

No.F.4/1/2023-PPD(pt.)
Government of India
Ministry of Finance
Department of Expenditure
Procurement Policy Division

516, Lok Nayak Bhawan,
Khan Market, New Delhi,
15.01.2025

OFFICE MEMORANDUM

Subject: Relaxation under Rule 161(iv) of General Financial Rules (GFRs) 2017 for issuance of Global Tender Inquiry (GTE) for procurement of Drugs.

Reference: Department of Expenditure OM No. 4/1/2023-PPD(pt.) dated 09.08.2024.

Attention is invited to this Department's OM No. F.12/17/2019-PPD dated 15.05.2020 regarding amendment in Rule 161(iv) of General Financial Rules (GFRs) 2017 stipulating that no Global Tender Enquiry (GTE) shall be invited for tenders up to Rs. 200 crores. However, in exceptional cases, where the Ministry or the Department feels that there are special reasons for issuance of GTE, it may record its detailed justification and seek prior approval for relaxation to the above Rule from the competent authority i.e. Secretary (Coordination), Cabinet Secretariat.

2. Exemption from the above instructions was given for procurement of 127 drugs vide this Department's OM No. 4/1/2023-PPD(pt.) dated 09.08.2024 till 31.03.2027, on the recommendations of Ministry of Health & Family Welfare (MoH&FW).

3. On the additional recommendation of MoH&FW, it has now been decided to include one more drug i.e. "Varicella Vaccine, Live Attenuated, Monovalent, Containing at least 1000 PFU per 0.5 ml" in the list of exempted drugs as above.


(Sher Bahadur)
Under Secretary (Procurement Policy)
Tel.: 24653771
Email: sher.bahadur@nic.in

To

All the Secretaries and Financial Advisors to Government of India.

Copy to:

Secretary (Coordination), Cabinet Secretariat, Rashtrapati Bhawan, New Delhi.

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Subject: Relaxation under Rule 161(iv) of General Financial Rules 2017 for issuance of Global Tender Enquiry (GTE) for procurement of Drugs.

Attention is invited to this Department's OM No. F.12/17/2019-PPD dated 15.05.2020 regarding amendment in Rule 161(iv) of General Financial Rules (GFRs) 2017 stipulating that no Global Tender Enquiry (GTE) shall be invited for tenders upto Rs.200 crore. However, in exceptional cases, where the Ministry or the Department feels that there are special reasons for issuance of GTE, it may record its detailed justification and seek prior approval for relaxation to the above Rule from the competent authority i.e. Secretary (Coordination), Cabinet Secretariat.

2. In above context, on the recommendation of Ministry of Health and Family Welfare (MoH&FW), 120 drugs were exempted, vide this Department's OM No. 4/1/2023-PPD (pt.) dated 07.06.2024, from the instructions issued by this Department OMs No. 12/17/2019-PPD dated 15.05.2020 & 28.05.2020 till 31.03.2027 or further orders.

3. MoH&FW (efile No. 102-1/2023-24/CGHS/MSD) has now requested to exempt 07 more drugs from the above said instructions dated 15.05.2020 & 28.05.2020 regarding GTEs. As requested by MoH&FW, exemptions will now be available for 127 drugs listed at Annexure A till 31.03.2027 or further orders.

Encls: As above.


(Sher Bahadur)
Under Secretary (Procurement Policy)
Tel.: 24653771
Email: sher.bahadur@nic.in

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Annexure - A

S.No	Name of the Drug
1	Abemaciclib 50mg/100mg/150mg/200mg
2	Abrocitinib Tab 50 mg/100mg/ 200 mg
3	AFLIBERCEPT 40 MG
4	ALECENSA 150 MG {(Alectinib (150mg)}
5	Alglucosidase Alfa vial for Inj.
6	Amivantamab 350 mg
7	ATEZOLIZUMAB 840 MG/ 1.2MG
8	Avalglucosidase Alfa-ngpt vial for inj.
9	Avelumab injection: 200 mg/10 mL (20 mg/mL) solution in single-dose vial
10	BASILIXIMAB 20 MG
11	Brolucizumab solution for injection 120 mg/ml(vial + filter needle)
12	Capmatinib Film-coated Tabler 200 mg
13	Catidecaceg (rDNA factor XIII 2500IU)
14	Crizanlizumab 100mg/ 10ml
15	Crizotinib Tab/Capsule (250 Mg)
16	Dabrafenib capsules 75 mg
17	DARATUMUMAB 100 MG 400mg & Daratumumab Subcutaneous(Faspro) 1800 mg
18	DEGLUDEC 100 IU/ML INSULIN. PREFILLED PEN 3 ML.
19	Desflurane Anaesthetic Liquid (SUPRANE)
20	Detemir Insulin 100 IU/ml 3ml Pen
21	Dulaglutide 0.75 MG (BRAND TRULICITY 0.75MG pre-filled pen) & Dulaglutide Inj- {Brand TRULICITY 1.5mg Pre Filled Pen}
22	Dupilumab Injection 300ng/2ml and 200mg/1.14ml
23	DURVALUMAB 120 MG/ 500MG
24	EMPAOLIFLOZIN + METFORMIN TABS VARIOUS FIXED DOSE COMBINATION)
25	Evrysdi 0.75MG/1ML 80 POSO IN (Risdiplam)
26	Fabrazyme (Agalsidase beta)

