

संख्या / F. No. 19(697)/2016/Div. II/NPPA
भारत सरकार

Government of India
रसायन और उर्वरक मंत्रालय
Ministry of Chemicals & Fertilizers
औषध विभाग
Department of Pharmaceuticals
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण
National Pharmaceutical Pricing Authority

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1, Jai Singh Road, N. Delhi - 110001.
दिनांक :- 06.7.2017

OFFICE MEMORANDUM

Subject: NLEM, 2015 formulations under provisions of DPCO, 2013 (Consolidated list as on 30.6.2017) - no data/monopoly cases.

Reference is invited to OM of even no dated 10.01.2017 on the above subject. As AIOCD (Pharmatrac) is not capturing the PTR & MAT of these formulations (no data monopoly cases), all the concerned manufacturers / marketing companies are requested to furnish the **Price to Retailer (PTR) and Moving Annual Turnover (MAT)** in value terms, duly self attested with proper authorized signature & seal of the authorized officer of the company, for the formulations mentioned in NLEM, 2015 (revised Schedule - I of DPCO, 2013) i.e. **Annexure - I** and **Annexure - II** for the month of **August 2015, by 21.7.2017**, for enabling NPPA to take appropriate action for ceiling price fixation under provisions of DPCO, 2013.

It may be noted that manufacturers/marketing companies have not positively responded to our earlier several OMs. You are once again requested to provide the requisite information positively. In case, manufacturers/marketing companies fail to provide requisite data on or before the deadline, NPPA will have no option but to proceed with price fixation of these formulations based on other available information.

Encl: Annexure - I & II


(APS Sawhney)
Director (Pricing)

Copy to:

Apex Pharma Associations i.e. OPPI, IDMA, FICCI, CII, IPA and FOPE for information & necessary action please.

List of formulations having No Data

Sl No	Section of NLEM No.	Medicines	Dosage form and Strength
1	1.1.4	Nitrous oxide	Inhalation
2	1.1.5	Oxygen	Inhalation (Medicinal gas)
3	1.1.7	Sevoflurane	Inhalation
4	1.2.3	Lignocaine (A) + Adrenaline (B)	Injection 1% (A) + 1:200000 (5 mcg/ml) (B)
5	1.3.3	Midazolam	Oral liquid 2 mg/ml
6	1.3.3	Midazolam	Tablet 7.5 mg
7	2.1.1	Acetylsalicylic acid	Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg
8	2.1.1	Acetylsalicylic acid	Tablet 300 mg
9	2.1.1	Acetylsalicylic acid	Tablet 300 mg to 500 mg (351mg to 500mg)
10	2.1.1	Acetylsalicylic acid	Tablet 350 mg
11	2.1.4	Mefenamic acid	Capsule 250 mg
12	2.1.4	Mefenamic acid	Capsule 500 mg
13	3.3	Chlorpheniramine	Oral liquid 2 mg/5 ml
14	4.1.1	Activated charcoal	Powder (as licensed)
15	4.2.1	Atropine	Injection 1 mg/ml
16	4.2.4	Dimercaprol	Injection 50 mg/ml
17	4.2.5	Methylthionium chloride (Methylene blue)	Injection 10 mg/ml
18	4.2.12	Sodium nitrite	Injection 30 mg/ml
19	4.2.13	Sodium thiosulphate	Injection 100 mg/ml
20	5.1	Carbamazepine	Oral liquid 200 mg/5 ml
21	6.1.3.1	Praziquantel	Tablet 600 mg
22	6.2.1.12	Cloxacillin	Oral Liquid 125 mg/5 ml
23	6.2.1.12	Cloxacillin	Powder for Injection 250 mg
24	6.2.2.5	Doxycycline	Dry Syrup 50mg/5 ml
25	6.2.3.2	Dapsone	Tablet 25 mg
26	6.2.3.2	Dapsone	Tablet 50 mg
27	6.2.4.2	Cycloserine	Capsule 125 mg
28	6.2.4.4	Ethionamide	Tablet 125 mg
29	6.2.4.5	Isoniazid	Oral liquid 100 mg/5 ml
30	6.2.4.5	Isoniazid	Tablet 50 mg
31	6.2.4.9	Moxifloxacin	Tablet 200 mg
32	6.2.4.10	Para-aminosalicylic acid	Granules (As licensed)
33	6.2.4.10	Para-aminosalicylic acid	Tablet 500 mg
34	6.2.4.12	Rifabutin	Capsule 150 mg
35	6.3.4	Griseofulvin	Tablet 125 mg
36	6.3.5	Nystatin	Oral Liquid 100,000 IU/ml
37	6.3.5	Nystatin	Pessary 100,000 IU
38	6.3.5	Nystatin	Tablet 500,000 IU
39	6.4.3.1.1	Abacavir	Tablet 60 mg
40	6.4.3.1.4	Lamivudine (A) + Zidovudine (B)	Tablet 30 mg (A) + 60 mg (B)
41	6.4.3.1.5	Stavudine (A) + Lamivudine (B)	Dispersible Tablet 6 mg (A) + 30 mg (B)
42	6.4.3.1.8	Zidovudine	Oral liquid 50 mg/5 ml
43	6.4.3.1.9	Zidovudine (A) + Lamivudine (B) + Nevirapine (C)	Tablet 60 mg (A) + 30 mg (B) + 50 mg (C)
44	6.4.3.2.1	Efavirenz	Tablet 50 mg
45	6.4.3.2.2	Nevirapine	Dispersible Tablet 50 mg
46	6.4.3.4.3	Lopinavir (A) + Ritonavir (B)	Oral liquid 400 mg (A) + 100 mg (B)/ 5ml
47	6.5.1.1	Dioxanide furoate	Tablet 500 mg

