

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

Notice for Stakeholders comments

NPPA has undertaken a detailed study of the drugs already included in National List of Essential Medicines, 2011 (NLEM) with a view to ensuring that all Life Saving and Essential drugs of mass consumption are included in the NLEM for safeguarding the public interest in consonance with the directions received from the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers vide their letter no.31026/24/2010-PI.I dated 07.08.2014.

2. Accordingly, NPPA has carried out consultations with civil society stakeholders, public health experts, state drugs controllers, pharma industry associations & trade associations. In the first part of the study, certain anomalies / discrepancies in specification / description in the NLEM 2011 has been identified with reference to drugs specified in Indian Pharmacopoeia, National Formulary of India and market data, as specified in the following table, which requires rectification. The proposed rectification is considered necessary to comply with the above stated objective in respect of drug formulations already included in NLEM 2011. In this regard, NPPA invites comments of all the stakeholders / Industry Associations within a period of three weeks for further necessary action in the matter.

S.No	Medicines	Route of Administration	Strengths	Correction / modification proposed
(1)	(2)	(3)	(4)	(5)
1	Propofol	Injection	1% oil suspension	Strength: '10mg per ml or 1% w/v '
2	Paracetamol	Syrup	125 mg / 5ml	Strength: 'as per I.P.' Dosage: 'oral Liquids'
3	Tramadol	Capsule	50mg, 100mg	Dosage: 'Tablet / capsule'
4	Sodium Valproate	Syrup	200 mg/5ml	Dosage: 'oral liquids'
5	Sodium Valproate	Injection	100mg/ml	Strength: '20mg/ml'
6	Amoxicillin	Powder for suspension	125mg/5ml	Dosage: 'oral suspension / Dry syrup'

7	Ampicillin	Powder for suspension	125mg/5ml	<u>Dosage:</u> 'oral suspension / Dry syrup'
8	Cephalexin	Syrup	125mg/5ml	<u>Dosage:</u> 'oral suspension / Dry syrup'
9	Cloxacillin	Liquid	125mg/5ml	<u>Dosage:</u> 'oral suspension / Dry syrup'
10	Erythromycin Estolate	Syrup	125 mg / 5 ml	<u>Medicine :</u> 'Erythromycin' <u>Dosage:</u> 'oral liquid'
11	Erythromycin Estolate	Tablets	250 mg, 500 mg	<u>Medicine :</u> 'Erythromycin'
12	Metronidazole	Syrup	100mg/5ml	<u>Strength:</u> 'as per I.P.' <u>Dosage:</u> 'oral Liquids'
13	Clotrimazole	Gel	2%	<u>Strength:</u> 'as per I.P.' <u>Dosage:</u> 'topical preparation'
14	Didanosine	Tablets	250 mg, 400 mg	<u>Dosage:</u> 'tablet/ capsule'
15	Zidovudine	Tablet	100mg, 300mg	<u>Dosage:</u> 'tablet/ capsule'
16	Efavirenz	Capsules	200 mg,600mg	<u>Dosage:</u> 'tablet/ capsule'
17	Nevirapine	Capsules	200 mg	<u>Dosage:</u> 'tablet/ capsule'
18	Nelfinavir	Capsules	250 mg	<u>Dosage:</u> 'tablet/ capsule'
19	Ritonavir	Capsules	100 mg,	<u>Dosage:</u> 'tablet/ capsule'

20	Chloroquine phosphate	Syrup	50 mg / 5 ml	<u>Medicine :</u> 'Chloroquine' <u>Dosage:</u> 'oral liquid'
21	Clindamycin	Tablet	150, 300mg	<u>Dosage:</u> 'Capsule' <u>Strength:</u> '150mg, 300mg'
22	Danazol	Capsules	50 mg, 100 mg	<u>Dosage:</u> 'capsule / tablet'
23	Gemcitabine hydrochloride	Injection	200 mg, 1gm	<u>Medicine :</u> 'Gemcitabine'
24	Imatinib	Tablet	100mg, 400mg	<u>Dosage:</u> 'capsule / tablet'
25	Ferrous Sulphate/ Fumrate	Tablets	Tablets equivalent to 60 mg elemental iron	<u>Strength:</u> '200mg' or Tablets equivalent to 60 mg / 65 mg elemental iron
26	Povidone Iodine	Solution or Ointment	5%	<u>Dosage:</u> 'topical preparation'
27	Permethrin	Lotion	1%, 5%	<u>Dosage:</u> 'topical preparation'
28	Benzoin Compound	Tincture		<u>Strength:</u> 'as per IP'
29	Aluminium Hydroxide + Magnesium Hydroxide	Tablet		<u>Medicine :</u> 'Antacid tablets of Aluminium + Magnesium + Methicon salt / MPS salts' <u>Strength :</u> 'need not to mention'