AB

27	FACTOR EIGHT INHIBITOR BYPASSING ACTIVITY - Containing : Factor Eight Bypassing activity, Anti-Inhibitor-Cogulant Complex. 500 IU.
28	FASENRA™ (Benralizumab, prefilled syringe) Benralizumab Each injection contains Benralizumab 30mg
29	FINERENONE 10 MG / 20 mg TAB
30	Genryzon (Somatotropin)
31	Golimumab 50mg/0.5ml [Simponi 50mg Injection-J&J]
32	Herpes Zoster Vaccine recombinant adjuvanted Brand Name: Shingrix
33	HUMAN COAGULATION FACTOR VII INJ - Each vial to contain: Human Recombinant Coagulation Factor VII activated (r-DNA origin) 1 mg Each vial to contain: Human Recombinant Coagulation Factor VII activated (r-DNA origin) 2mg
34	Idursulfase injection : 6 mg/3 ml, (2 mg/mL) in single-use vial
35	Imiglucerase injection: 400 units of imiglucerase as a lyophilized powder in a single-dose vial.
36	Inj Natalizumab 300mg/15ml
37	INJ PANITUMUMAB 100 MG
38	INJ PEMBROLIZUMAB 100 MG
39	Inj Spesolimab IV infusion 450 mg/7.5ml
40	Inj Tissue type plasminogen activator (tPA)
41	Inj. Insulin Degludec 70% + Insulin Aspart 30% 100 IU/ml., 3 ml. Cartridge (RYZODEG PENFILL.)
42	Inj. Ixekizumab 80mg (Copellor)
43	INJ. MEPOLIZUMAB SOLUTION 100 MG
44	Inj. Thyrotropin alfa 1.1 mg (THYROGEN)
45	Inonza (Inotuzumab Ozogamicin)
46	Insulin Analogue of 50% Insulin Aspart + 50% longer acting analogue 100 IU/ml.
47	Insulin Aspart Inj- Each Vial to contain: Insulin Aspart (r-DNA Origin)
48	INSULIN GLULISINE INJECTION(MONOCOMPONENT INSULIN GLULISINE) 100 I.U./ML,3ML

NB

49	Insulin Inj-Each Cartridge to contain: 25% Lispro And 75% Lispro Protamine Suspension (100 IU/ml) [Monocomponent Insulin, Recombinant DNA Origin] & 3ml Cartridge. Each Cartridge to contain: 50% Lispro And 50% Lispro Protamine Suspension (100 IU/ml) [Monocomponent Insulin, Recombinant DNA Origin] & 3ml Cartridge
50	Intravitreal Dexamethasone Implant- Each inj to contain: Intravitreal Dexamethasone 0.7mg
51	KADCYLA (Trastuzumab emtansine) (Sterile powder for concentrate for infusion solution 100mg and 160mg vial [20mg/ml])
52	Kyzifive® (Ascliminiib film-coated tablets 40 mg)
53	Laronidase injection: 2.9 mg/5 mL (0.58 mg/mL) of Laronidase in a single-dose vial
54	Lemtrada (Alemtuzumab)
55	Lorbiqua® (Lorlatinib)
56	Luspatercept 25 mg and 75 mg [Brand Name: Rojuvudza]
57	Lutropin Alfa-r-DNA (Recombinant Leutinising Hormone 75 IU) Powder with 1ml solvent for solution for injection
58	Miglustat (Zavesca) (Olpofolda)
59	Obinutuzumab Inj- Each Vial to contain: Obinutuzumab 1000 mg
60	OCREVUS (Ocrelizumab)Concentrate for solution for infusion 300 mg/10 mL vial [30 mg/mL]
61	Olipudase alfa-rpcp vial for Inj.
62	Pertuzumab Inj- Each 14ml Vial to contain: Pertuzumab 420mg (30mg/ml)
63	PHESGO Solution for subcutaneous injection 600mg + 600 mg (10 ml/15cc vial) 1200mg + 600mg (15ml/20cc vial) Pertuzumab (600mg) + Trastuzumab (600mg) Pertuzumab (1200mg) + Trastuzumab (600mg)
64	Pneumovax 23(pneumococcal vaccine polyvalent for 23 serotypes) & Pneumococcal Vaccine- Each 0.5ml to contain: Pneumococcal Polysaccharide Conjugate Vaccine (13 Valient)

