

मिसिलस.- 8(20)/2015डी.पी./एमपीपीए- डीवी-II

F. No. 8(20)/2015/DP/NPPA-Div. II

कार्यवाहीस. : 152/20/2015/F

Proceeding No : 152/20/2015/F

Minutes of the 152nd and 20th meeting of Authority under DPCO, 2013 held on 05th February, 2015 at 12.00 Noon

The 152nd overall meeting of the Authority, which is the 20th under the DPCO, 2013 was held on 05th February, 2015 at 12.00 Noon under the Chairmanship of Shri Injeti Srinivas, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Shri Amit Khare, Member Secretary, NPPA.
- (ii) Dr. K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Deptt. of Economic Affairs.
- (iii) Shri L.M. Kaushal, Member (Ex-Officio), Director (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Dr. R. Chandershekhar, Deputy Drug Controller General, Department of Health & Family Welfare.

The following officers also attended the meeting and assisted the Authority in its deliberations:-

- (i) Shri Kalyan Nag, Adviser (Cost)
- (ii) Shri LalSanglur, Director (Overcharging -II)
- (iii) Shri Jagdish Kumar, Director (M&E)
- (iv) Shri A.K. Khurana, Director (Pricing & Admn.)
- (v) Shri Suneel Chopra, Dy. Director (Legal)

Chairman, NPPA welcomed all the members present in the meeting and introduced Sh. Kalyan Nag, Adviser (Cost) who joined NPPA on 04.02.2015.

1. Agenda Item no. 1: Confirmation of Minutes of the 19th Meeting held on 10.12.2014

1.0 Members of the Authority who participated in the 151th and the 19th Meeting under DPCO, 2013 confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

2.0 Noted.

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Agenda Item no. 3: A study on NLEM 2011 incorporated in Schedule I of DPCO, 2013.

3.1 Chairman briefed about the action/comprehensive study, related to the drugs already included in NLEM, 2011 with a view to ensuring that all Essential drugs of mass consumption are included in the NLEM for safeguarding the public interest, in pursuance with directions received from the Department of Pharmaceuticals vide their letter no. 31026/24/2010-PI.I dated 07.08.2014. Shri L.M. Kaushal raised the issue of medicines/drugs used mainly for institutional supplies and not having movement in the retail market. Dr. R. Chandrashekhkar wanted to know if the recommendations are being made in the context of the Core Committee set up under the Chairmanship of Dr. V. K. Katoch, Secretary, Health Research Department and DG, ICMR, which is looking into revision of NLEM 2011. It was confirmed that the exercise was undertaken on the direction received from the Department of Pharmaceuticals in the context of the ongoing exercise for revision of NLEM 2011. The focus of NPPA is from price control angle with a view to making essential medicines of mass consumption affordable to all. On the issue regarding NLEM drugs not having movement in the retail market, it was explained that a report is under preparation to seek further directions from the Government, as NPPA has not been able to fix ceiling prices with respect to such medicines in the absence of data base on their retail prices. Thereafter, a detailed presentation of the said study conducted by the NPPA was made by the Director (M&E) before the Authority.

The Authority after detailed deliberation in the matter approved the following for making recommendation to Department of Pharmaceutical for further necessary action, as deemed fit:-

- (i) Correction/modifications in respect of anomalies/discrepancies in specification/descriptions in the NLEM (Annexure-1).
- (ii) Recommendation for addition of 43 medicines/drugs with specified dosage/strength in the NLEM (Annexure-2).
- (iii) Two separate studies in respect of anti-cancer drugs and medical devices for making recommendations for inclusion in the NLEM/Schedule-I of DPCO, 2013.
- (iv) Final report by NPPA on the study done by the NHSRC on current pricing practice followed with regard to cardiac stents and reasonable pricing of Bare Metal Stents and Drug Eluting Stent.
- (v) Differential pricing of NLEM drugs based on product distinctiveness i.e. source of origin, process differentiation, drug delivery system, site specific delivery, therapeutic benefit in terms of increased efficiency of the drug etc.
- (vi) Price fixation of injectable dosage form specified in the NLEM as per standard dosage unit.
- (vii) Ministry of Health and Family Welfare may be requested to work on the list of Life Saving Drugs.

4: Besides, the Authority discussed the issues relating to fixation of retail price based on Form-I applications received from the manufacturers/marketing companies for the new drug under DPCO, 2013. After deliberations, it was decided that in continuation of decision taken by the

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authority in 19th meeting stating that the manufacturing permission granted by the State Licensing Authority before 01.10.2012 and/or its renewals thereafter, if applicable, (as per DCG(I) order F. No. 4-01/2013-DC (Misc 13-PSC) dated 15.01.2013) will continue to be in operation, therefore, Form-I applications of new drugs based on such manufacturing permissions will be considered for price fixation under DPCO, 2013 as well as cases having DCGI approval before or after 01.10.2012 will also be considered. It was further decided that-

(i) Cases having valid SDC's manufacturing permission having names of both manufacturer as well as marketing company, as mentioned in Form-I, will be considered for price fixation under DPCO, 2013.