30	Aluminium Hydroxide + Magnesium Hydroxide	Suspension		<p><u>Medicine :</u></p> <p>'Antacid oral syrup / suspension of Aluminium + Magnesium + Methicon salt / MPS salts'</p> <p><u>Strength :</u></p> <p>'need not to mention'</p>
31	Miconazole	Drops	1%	<p><u>Dosage:</u></p> <p>'drops not available'</p>
32	Miconazole	Ointment or Cream	2%	<p><u>Dosage:</u></p> <p>'topical preparation'</p> <p><u>Strength :</u></p> <p>2% w/w</p>
33	Acetazolamide	Tablets	250 mg	<p><u>Dosage:</u></p> <p>'tablet/ capsule'</p>
34	Misoprostol	Tablets	100ug	<p><u>Strength :</u></p> <p>'200mcg'</p>
35	Potassium Chloride	Injection	11.2% Sol.	<p><u>Strength :</u></p> <p>'11.2% w/v'</p>
36	Multivitamins (As per Schedule V of Drugs and Cosmetics Rules)	Tablets		<p><u>Dosage:</u></p> <p>'tablet/ capsule'</p>
37	Bupivacaine Hydrochloride	Injection	0.25%, 0.5%, 0.5% to be mixed with 7.5% glucose solution	<p><u>Strength:</u></p> <p>'as per IP'</p>
38	Paracetamol	Injection	150mg/ml	<p><u>Strength:</u></p> <p>'125mg/ml'</p>
39	Lignocaine Hydrochloride	Injection	1-2%,	<p><u>Strength:</u></p> <p>'1% wiv, 2% wiv'</p>
40	Lignocaine Hydrochloride	Topical Forms,	2-5%	<p><u>Dosage:</u></p> <p>'Topical preparation'</p> <p><u>Strength :</u></p> <p>2%, 5%</p>

41	Lignocaine Hydrochloride + Adrenaline	Injection	1%, 2% + Adrenaline 1:200,000	<u>Strength:</u> 'as per IP'
42	Fentanyl	Injection	50ug/ml 2ml ampoule	<u>Strength :</u> '50mg/ml'
43	Hydroxychloroquine phosphate	Tablets	200 mg	<u>Medicine :</u> 'Hydroxychloroquine sulphate'
44	Leflunomide	Tablets	10mg, 20 mg tab	<u>Strength :</u> '10mg, 20mg'
45	Activated Charcoal	Oral		<u>Dosage:</u> 'Tablet'
46	Specific Antisnake venom	Injection Polyvalent, Solution/ Lyophilized, Polyvalent Serum		<u>Dosage:</u> 'Categorised separately',
47	Pralidoxime Chloride(2-PAM)	Injection	25 mg/ml	<u>Medicine :</u> 'Pralidoxime Chloride'
48	N-acetylcysteine	Injection	200 mg/ml(5ml)	<u>Strength :</u> '200mg/ml'
49	Sodium Valproate	Injection	100 mg/ml	<u>Strength :</u> '20mg/ml'
50	Piperazine	Tablet	4.5gm	<u>Strength :</u> '500mg/Tab'
51	Amoxicillin+Clavulanic acid	Tablets	625mg	<u>Strength :</u> '(500mg + 125mg)'
52	Amoxicillin+Clavulanic acid	Powder for suspension	228.5mg/5 ml	<u>Dosage:</u> 'Oral Suspension' <u>Strength :</u> '(200mg + 28.5mg)/5ml '

