

No. 31026/176/2021-MD (Part-3)
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi – 110 001
Dated 21 November 2025

Public Notice No. 1/2025

Subject: Exemption from Global Tender Enquiry under rule 161(iv) of the General Financial Rules, 2017

Subsequent to the exemption of 128 drugs/vaccines for tenders up to 200 crore₹ until 31.3.2027 or till further orders from the applicability of Global Tender Enquiry (GTE) under rule 161(iv) of the General Financial Rules, 2017 *vide* Department of Expenditure's OM no. 4/1/2023-PPD (Pt.), dated 15.1.2025, this Department has received requests from—

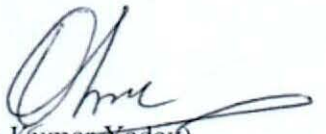
(a) the Directorate General of Armed Forces Medical Services and the Indian Council of Medical Research for—

- (i) inclusion of certain formulations under the GTE exemption list; or/and
- (ii) identification of local manufacturers, for certain formulations; and
- (b) Central Government procuring agencies and the pharmaceutical industry for inclusion of patented or proprietary formulations under the GTE exemption list, on account of absence of domestic manufacturing.

2. A list of the formulations to which these requests relate is at Annex A.

3. Against this backdrop, local manufacturers are hereby invited to submit objections (based on domestic manufacturing availability) against inclusion of any formulations listed at Annex A in the GTE exemption list, in the form set out at Annex B, by 05.12.2025 through email sent to SO-PharmaPolicy@pharma-dept.gov.in

4. This issues with the approval of competent authority.


(Dharmendra Kumar Yadav)
Under Secretary to the Government of India
Tel.: 011 23071162

**Drugs under consideration for inclusion in Global Tender Enquiry (GTE) exemption list in
FY 2025-26**

Request received from Industry (Part-I)

S. No	Pharmaceutical formulation and strength	Status- Patented or Proprietary (based on submission from industry)
1.	Pancreatin Minimicrospheres 10000, 25000, 40000	Patented
2.	Venetoclax 10mg, 50 mg and 100mg	Patented
3.	Botulinum Toxin Type A 200U Powder for solution for Injection	Patented
4.	Evolocumab Solution for Injection 140mg/ml (r-DNA origin)	Patented
5.	Enfortumab Vedotin – 20 mg and 30 mg powder concentrate for solution for infusion	Patented
6.	Gilteritinib - 40 mg film-coated tablets	Patented
7.	Eculizumab Concentrate for solution for infusion 300 mg (10mg/ml)	Proprietary
8.	Tremelimumab Concentrate for Solution for infusion 20 mg/ml (25 mg/1.25 ml and 300 mg/15 ml presentations)	Proprietary
9.	Budesonide 160mcg + Glycopyrronium 7.2mcg + Formoterol Fumarate Dihydrate 5 mcg inhalation preparations	Patented
10.	Darolutamide 300 mg Film-coated Tablets	Patented
11.	Dienogest + Estradiol valerate Film-coated tablet, 3 mg + 3 mg	Proprietary
12.	Peg interferon Beta-1A 125mcg/0.5 ml PFS	Patented
13.	Alteplase 20mg and 50mg	Proprietary
14.	Lemborexant 5mg and 10 mg Tablet	Patented
15.	a) Tirzepatide 2.5 mg/0.5ml, b) Tirzepatide 5 mg/0.5ml, c) Tirzepatide 7.5 mg/0.5ml d) Tirzepatide 10 mg/0.5ml e) Tirzepatide 12.5 mg/0.5ml	Patented