	6.5.2.2	Miltefosine	Capsule 10 mg
49	6.5.2.2	Miltefosine	Capsule 50 mg
50	6.5.2.3	Paromomycin	Injection 375 mg/ml
51	6.5.3.1.3	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Combi pack 1 Tablet 100 mg (A) + 1 Tablet (750 mg + 37.5 mg) (B)
52	6.5.3.1.3	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Combi pack 1 Tablet 150 mg (A) + 2 Tablet (500 mg + 25 mg) (B)
53	6.5.3.1.3	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Combi pack 1 Tablet 200 mg (A) + 2 Tablet (750 mg + 37.5 mg) (B)
54	6.5.3.1.3	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Combi pack (A+B) 1 Tablet 25 mg (A) + 1 Tablet (250 mg + 12.5 mg) (B)
55	6.5.4.2	Pentamidine	Powder for Injection 200 mg
56	8.1.4	All-trans retinoic acid	Capsule 10 mg
57	8.1.8	Calcium folinate	Injection 3 mg/ml
58	8.1.13	Cyclophosphamide	Tablet 200 mg
59	8.1.16	Daunorubicin	Injection 5 mg/ml
60	8.1.19	Etoposide	Capsule 100 mg
61	8.1.28	Oxaliplatin	Injection 5 mg/ml
62	8.3.2	Cyclosporine	Capsule 10 mg
63	8.4.12	Morphine	SR Tablet 30 mg
64	8.4.12	Morphine	Tablet 20 mg
65	10.1.2	Ferrous salts	Oral liquid equivalent to 25 mg of elemental iron/ml
66	10.1.2	Ferrous salts	Tablet equivalent to 60 mg of elemental iron
67	10.1.3	Ferrous salt (A) + Folic acid (B)	Oral liquid 20 mg elemental iron (A) + 100 mcg (B)/ml
68	10.1.3	Ferrous salt (A) + Folic acid (B)	Tablet 100 mg elemental iron (A) + 500 mcg (B)
69	10.1.3	Ferrous salt (A) + Folic acid (B)	Tablet 45mg elemental iron (A) + 400 mcg (B)
70	10.1.5	Hydroxocobalamin	Injection 1 mg/ml
71	10.2.3	Phytomenadione (Vitamin K1)	Tablet 10mg
72	11.1.1	Fresh frozen plasma	As licensed
73	11.1.2	Platelet rich plasma	As licensed
74	11.1.3	Red blood cell	As licensed
75	11.1.4	Whole blood	As licensed
76	11.2.1	Dextran-40	Injection 10%
77	11.3.1	Coagulation factor IX	Powder for Injection 600 IU
78	11.3.3	Cryoprecipitate	As licensed
79	12.4.1	Digoxin	Oral liquid 0.05 mg/ml
80	14.2.1	Framycetin	Cream 0.5%
81	14.2.3	Methyrosanilinium chloride (Gentian Violet)	Topical preparation 0.25% to 2%
82	14.4.2	Coal tar	Solution 5%
83	14.4.3	Podophyllin resin	Solution 10% to 25%
84	14.6.1	Glycerin	Oral Liquid
85	14.6.2	White Petrolatum	Jelly 100%
86	15.1.1	Fluorescein	Eye drop 1%
87	15.1.2	Lignocaine	Eye drop 4%
88	15.2.1	Barium sulphate	Oral liquid 100% w/v
89	15.2.1	Barium sulphate	Oral liquid 250% w/v
90	15.2.2	Gadobenate	Injection 529 mg/ml
91	16.1	Haemodialysis fluid	As licensed
92	16.2	Intraperitoneal dialysis solution	As licensed
93	17.1.2	Chlorhexidine	Solution 5% (Concentrate for dilution)
94	17.1.3	Ethyl alcohol (Denatured)	Solution 70%
95	17.1.4	Hydrogen peroxide	Solution 6%

