

मिसिलस.- 8(28)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(28)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 160/28/2016/F
Proceeding No : 160/28/2016/F

Minutes of the 160th and 28th meeting of Authority under DPCO, 2013 held on 12.4.2016 at 11.00 AM.

- I. 1. The 160th overall meeting of the Authority, which is the 28th under the DPCO, 2013 was held on 12th April, 2016 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
- (ii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iii) Shri R. Chandrashekar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCGI).

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

- (i) Shri Kalyan Nag, Adviser (Cost)
- (ii) Shri A.K. Khurana, Director (Pricing)
- (iii) Shri A.P.S. Sawhney, Director (Overcharging)
- (iv) Shri T.R. Sathishchandran, Asstt. Director (Pricing)
- (v) Shri Baljit Singh, Asstt. Director (Pricing)
- (vi) Shri Suneel Chopra, Pr. Legal Consultant

1.2 Chairman, NPPA welcomed all the members present in the meeting.

II. Agenda Items

1. Agenda Item no. 1: Confirmation of Minutes of the 27th Meeting held on 29.3.2016.

As no comments were received on the minutes of 158th and the 26th Meeting under DPCO, 2013, the Authority confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

Noted.

3. Agenda Item no. 3: Fixation of Ceiling Prices of Scheduled formulations in the revised Schedule-I of DPCO, 2013 (NLEM, 2015).

3.1 The Authority was apprised of the amendment made by the DOP in para 11 of DPCO, 2013 vide S.O. 1192(E) dated 22.3.2016 by inserting the following sub-paras after sub-para (2) as under:-

"(3) Notwithstanding anything contained in sub-paragraphs (1) and (2), in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specific therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.

(4) The Government shall form a Committee of Experts, as it may deem fit, within a period of fifteen days from the date of issue of this order, to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameters".

3.2 The Authority discussed this amendment in detail and decided that para 11(3) is a clause which may be used under exceptional circumstances/situations where price variations/aberrations occur with reference to pack sizes which may lead to shortage in supply of certain packs; or where there are representations from company(ies) requesting separate prices under the said pack for specific item because of some price anomaly or distortion. As a general rule, price fixation is supposed to be done under para 11(1&2) e.g. per tablet, per capsule, per ml, per injection, as the case may be.

3.3 Accordingly, ceiling prices have been fixed on unit size basis of the formulations in order to arrive at ceiling price per tablet, per capsule, per ml, injection, per pack etc. as the case may be. The list of the new formulations (i.e. which are in NLEM, 2015 only, not appearing in NLEM, 2011) for which price fixation is to be done, may rise from 373 to 750 (approx) [less than from the earlier estimate of 1000 (approx) considering the pack sizes of different variants of 373 formulations].

3.4 Further, it was also discussed that this principle of unit size may also be applied in case of oral liquid dosages i.e. syrup, suspensions, elixirs, etc; injectable dosages; and topical dosage forms i.e. ointment, cream, lotion, drops, etc.

3.5 A Table showing the list of 70 scheduled formulations and approved ceiling prices is given below:

Sl. No	NLEM Number	Formulation	Strength	Unit for ceiling price	Ceiling Price (Rs.)
Newly added formulations					
1	1.3.2	Glycopyrrolate	Injection 0.2 mg/ml	Per ml	11.41
2	2.4.4	Methotrexate	Injection 25 mg/ ml	Per ml	42.80
3	6.2.1.3	Ampicillin	Powder for Injection 1 g	Each Pack	19.81
4	6.2.1.7	Cefazolin	Powder for Injection 1 g	Each Pack	22.78
5	6.2.1.9	Cefotaxime	Powder for Injection 1 g	Each Pack	31.24
6	6.2.1.11	Ceftriaxone	Powder for Injection 500 mg	Each Pack	41.83
7	6.2.1.11	Ceftriaxone	Powder for Injection 2 g	Each Pack	118.90
8	6.2.1.13	Piperacillin (A) + Tazobactam (B)	Powder for Injection 1 g (A) + 125 mg (B)	Each Pack	82.02
9	6.2.1.13	Piperacillin (A) + Tazobactam (B)	Powder for Injection 2 g (A) + 250 mg (B)	Each Pack	194.03
10	6.2.1.13	Piperacillin (A) + Tazobactam (B)	Powder for Injection 4 g (A) + 500 mg (B)	Each Pack	407.59
11	6.2.4.1	Capreomycin	Powder for Injection 1 g	Each Pack	321.38
12	6.2.4.6	Kanamycin	Powder for Injection 750 mg	Each Pack	33.81
13	6.2.4.6	Kanamycin	Powder for Injection 1 g	Each Pack	36.27
14	6.3.3	Fluconazole	Injection 200 mg /100 ml	Each Pack	98.74
15	6.5.3.1.2	Artesunate	Powder for Injection 60 mg	Each Pack	194.49
16	6.5.3.1.2	Artesunate	Powder for Injection 120 mg	Each Pack	370.29
17	8.1.7	Bortezomib	Powder for Injection 2mg	Each Pack	11411.58
18	8.1.8	Cetuximab	Powder for Injection 500 mg	Each Pack	11411.58

