification of Local Content:
   a. The 'Class-I local supplier'/ Class-II local Supplier' at the time of tender, bidding or solicitation shall be required to indicate percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local supplier'/ Class-II local supplier', as the case may be. They shall also give details of the location(s) at which the local value addition is made.

   b. In cases of procurement for a value in excess of Rs. 10 crores, the 'Class-I local supplier'/ 'Class-II local supplier' shall be required to provide a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content.

   c. The following Committee is being formed for independent verification of self-declarations and auditor's/accountant's certificate on random basis and in the case of complaints-

      1. Chairman – MD, Karnataka Antibiotics & Pharmaceuticals Limited
      2. Member – Representative from NIPER Ahmedabad
      3. Member – Representative from the NPPA
      4. Member - Representative from the CDSCO
      5. Member - Joint Director (Pricing), D/o Pharmaceuticals

d. In case of reference of any complaint by the concerned bidder, there would be a fee of Rs. 2 lakh or 1% of the value of the pharmaceutical formulations being procured (subject to a maximum of Rs. 5 lakh), whichever is higher, to be paid by way of a Demand Draft to be deposited with the procuring entity, along with the complaint by the complainant. In case, the complaint is found to be incorrect, the complaint fee shall be forfeited. In case, the complaint is upheld and found to be substantially correct, deposited fee of the complainant would be refunded without any interest.

5. These guidelines shall be applicable to all Central Sector Schemes/Centrally Sponsored Schemes for procurement made by States and local bodies if project or scheme is fully or partially funded by Government of India.

6. All other provisions of Public Procurement (Preference to Make in India) Order 2017, as revised by DPIIT on 16.09.2020, shall be applicable as such and shall be adhered to by all procuring agencies for procurement of any pharmaceutical formulation.

7. These guidelines shall remain applicable, until further orders, from the date of issuance.

8. These guidelines will supersede the guidelines issued earlier by DoP vide Order No. 31026/4/2018-Policy dated 01.01.2019, Order No. 31026/4/2018-Policy dated 14.01.2019 and O.M. No. 31026/4/2018-Policy dated 25.02.2019.

30/12/20

(Dr. Sumit Garg)
Deputy Secretary
Email: sumit.g@nic.in
Tele: 011-23389840

ANNEXURE-III

No.31026/4/2018-Policy
Government of India
Ministry of Chemicals& Fertilizers
Department of Pharmaceuticals
*****

Shastri Bhawan, New Delhi
Dated the 1st January, 2019

ORDER

Subject:- Public Procurement (Preference to Make in India), Order, 2017 (revised) -Notifying provisions about Pharmaceutical Formulations in furtherance to the Order.

Reference:- Department of Industrial Policy & Promotion (DIPP) Order No. P-45021/2/2017-PP (BE-II) dated 28.05.2018.

The Government has issued revised Public Procurement (Preference to Make in India), Order 2017 vide the Department of Industrial Policy & Promotion (DIPP) Order No. P-45021/2/2017-PP(BE-II) dated 28.05.2018 to encourage 'Make in India' and to promote manufacturing and production of goods and services in India with a view to enhancing income and employment.

2. DIPP has identified Department of Pharmaceuticals as the nodal Department for implementing the provisions related to goods, services or works related to Pharmaceutical sector.

3. In furtherance of the above mentioned order of DIPP, the Department of Pharmaceuticals (DoP) hereby notifies that purchase preference shall be provided by all Government Procuring Entities to local suppliers of Pharmaceutical Formulations in various dosage forms, as per the minimum local content prescribed in this order.