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65	POLIVY (Polatuzumab vedotin) [20mg/mL] Powder for concentrate for solution for infusion 30mg/vial and 140 mg/vial
66	RAMUCIRUMAB 100 mg & 500 MG(BRAND-CYRAMZA)
67	RECOMBINANT ANTI HEMOPHILIC FACTOR-VIII
68	RUXOLITINIB 5MG, 15 MG, 20MG TABLET
69	Secukinumab Inj- Each 1 ml to contain: Secukinumab 150mg, Sucrose 92.43mg, L-Histidine / L- Histidine Hcl Monohydrate 4.656 mg. Polysorbate 80 - 0.60mg.
70	Selumetinib (Koselugo)
71	SEMAGLUTIDE 3 mg/ 7 mg/14 mg TAB
72	Sybrava (Inclisiran solution for injection in pre-filled syringe 284 mg/1.5 mL)
73	Tab. Dacomitinib Monohydrate 30 mg.(Tab Dacoplice 30 Mg.)
74	Thymoglobulin (Anti human thymocyte immunoGlobulin (rabbit). 25 mg/ml)
75	Trametinib 0.5 mg and 2 mg tablets
76	Trelegy Ellipta {(Fluticasone Furoate (100mcg) + Umeclidinium (62.5mcg) + Vilanterol (25mcg)}
77	Ustekinumab 90 mg and 130 mg
78	VABYSMO (Faricimab) [120mg/mL]
79	VERICIGUAT 2.5 mg/ 5 mg/ 10 mg
80	VERTEPORFIN 15 MG
81	YERVOI®(Ipilimumab)
82	Follitropin Alfa 450 IU (r-hFSH) + Lutropin Alfa 225 IU (r-FSH) in Pre-filled Pen (Pergoveris™ 450IU Pre-Filled Pen) & Follitropin Alfa 900 IU (r-hFSH) + Lutropin Alfa 450 IU (r-FSH) (Pergoveris™ 900IU Pre-Filled Pen)
83	TEPOTINIB HYDROCHLORIDE HYDRATE 250 MG EQUIVALENT TO TEPOTINIB 225 MG
84	GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) Suspension for intramuscular injection & Human Papillomavirus- Each 0.5ml to contain: Human Papillomavirus Quadrivalent (6.11.16.18) Vaccine, Recombinant

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85	Synvisc One (Hylan Polymer (A&B)G-F 20) (8mg/ml) & Hyaluronic Acid (20 mg) & Cross Linked Sodium Hyaluronic Acid, 1-2.9 mDa, 22 mg/ml 4ml PFS
86	CANAGLIFLOZIN 100/ 300 MG TABS
87	Canagliflozin 50mg + Metformin 1000 mg & Canagliflozin 50mg + Metformin 500 mg
88	EMPAGLIFLOZIN + LINAGLIPTIN TABS VARIOUS FIXED DOSE COMBINATION) & EMPAGLIFLOZIN 10 MG+LINAGLIPTIN 5 MG TAB/CAP
89	EMPAGLIFLOZIN 10 MG /25MG
90	OSIMERTINIB 80 MG
91	RIBOCICLIB TABLET(CAPSULE 200 MG
92	Tab. Baricitinib 2mg/ 4mg
93	CETUXIMAB 100 MG/ 500 MG
94	Inactivated Influenza Vaccine (Surface Antigen) (Quadrivalent)
95	TOUJEO SOLOSTAR 1.5ML PEN(INSULIN GLARGINE INJECTION 300 U/ML)
96	Injection Human Rabies Immunoglobulin (HRIG) 150 IU/ML in 2ML PFS
97	Emicizumab Inj- Each Vial Contains : Emicizumab 30mg For Sub Cut Injection (R-DNA Origin), Each Vial Contains , Emicizumab 60mg For Sub Cut Injection (R-DNA Origin)
98	Flavedon OD 80 mg {(Trimetazidine (80mg)} (Prolonged Release)
99	Ibrutinib Tab/Cap- Each Cap/Tab to contain : Ibrutinib 140 mg.
100	NIVOLUMAB 100 MG INJ, Nivolumab 40mg
101	Nonacog Beta Pegol 500 IU/1000 IU/2000 IU
102	Trastuzumab deruxtecan (Enhertu)
103	ACTEMRA (Tocilizumab) Concentrate solution for infusion 80mg/4ml vial, 200 mg/10ml vial and 400 mg/20 ml vial [20mg/ml]