	f) Tirzepatide 15 mg/0.5ml All solution for injection in a single dose vial/ PFS	
16.	Teclistamab Solution for Injection 30mg and 153 mg	Patented
17.	Guselkumab Solution for Injection 100 mg	Patented
18.	Methylphenidate Hydrochloride Extended-Release Tablets 18mg, 36mg and 54mg	Proprietary
19.	Follitropin Alfa 450IU/0.75ml (33mcg/0.75 ml)	Proprietary
20.	Ceritinib Hard Gelatin Capsule 150 Mg	Patented
21.	Ofatumumab 20 mg/0.4 mL solution for injection in pre-filled syringe	Proprietary
22.	Erenumab solution for injection 70 mg/ml in pre-filled syringe	Patented
23.	Turoctocog Alfa Pegol (Glycopegylated r-DNA origin Factor VIII)- 500 IU/1000 IU/1500 IU/2000 IU	Patented
24.	Degludec 100 IU/ml in 3 ml Pre-filled syringes (PFS)/Penfill	Patented
25.	Insulin Degludec 70% + Insulin Aspart 30 % 100 IU/ml in 3ml PFS/Penfill	Patented
26.	Etonogestrel Implant 68mg (Radiopaque)	Patented
27.	a) Recombinant Follitropin Beta 600IU (Follicle Stimulating Hormone Injection I.P.) b) Recombinant Follitropin Beta 300IU (Follicle Stimulating Hormone Injection I.P.)	Proprietary
28.	Romosozumab (r-DNA origin) Injection 105mg/1.17mL	Patented
29.	a) 100 u/ml Insulin glargine with 50 mcg/ml Lixisenatide b) 100 u/ml Insulin glargine with 33 mcg/ml Lixisenatide	Patented
30.	a) Pegylated Liposomal Irinotecan 4.3 mg/ml concentrate for dispersion for infusion	Patented
31.	a) Bisoprolol Fumarate 5mg + Perindopril Arginine 5mg tablets b) Bisoprolol Fumarate 5mg + Perindopril arginine 10 mg tablets	Proprietary
32.	Sulbutiamine 200 mg	Proprietary
33.	Piribedil 50mg	Proprietary

34.	Perindopril Erbumine 8mg + Indapamide 2.5mg	Proprietary
35.	a) Perindopril Erbumine 4 mg + Amlodipine Besilate Tablets 10 mg b) Perindopril Erbumine 8 mg + Amlodipine Besilate Tablets 10 mg c) Perindopril Erbumine 8mg + Amlodipine Besilate Tablets 5 mg	Proprietary
36.	a) Indapamide IP as sustained release (1.5 mg) + Amlodipine Besilate IP Tablets (2.5 mg) b) Indapamide IP sustained release (1.5 mg) + Amlodipine Besilate IP Tablets (5 mg) c) Indapamide IP sustained release (1.5 mg) + Amlodipine Besilate IP Tablets (10 mg)	Proprietary
37.	Brentuximab Vedotin 50 mg	Proprietary
38.	Vedolizumab 300 mg	Patented
39.	Velaglucerase Alfa (r-DNA Origin) 400 Units	Proprietary
40.	Agalsidase alfa (r-DNA origin) - 1 mg/ml	Proprietary
41.	Coagulation Factor IX (Recombinant)	Proprietary
42.	Ruriocog Alfa Pegol (PEGylated Recombinant Human FVIII)	Proprietary
43.	Toripalimab inj	Patented
44.	Entrectinib (100mg & 200 mg)	Patented
45.	Sodium Zirconium Cyclosilicate Powder for Oral Suspension 5g & 10 g	Patent (applied for)
46.	Belumosudil Tablet 200mg	Patented
47.	Palivizumab solution for injection 50 mg/0.5 mL	Proprietary
48.	Plazomicin	Patented
49.	Aminoven Infant 10% 100 ml Each 100 ml contains: active constituents: L-Ieucine 1.30 g, L-isoleucine 0.80 g, L -lysine acetate 1.20 g, L-lysine 0.851 g, L-methionine 0.312 g, L-phenylalanine 0.375 g, L-threonine 0.440 g, L-tryptophan 0.201 g, L-valine 0.900 g, L-arginine	Proprietary