4. This Order comes into effect immediately and shall remain valid till revised.

5. Minimum local content and Phased Manufacturing Programme (PMP).

5.1 For formulations which are manufactured in India, the minimum local content for all Pharma products shall be as per the table below:-

Pharma Products	Minimum Local Content (%)			
	2018-19	2019-21	2021-23	2023-25
All Pharmaceutical formulations in different dosage forms and strengths	75	80	85	90

5.2 For formulations which are not manufactured in India, the minimum local content for all Pharma products shall be as per the table below:-

Pharma Products	Minimum Local Content (%)			
	2018-19	2019-21	2021-23	2023-25
All Pharmaceutical formulations in different dosage forms and strengths	10	15	20	30

6. Procedure for calculating local content for Pharmaceutical Formulations.

6.1 Bill of Material sourced from domestic manufacturers (Dom-BOM) may be calculated based on one of the following depending on data available. Each of these calculations should provide consistent result:-

(a) Sum of the costs of all inputs which go into the product (including duties and taxes levied on procurement of inputs except those for which credit/ set-off can be taken) and which have not been imported directly or through a domestic trader or an intermediary.

(b) Ex-Factory Price of product minus profit after tax minus sum of imported Bill of material used (directly or indirectly) as inputs in producing the product (including duties and taxes levied on procurement of inputs except those for which credit/ set-off can be availed).

(c) Market price minus post-production freight, insurance and other handling costs minus profit after tax minus warranty costs minus sum of Imported Bill of material used as inputs in producing the product (including duties and taxes levied on procurement of inputs except those for which credit / set-off can be taken) minus sales and marketing expenses.

6.2 Total bill of Material (Total-BOM) may be calculated based on one of the following depending on data available. Each of these calculations should provide consistent result:-

(a) Sum of the costs of all inputs which go into the product (including duties and taxes levied on procurement of inputs except those for which credit / set-off can be availed).

(b) Ex-factory Price of product minus profit after tax.

(c) Market price minus post-production freight, insurance and other handling costs minus profit after tax, minus sales and marketing expenses.

6.3 The percentage of local content value-addition may be calculated as per the following formula:-

Percentage of local content= (Dom-BOM/Total-BOM) x100

It is recommended that each assessing agency should calculate the domestic local content/value addition using at least two of the above formulae so as to validate the assessments in this regard and ensure that the local content that is claimed is consistent.

7. It is clarified that this order shall also be applicable to procurement of medicines made by State Governments or PSUs under State Governments or local bodies under Centrally Sponsored schemes that are fully or partially funded by Government of India.

8. Every procuring entity shall constitute a Committee with internal and external experts for independent verification of self-declaration and auditors /accountants certificates on random basis and for the complaints that are received/ referred. In case any clarification is needed by this committee on any particular point, the matter may be referred to the following committee in the Department of Pharmaceuticals:-

(i) Chairperson - Joint Secretary (Policy)
(ii) Member - Joint Secretary (PSU) or representative thereof.
(iii) Member - Member Secretary (NPPA) or representative thereof.

9. In case a complaint is received by a procuring entity against the claim of a bidder regarding local content, the same shall be referred to the committee of the procuring entity as referred to in para- 8 above. The Committee should dispose of the complaint within 4 weeks, as far as possible, from the date of receipt of complaint alongwith all necessary documentation in support of local content claimed by the bidder.

10. There will be a complaint fee of Rs. 10,000/- per complaint to be deposited with the said procuring entity alongwith the complaint by the complainant. In case, the complaint is found to be incorrect, the complaint fee shall be forfeited. In case, the complaint is upheld in part or full, deposited fee of the complaint will be refunded without any interest.

11. All other terms & conditions will be as per the Department of Industrial Policy & Promotion (DIPP) Order no. P-45021/2/2017-PP(BE-II) dated 28.05.2018.

(Navdeep Rinwa)
Joint Secretary to the Govt. of India
Ph. 23385131

Copy to:-

1. All Ministries/Departments of Government of India
2. Cabinet Secretariat
3. Prime Minister's Office
4. NITI Aayog
5. Comptroller & Auditor General of India
6. Internal Circulation in the Department of Pharmaceuticals
7. Senior Director, NIC, DoP with request to upload the same on the Department's website.