53	Amikacin	Injection	250 mg / 2ml	<u>Strength :</u> '250mg/ml'
54	Ciprofloxacin Hydrochloride	Injection	200 mg /100 ml	<u>Medicine :</u> 'Ciprofloxin' <u>Strength :</u> '2mg/ml'
55	Metronidazole	Injection	500mg/100 ml	<u>Strength :</u> '5mg/ml'
56	Amphotericin B	Injection	50 mg	<u>Strength :</u> '50mg/ml'
57	Chloroquine phosphate	Tablets	150 mg base	<u>Medicine :</u> 'Chloroquine' <u>Strength :</u> '250mg'
58	Quinine sulphate	Injection	300 mg / ml	<u>Medicine :</u> 'Quinine dihydrochloride ,
59	Cyclosporine	Concentrate for Injection	100 mg/ml	<u>Dosage:</u> 'Injection'
60	Doxorubicin	Injection	10 mg, 50 mg	<u>Strength :</u> '2mg/ml'
61	Etoposide	Injection	100 mg/ 5 ml vial	<u>Strength :</u> '20mg/ml'
62	Filgrastim	Injection	1 ml vial	<u>Strength :</u> '300mcg'
63	Ferrous Sulphate/ Fumrate	Oral solution	25mg elemental iron (as sulphate)/ml	<u>Dosage:</u> 'Oral Liquid' <u>Strength :</u> 'Combination with other drug'

64	Sodium Nitroprusside	Injection	50 mg/ 5 ml	<u>Strength :</u> '50mg /ml'
65	Acyclovir	Cream	5%	<u>Dosage:</u> 'Tropical preparation' <u>Strength :</u> '5% w/w'
66	Framycetin Sulphate	Cream	0.50%	<u>Dosage:</u> 'Tropical preparation' <u>Strength :</u> '1% w/w'
67	Methylrosanilinium Chloride (Gentian Violet)	Aqueous solution	0.50%	<u>Strength :</u> '5% w/w'
68	Silver Sulphadiazine	Cream	1%	<u>Dosage:</u> 'Tropical preparation' <u>Strength :</u> '1% w/w'
69	Betamethasone Dipropionate	Cream / Ointment	0.05%	<u>Dosage:</u> 'Tropical preparation' <u>Strength :</u> '0.05% w/w'
70	Calamine	Lotion		<u>Strength :</u> 'as per I.P.'
71	Gentian Violet	Paint	0.5%,	<u>Strength :</u> '5% w/v'
72	Ondansetron	Syrup	2 mg/ml	<u>Dosage:</u> 'Oral Liquid' <u>Strength :</u> '2mg / 5ml'
73	Ondansetron	Injection	2mg/ml	<u>Strength :</u> 'as per I.P.'
74	Ispaghula	Granules		<u>Dosage:</u> 'powder/ granules'
75	Chloramphenicol	Drops/ Ointment	0.4%, 1%	<u>Strength :</u> 'Ear drops - 0.4%w/v, 0.5%w/v Eye Drop - 0.5%w/v Ointment - 1%w/w'

76	Ciprofloxacin Hydrochloride	Drops/Ointment	0.30%	<u>Medicine</u> 'Ciprofloxacin' <u>Strength :</u> '0.3%w/w'
77	Gentamicin	Drops	0.30%	<u>Strength :</u> '0.3%w/v'
78	Sulphacetamide Sodium	Drops	10%,20%	<u>Strength :</u> '10%w/v, 20% w/v'
79	Prednisolone Acetate	Drops	0.10%	<u>Strength :</u> '1%w/v'
80	Prednisolone Sodium Phosphate	Drops	1%	<u>Strength :</u> '1%w/v'
81	Betaxolol Hydrochloride	Drops	0.25%,0.5%	<u>Strength :</u> '0.25%w/v,0.5%w/v'
82	Timolol Maleate	Drops	0.25%, 0.5%,	<u>Strength :</u> '0.25%w/v,0.5%w/v'
83	Homatropine	Drops	2%	<u>Strength :</u> '2%w/v'
84	Intraperitoneal Dialysis Solution		4Of approximate composition	<u>Strength :</u> 'As per available details'
85	Thiopentone Sodium	Injection	0.5 g, 1 g powder	<u>Strength :</u> '0.5 g, 1 g'
86	Enalapril Maleate	Injection	1.25mg/ml	<u>Medicine</u> 'Enalaprilat'

Pharma Industry Associations / Stakeholders may also give their comments in respect of medicine specified in NLEM-2011 other than the above medicines.


(Injeti Srinivas)
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