96	17.2.1	Bleaching powder	Containing not less than 30% w/w of available chlorine (as per I.P)
97	17.2.3	Potassium permanganate	Crystals for topical solution
98	18.1	Furosemide	Oral liquid 10 mg/ml
99	18.3	Mannitol	Injection 10%
100	20.4.1	Dicyclomine	Oral Solution 10mg/5ml
101	20.4.1	Dicyclomine	Tablet 10 mg
102	21.1.3	Hydrocortisone	Injection 100mg/ml
103	21.1.4	Methylprednisolone	Tablet 32 mg
104	21.2.1.2	Ethinylestradiol (A) + Norethisterone	Tablet 0.035 mg (A) + 1 mg (B)
105	21.2.3.1	Condom	As per the standards prescribed in Schedule R of Drugs and Cosmetics rules, 1945
106	21.6.1	Medroxyprogesteroneacetate	Tablet 5 mg
107	22.1.1	Tuberculin, Purified Protein derivative	
108	22.2.2	Anti-tetanus immunoglobulin	
109	22.2.4	Diphtheria antitoxin	
110	22.2.5	Hepatitis B immunoglobulin	
111	22.3.1.7	Oral poliomyelitis vaccine	
112	22.3.1.7(N1)	Inactivated Polio	
113	25.1.6	Povidone iodine	Drops 0.6%
114	25.1.6	Povidone iodine	Drops 5%
115	25.2.1	Prednisolone	Drops 0.1%
116	25.4.2	Pilocarpine	Drops 4%
117	25.5.3	Phenylephrine	Drops 5%
118	27.4.1	Clomipramine	Capsule 10 mg
119	27.4.1	Clomipramine	Capsule 25 mg
120	27.4.1	Clomipramine	Capsule 75 mg
121	29.7	Sodium chloride	Injection 0.45%
122	30.1	Ascorbic acid (Vitamin C)	Tablet 100 mg
123	30.2	Calcium carbonate	Tablet 250 mg
124	30.2	Calcium carbonate	Tablet 500 mg
125	30.5	Nicotinamide	Tablet 50 mg
126	30.6	Pyridoxine	Tablet 10 mg
127	30.6	Pyridoxine	Tablet 50 mg
128	30.7	Riboflavin	Tablet 5 mg
129	30.9	Vitamin A	Capsule 100000 IU
130	30.9	Vitamin A	Capsule 5000 IU
131	30.9	Vitamin A	Capsule 50000 IU
132	30.9	Vitamin A	Injection 50000 IU/ml
133	30.9	Vitamin A	Oral liquid 100000 IU/ml

List of formulations having monopoly situation

Sl No	Section of NLEM No.	Medicines	Dosage form and Strength
1	1.3.3	Midazolam	Tablet 15 mg
2	2.1.1	Acetylsalicylic acid	Tablet 325 mg
3	4.2.2	Calcium gluconate	Injection 100 mg/ml
4	4.2.3	Desferrioxamine	Powder for Injection 500 mg
5	6.2.1.5	Benzyl penicillin	Powder for Injection 10 lac units
6	6.2.1.12	Cloxacillin	Capsule 250 mg
7	6.2.1.12	Cloxacillin	Capsule 500 mg
8	6.2.4.5	Isoniazid	Tablet 100 mg
9	6.2.4.5	Isoniazid	Tablet 300 mg
10	6.3.3	Fluconazole	Oral liquid 50 mg/5 ml
11	7.1.3	Sumatriptan	Injection 5 mg/ 0.5 ml
12	7.1.3	Sumatriptan	Tablet 25 mg
13	7.1.3	Sumatriptan	Tablet 50 mg
14	8.1.3	Actinomycin D	Powder for Injection 0.5 mg
15	8.1.22	Ifosfamide	Powder for Injection 1 g
16	8.1.22	Ifosfamide	Powder for Injection 2 g
17	8.1.35	Vinblastine	Injection 1 mg/ml
18	10.2.3	Phytomenadione (Vitamin K1)	Injection 10 mg/ml
19	12.1.1	Acetylsalicylic acid	Effervescent/ Dispersible/ Enteric coated Tablet 100 mg
20	12.5.2	Alteplase	Powder for Injection 20 mg
21	12.5.2	Alteplase	Powder for Injection 50 mg
22	14.2.5	Silver sulphadiazine	Cream 1%
23	15.2.3	Iohexol	Injection 140 to 350 mg iodine/ml { 300mg}
24	15.2.3	Iohexol	Injection 140 to 350 mg iodine/ml { 350ml}
25	17.2.2	Glutaraldehyde	Solution 2%
26	22.2.3	Anti-D immunoglobulin	
27	22.3.1.1	BCG vaccine	
28	22.3.1.6	Measles vaccine	
29	22.3.1.6(N1)	Measles Rubbela Vaccine	
30	25.1.3	Erythromycin	Ointment 0.5%
31	29.1	Glucose	Injection 50%
32	29.7	Sodium chloride	Injection 3%