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104	CAPD Bag- Each bag to contain: CAPD Bag 7.5% Of Icodextrin With Asymmetrical Y Connector
105	Goserelin Inj- Each PFS to contain: Goserelin 3.6mg or 10.8mg
106	Floseal 5ml (Haemostatic- Each 5ml to contain: Haemostatic Matrix With Prefilled Gelatin Granules In Syringes) & Floseal 10 ml (Hemostat- Each PFS to contain: Hemostatic Matrix With Thrombin In Prifilled Syringe 10ml)
107	Infliximab (Powder for Concentrate for Solution for Infusion 100 mg)
108	Isavuconazole 100 mg caps.
109	LIRAGLUTIDE 6 MG/ML 3ml
110	Meningococcal tetravalent Conjugated
111	Methoxy Polyethylene Glycol- Epoetin Beta Each PFS to contain: Methoxy Polyethylene Glycol-Epoetin Beta 100mcg. Methoxy Polyethylene Glycol- Epoetin Beta Each PFS to contain: Methoxy Polyethylene Glycol-Epoetin Beta 50mcg. Methoxy Polyethylene Glycol- Epoetin Beta Each PFS to contain: Methoxy Polyethylene Glycol-Epoetin Beta 75mcg
112	Omalizumab 150mg PFS
113	Paliperidone palmitate - Prolonged-Release Suspension for Inj. 75mg, 100mg & 150 mg
114	Ranibizumab 1.650mg/ 0.165ml PFS
115	Risperidone prolonged-release suspension Injection 25.0 mg/37.5 mg/50.0 mg
116	Tab./ Cap. (Netupitant 300 mg. + Palanosetron 0.5 mg.) (AKYNZEO CAPS.)

	<p>Triple Chamber Bag- Each Bag to contain: Triple Chamber Bag With Lipid Emulsion (80% Olive Oil & 20% Soya Oil), Amino Acids, Glucose And Electrolytes Separated By Peel Seals For Central Intravenous.</p>
117	<p>&</p> <p>Triple Chamber Bag- Each Bag to contain: Triple Chamber Bag With Lipid Emulsion (80% Olive Oil & 20% Soya Oil), Amino Acids, Glucose And Electrolytes Separated By Peel Seals For Peripheral Intravenous</p>
118	<p>Triptorelin Pamoate Inj- Each Single Dose Vial Contains: (Sterile Lypholized) Triptorelin Pamoate Equivalent to Triptorelin 11.25mg</p>
119	<p>Peritoneal Dialysis Solution With 1.5% Dextrose & Peritoneal Dialysis Solution With 2.5% Dextrose</p>
120	<p>Human Growth Hormone- Each Cartridge to contain: Somatropin 16 IU (R-DNA Origin)/ Somatropin 5.3mg/ml (R-DNA Origin)</p>

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Sr. No.	Name of the drug	
121.	Highly Purified menotropin coresponding to activity of FSH & LH Each of 1200 IU +1 PRE filled solvent syring containing water for injection with mcresol 1.1 ML	Vial
122.	Highly Purified menotropin coresponding to activity of FSH & LH Each of 600 IU +1 PRE filled solvent syring containing water for injection with mcresol 1.1 ML	Vial
123.	Menotropin coresponding to activity of FSH & LH Each of 75 IU + 1 PRE filled solvent syring containing water for injection with M cresol 1.1 ML	Vial
124.	Somatropin EP (Recombinant Human Growth Hormone) 4 MG (12 IU) +1 Ampoule of Bacteriostatic Sodium Chloride Inj. USP 3.5 ML	Vial
125.	Carbomer 980 2 MG+Hypromellose 3 MG Drops	Tube of 10 gms
126.	Sodium Hyaluronate 0.15% Polyethylene Glycol 400 0.4%, Propylene Glycol 0.3%, Hydroxypropyl Guar 8A, Boric acid, sorbitol and polyquaternium-1 0.001% Preservative with drop- Tainer Dispensing System	Bottle of 10 ml
127.	Dinoprostone (PGE2) 10 MG	1 Vaginal Pessary

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