	0.750 g, L-histidine 0.476 g, Glycine 0.415 g, Taurine 0.040 g, L-serine 0.767 g, L-alanine 0.930 g, L-proline 0.971 g, N-acetyl-L-tyrosine 0.5176 g, L-tyrosine 0.420 g, N-acetyl-L-cysteine 0.070 g, L-cysteine 0.052 g, L-malic acid 0.262 g, Water for injections q.s.Total amino acids 100 g/l, Total nitrogen content 14.9 g/l, Theor.osmolality 885 mosm/l	
50.	SmofLipid 20% (100 ml, 250 ml, 500ml) Parenteral lipid emulsion with a combination of 4 different oils in concentrations : 30% Soyabean oil, 30% MCT, 25% Olive Oil and 15% Fish oil with a Omega 6: Omega 3 ratio of 2.5:1.	Proprietary
51.	Omegaven 10% 50 ml Injection Intravenous Fat Emulsion with Omega 3 Fatty Acids, Highly refined fish oil 10 g , Eicosapentaenoic acid (EPA)1.25-2.82g, Docosahexaenoic acid (DHA) 1.44-3.09 g, alpha tocopherol as antioxidant., Glycerol, Purified egg phosphate, sodium oleate, sodium hydroxide.	Proprietary
52.	SMOFKabiven Central 1477 ml New Generation 3 Chambered Bag for parenteral nutrition (IV injection for central line) 1477 ml containing combination of SMOFLipid 20%; refined soyabean oil 16.9 g, Medium Chain triglycerides 16.9 g, Refined Olive Oil 14.1 g and Fish oil rich in Omega-3-acids 8.4 g as source of calories with 75 g Amino acids,taurine, zinc, electrolytes and 42% Glucose solution with environment friendly bag material having tamper evident arrows flaps providing 1600 total calories in 1477 ml -1300 non protein energy	Proprietary
53.	SMOFKabiven Central 1970 ml New Generation 3 Chambered Bag for parenteral nutrition (IV injection for central line) 1970 ml containing combination of SMOFLipid 20%; refined soyabean oil 22.5 g, Medium Chain triglycerides 22.5 g, Refined Olive Oil 18.8 gm and Fish oil rich in Omega-3-acids 11.3 g with 100 gm Amino acids,taurine, zinc, electrolytes and 42% Glucose solution with environment friendly bag material having tamper evident arrows flaps providing 2100 total calories in 1970 ml -1700 non protein energy	Proprietary
54.	SMOFKabiven Central 986 ml New Generation 3 Chambered Bag for parenteral nutrition (IV injection for central line) 986 ml containing combination of SMOFLipid 20%; refined soyabean oil 11.3 g, Medium Chain triglycerides 11.3 g, Refined Olive Oil 9.4 gm and Fish oil rich in Omega-3-acids 5.6 g with 50 g Amino acids,taurine, zinc, electrolytes and 42% Glucose solution with environment friendly bag material having tamper evident arrows flaps providing 1100 total calories in 986 ml - 900 non protein energy	Proprietary

55.	SMOFKabiven Peripheral 1206 ml New Generation 3 Chambered Bag for parenteral nutrition (IV injection for peripheral line) 1206 ml containing combination of SMOFlipid 20%; refined soyabean oil 10.2 g, Medium Chain triglycerides 10.2 g, Refined Olive Oil 8.5 gm and Fish oil rich in Omega-3-acids 5.1 g with 38 g Amino acids,taurine, zinc, electrolytes and 13% Glucose solution with environment friendly bag material having tamper evident arrows flaps providing 800 total calories in 1206 ml -700 non protein energy	Proprietary
56.	SMOFKabiven Peripheral 1448 ml New Generation 3 Chambered Bag for parenteral nutrition (IV injection for peripheral line) 1448 ml containing combination of SMOFlipid 20%; refined soyabean oil 12.3 g, Medium Chain triglycerides 12.3 g, Refined Olive Oil 10.1 g and Fish oil rich in Omega-3-acids 6.1 g with 46 g Amino acids,taurine, zinc, electrolytes and 13% Glucose solution with environment friendly bag material having tamper evident arrows flaps providing 1000 total calories in 1448 ml -800 non protein energy	Proprietary
57.	SMOFKabiven Peripheral 1904 ml New Generation 3 Chambered Bag for parenteral nutrition (IV injection for peripheral line) 1904 ml containing combination of SMOFlipid 20%; refined soyabean oil 16.1 g, Medium Chain triglycerides 16.1 g, Refined Olive Oil 13.4 g and Fish oil rich in Omega-3-acids 8 g with 60 g Amino acids,taurine, zinc, electrolytes and 13% Glucose solution with environment friendly bag material having tamper evident arrows flaps providing 1300 total calories in 1904 ml -1100 non protein energy	Proprietary
58.	Nirsevimab solution 50mg and 100mg (r-DNA origin)	Patented
59.	Cross linked Sodium Hyaluronate 1-2.9 mDA, 22mg/ml (88mg/4ml) with Triamcinolone Hexacetonide 18mg (4ml Prefilled Syringe)	Proprietary
60.	Semaglutide 0.25 mg/0.5 mg/ 1mg/1.7 mg/2.4 mg solution for Injection (r-DNA origin) in PFS	Patented
61.	Pneumococcal polysaccharide conjugate vaccine (adsorbed) I.P., 20-valent	Patented
62.	Niraparib Tablets 100 mg	Patented
63.	Dostarlimab concentrate for solution for infusion 500 mg/10 mL	Patented
64.	Brigatinib tablets- 30 mg/90 mg/180 mg	Proprietary
65.	Concizumab Injection 15mg/1.5 mL, 60mg/1.5 mL, 150mg/1.5 mL, 300mg/3 mL	Patented
66.	Aztreonam 1.5g + Avibactam 0.5g powder for concentrate for solution for Infusion	Proprietary