(ii) As clarified by the representative of DCG(I), amended in Rule 122E clause (c) vide GSR 724(E) dated 07.11.2013 issued by Deptt. of Health, Ministry of Health & family Welfare, any formulation as included in Indian Pharmacopoeia (IP) till 07.11.2013 has the approval of DCGI for manufacturing/marketing in the country. Accordingly, cases having formulation included in IP till 07.11.2013 will also be considered for price fixation under DPCO, 2013.

5. This issues with the approval of Chairman, NPPA.

Amit Khare
6.2.13

(Amit Khare)
Member Secretary

ANNEXURE- 1

Correction /modification in respect of anomalies / discrepancies in specification /
description in the NLEM 2011

S.No	Medicines	Route of Administration	Strengths	Correction / modification proposed
(1)	(2)	(3)	(4)	(5)
1	Propofol	Injection	1% oil suspension	<u>Strength:</u> '10mg per ml or 1% w/v'
2	Paracetamol	Syrup	125 mg / 5ml	<u>Strength:</u> 'as per I.P.' <u>Dosage:</u> 'oral Liquids'
3	Tramadol	Capsule	50mg, 100mg	<u>Dosage:</u> 'Tablet / capsule'
4	Sodium Valproate	Syrup	200 mg/5ml	<u>Dosage:</u> 'oral liquids'
5	Sodium Valproate	Injection	100mg/ml	<u>Strength:</u> '20mg/ml'
6	Amoxicillin	Powder for suspension	125mg/5ml	<u>Dosage:</u> '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%	Strength: 'as per I.P.' Dosage: 'topical preparation'
14	Didanosine	Tablets	250 mg, 400 mg	Dosage: 'tablet/ capsule'
15	Zidovudine	Tablet	100mg, 300mg	Dosage: 'tablet/ capsule'
16	Efavirenz	Capsules	200 mg, 600mg	Dosage: 'tablet/ capsule'
17	Nevirapine	Capsules	200 mg	Dosage: 'tablet/ capsule'
18	Nelfinavir	Capsules	250 mg	Dosage: 'tablet/ capsule'
19	Ritonavir	Capsules	100 mg,	Dosage: 'tablet/ capsule'
20	Chloroquine phosphate	Syrup	50 mg / 5 ml	Medicine : 'Chloroquine' Dosage: 'oral liquid'
21	Clindamycin	Tablet	150, 300mg	Dosage: 'Capsule' Strength: '150mg, 300mg'
22	Danazol	Capsules	50 mg, 100 mg	Dosage: 'capsule / tablet'
23	Gemcitabine hydrochloride	Injection	200 mg, 1gm	Medicine: 'Gemcitabine'
24	Imatinib	Tablet	100mg, 400mg	Dosage: 'capsule / tablet'
25	Ferrous Sulphate/ Fumrate	Tablets	Tablets equivalent to 60 mg elemental iron	Strength: '200mg' or Tablets equivalent to 60 mg / 65 mg elemental iron
26	Povidone Iodine	Solution or Ointment	5%	Dosage: 'topical preparation'
27	Permethrin	Lotion	1%, 5%	Dosage: '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		<u>Medicine:</u> 'Antacid oral syrup / suspension of Aluminium + Magnesium + Methicon salt / MPS salts' <u>Strength:</u> 'need not to mention'
31	Miconazole	Drops	1%	<u>Dosage:</u> 'drops not available'
32	Miconazole	Ointment or Cream	2%	<u>Dosage:</u> 'topical preparation' <u>Strength:</u> 2% w/w
33	Acetazolamide	Tablets	250 mg	<u>Dosage:</u> 'tablet/ capsule'
34	Misoprostol	Tablets	100ug	<u>Strength:</u> '200mcg'
35	Potassium Chloride	Injection	11.2% Sol.	<u>Strength:</u> '11.2% w/v'
36	Multivitamins (As per Schedule V of Drugs and Cosmetics Rules)	Tablets		<u>Dosage:</u> 'tablet/ capsule'
37	Bupivacaine Hydrochloride	Injection	0.25%, 0.5%, 0.5% to be mixed with 7.5% glucose solution	<u>Strength:</u> 'as per IP'
38	Paracetamol	Injection	150mg/ml	<u>Strength:</u> '125mg/ml'
39	Lignocaine Hydrochloride	Injection	1-2%	<u>Strength:</u> '1% w/v, 2% w/v'

40	Lignocaine Hydrochloride	Topical Forms,	2-5%	<u>Dosage:</u> 'Topical preparation' <u>Strength:</u> 2%, 5%
41	Lignocaine Hydrochloride + Adrenaline	Injection	1%, 2% + Adrenaline 1:20 0,0 00	<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+Clavulnic acid	Tablets	625mg	<u>Strength:</u> '(500mg + 125mg)'
52	Amoxicillin+Clavulnic acid	Powder for suspension	228.5mg/5ml	<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> 'Ciprofloxacin' <u>Strength:</u> '2mg/ml'