67.	Rimegepant 75mg	Patented
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Medicines yet to be launched - Request received from Industry (Part-2)

S. No	Pharmaceutical Formulation & strength, along with primary molecule(s)	Proprietary/Patent
1.	Mavacamten Capsules 2.5mg, 5mg, 10mg, 15mg	Proprietary
2.	Sotatercept 45 mg and 60 mg	Patented
3.	Ivosidenib 250 mg film-coated tablets	Patented
4.	Crovalimab 240mg/2 ml	Patented
5.	Selpercatinib 40mg/80mg Capsules	Patented
6.	Mirikizumab 300mg/15 ml (20mg/ml) single dose vial, Mirikizumab 100mg/ml solution in a single dose pre-filled syringe	Patented
7.	Insulin human Inhalation powder (r DNA origin) 4 units/8 units/12 units per cartridge plus Inhaler	Proprietary
8.	Onasemnogene abeparvovec	Proprietary

Request received from procuring entities (Part-3)

S. No	Pharmaceutical Formulation & strength, along with primary molecule(s)	Name of Procurer
1.	Tab. Dienogest 2 smg	ESIC
2.	Levonorgestrel releasing Intrauterine System- 52 mg	ESIC
3.	Anti-Inhibitor Coagulant Complex, Steam treated 1000 IU with 20 ml Sterile Water for Injection	ESIC
4.	Tab Saxagliptin 05 mg	DGAFMS
5.	Eye Drop Povidine 20 mg/ml preservative free comod System.	DGAFMS
6.	Eye Drop Travoprost with Polyquad	DGAFMS
7.	Eye Drop Timolol Maleate preservative free comod system	DGAFMS
8.	Eye Drop Sodium Hyaluronate 1 mg/ml, Preservative free, Phosphate free, with comod system	DGAFMS
9.	IV Infusion 4% Succenylated Gelatin Bottle of 500 ml	DGAFMS

Annex B

To:

Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India
Shastri Bhawan, New Delhi – 110 001

Subject: Exemption from Global Tender Enquiry under rule 161(iv) of the General Financial Rules, 2017 — Objections against inclusion of formulations listed at Annex A to Public Notice No. 1/2025 — regarding

Reference is invited to the Public Notice No. 1/2025 issued by the addressee Department inviting objections from local manufacturers (based on domestic manufacturing availability) against inclusion of formulations listed at Annex A to the said notice under the Global Tender Enquiry (GTE) exemption list.

2. In this connection, I give below the details of information regarding the formulation objected against for inclusion in the GTE exemption list on account of its domestic manufacturing availability with necessary particulars are furnished as under:

S. no	Details	Information
1	Name, serial number and parts of formulation from Annex-A against which objection is raised	
2	Name of the local manufacturing entity	
3	Address of the registered office and manufacturing location (complete postal address)	
4	Contact details, email id and phone numbers (mobile and office)	
5	Generic name of locally manufactured drug and its strength	
6	Brand name of drug mentioned against S. no. 5	
7	Local content percentage of the drug as per the DPIIT OM dated 19.7.2024	
8	Manufacturing capacity per annum	
9	Manufacturing license (mandatory)	
10	Patent certificate, if any.	

3. The aforesaid information is true and correct to the best of my knowledge and nothing material has been concealed therefrom.

Yours faithfully,

Place: _____

Date: _____

(Signature of the authorised signatory)

Name: _____

Designation: _____