55	Metronidazole	Injection	500mg/100ml	<u>Strength:</u> '5mg/ml'
56	Amphotericin B	Injection	50 mg	<u>Strength:</u> '50mg'
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		40f 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'

Annexure-2

List of 43 drugs recommended for addition in the NLEM-2011 based on analysis of top 300 SKUs in terms of MAT volume based on Pharma Trac data

(A) Widely used in the domestic market and covered in the WHO Model list and IP/NFI / DCG(I) approval:

Sr. no	Rank - volume	Name of SKU/ medicine	MAT Value (Rs.in crore)
1	1	Ranitidine 150mg Tablet	342.7
2	79	Acetyl Salicylic Acid 150mg Tablet	12.6
3	104	Amikacin Inj. 500mg	252.1
4	115	Vitamin D3 Tablet / Capsule / Powder (Cholecalciferol)	39.1
5	150	Amitriptyline 10mg Tablet	37.9
6	164	Mupirocin Ointment / Cream 2% w/w	105.6
7	170	Amikacin Inj. 100mg	39.7
8	248	Loperamide 2mg Capsule	25.4
9	251	Betamethasone 0.1% cream/ointment	16.3

(B) Widely used in the domestic market and specified in the NLEM- 2011 with different dosage forms/strengths:

Sr. no	Rank - volume	Name of SKU/ medicine	MAT Value (Rs.in crore)
10	2	Vitamin B complex with vitamin C capsule	255.8
11	38	Ranitidine 300mg Tablet	100.3
12	43	Diclofenac Inj 75mg/ml	102.4
13	47	Cefotaxime 1000mg Inj	108.5
14	49	Paracetamol 650mg Tablet	131.0
15	66	Famotidine 40mg Tablet	18.1
16	165	Atenolol 25mg Tablet	48.8
17	188	Ceftriaxone 500mg Inj	93.5
18	205	Chloroquine 300mg base/Tablet	6.5
19	77	Pantoprazole 40mg Tablet	414.4

(C) Widely used pediatric dosage forms sold with the approval of DCG(I) / Competent Licensing Authority in the domestic market:

Sr. no	Rank - volume	Name of SKU/ medicine	MAT Value (Rs.in crore)
20	83	Probiotic oral Suspension / Syrup as approved by DCG(I)	83.8
21	146	Ibuprofen 100mg + Paracetamol 162.5mg/5ml Syrup/Suspension	47.2
22	149	Probiotic / Prebiotic Microbes Powder / Granules	119.9
23	167	Paracetamol Syrup/Suspension 240mg/5ml, 250mg/5ml	114.6
24	191	Vitamin B Complex with Vitamin C Syrup	22.9
25	202	Xylometazoline drops	97.9
26	288	Cefixime 50mg/5ml dry Powder/Liquid	96.4

(D) Widely used combination formulations with the approval of DCG(I) / Competent Licensing Authority, as standard dosage treatment for chronic disease like tuberculosis, cardiovascular, diabetics and other commonly used drug for gastro intestinal disorder, iron and calcium deficiency, cough etc:

Sr. no	Rank - volume	Name of SKU/ medicine	MAT Value (Rs.in crore)
27	53	One Kit – 1Cap Rifampicin 450mg + 1Tab.Isoniazide 300mg +Ethambutol 800mg +2 Tab Pyrazinamide 750mg each	34.7
28	73	One Kit – 1Cap Rifampicin 450mg + 1Tab.Isoniazide 300mg +Ethambutol 800mg	17.8
29	262	Rifampicin 150mg + Isoniazide 100mg +Ethambutol 275mg + Pyrazinamide 500mg Tablet	28.1
30	28	Atenolol 50mg + Amlodipine 5mg Tablet	330.0
31	105	Atorvastatin 10mg + Aspirin 75mg capsule	62.8
32	273	Lorsatan 50mg + Hydrochlorthiazide 12.5mg Tablet	205.3
33	281	Aspirin 75mg + Clopidrogel 75mg Tablet / Capsule	52.9
34	25	Glipizide 5mg + Metformin 500mg Tablet	52.3
35	82	Glibenclamide 2.5mg + Metformin 500mg Tablet	51.9
36	134	Glimepride 1mg + Metformin 500mg Tablet	234.0
37	31	Aluminium + Dimethicone+ Magnesium Tablet (Antacid Tab)	38.9
38	266	Aluminium + Magnesium + Simethicone Tablet (Antacid Tab)	9.0
39	296	Aluminium + Dimethicone / Simethicone + Magnesium Liquid (Antacid Syrup)	75.8
40	75	Iron + Vit B12 +Folic Acid Liquid / Syrup	505.8
41	162	Iron + Folic Acid Tablet	322.9
42	67	Calcium Salt 500mg +Vitamin D3 Tablet (Cholecalciferol)	213.1
43	52	Chlorpheniramine 4mg + Codeine Phosphate 10mg /5ml Liquid / Syrup	510.7