19	8.1.11	Chlorambucil	Tablet 5 mg	Per Tablet	73.80
20	8.1.15	Dacarbazine	Powder for Injection 200 mg	Each Pack	407.61
	8.1.17	Docetaxel	Powder for Injection 20 mg	Each Pack	2777.35
	8.1.17	Docetaxel	Powder for Injection 80 mg	Each Pack	10559.66
23	8.1.20	Gefitinib	Tablet 250 mg	Per Tablet	397.68
24	8.1.24	L-Asparaginase	Powder for Injection 10000 IU	Each Pack	1489.49
25	8.1.31	Rituximab	Injection 10 mg/ml	Per ml	703.75
26	8.1.32	Temozolomide	Capsule 20 mg	Per Capsule	553.39
27	8.1.32	Temozolomide	Capsule 100 mg	Per Capsule	1933.28
28	8.1.32	Temozolomide	Capsule 250 mg	Per Capsule	4348.28
29	8.1.33	Thalidomide	Capsule 50 mg	Per Capsule	32.75
30	8.1.33	Thalidomide	Capsule 100 mg	Per Capsule	56.68
31	8.2.1	Bicalutamide	Tablet 50 mg	Per Tablet	63.65
32	8.2.2	Letrozole	Tablet 2.5 mg	Per Tablet	36.28
33	8.3.3	Mycophenolate mofetil	Tablet 250 mg	Per Tablet	36.94
34	8.3.3	Mycophenolate mofetil	Tablet 500 mg	Per Tablet	73.09
35	8.3.4	Tacrolimus	Capsule 0.5 mg	Per Capsule	16.76
36	8.3.4	Tacrolimus	Capsule 1 mg	Per Capsule	32.18
37	8.3.4	Tacrolimus	Capsule 2 mg	Per Capsule	71.00
38	8.4.2	Amitriptyline	Tablet 10 mg	Per Tablet	2.13
39	8.4.5	Filgrastim	Injection 300 mcg	Each Pack	1273.28
40	8.4.7	Haloperidol	Tablet 1.5 mg	Per Tablet	1.53
41	8.4.7	Haloperidol	Tablet 5 mg	Per Tablet	3.19
42	8.4.9	Loperamide	Tablet 2 mg	Per Tablet	1.83
43	10.1.1	Erythropoietin	Injection 2000 IU/ml	Each Pack	562.49
44	10.1.1	Erythropoietin	Injection 10000 IU/ml	Each Pack	2349.76
45	10.1.7	Iron sucrose	Injection 20 mg/ml	Per ml	49.87
46	10.2.5	Tranexamic acid	Injection 100 mg/ml	Per ml	13.29
47	11.3.2	Coagulation factor VIII	Powder for Injection 250 IU	Each Pack	3323.60
48	20.7.1	Somatostatin	Powder for Injection 3 mg	Each Pack	1410.23
49	27.1.1	Clozapine	Tablet 25 mg	Per Tablet	2.33
50	27.1.1	Clozapine	Tablet 50 mg	Per Tablet	4.46
51	27.1.1	Clozapine	Tablet 100 mg	Per Tablet	7.19
52	27.1.3	Haloperidol	Tablet 10 mg	Per Tablet	4.09
53	27.1.3	Haloperidol	Tablet 20 mg	Per Tablet	4.57
54	27.1.4	Risperidone	Tablet 1 mg	Per Tablet	2.85
55	27.1.4	Risperidone	Tablet 2 mg	Per Tablet	4.57
56	27.1.4	Risperidone	Tablet 4 mg	Per Tablet	9.29
57	27.2.1.1	Amitriptyline	Tablet 50 mg	Per Tablet	5.39
58	27.2.1.1	Amitriptyline	Tablet 75 mg	Per Tablet	5.21
59	27.2.1.2	Escitalopram	Tablet 5 mg	Per Tablet	4.25
60	27.2.1.2	Escitalopram	Tablet 10 mg	Per Tablet	7.52
61	27.2.1.2	Escitalopram	Tablet 20 mg	Per Tablet	11.88
62	27.2.1.3	Fluoxetine	Capsule 10 mg	Per Capsule	2.77
63	27.2.1.3	Fluoxetine	Capsule 40 mg	Per Capsule	5.14
64	27.2.1.3	Fluoxetine	Capsule 60 mg	Per Capsule	9.08
65	27.3.1	Clonazepam	Tablet 0.25 mg	Per Tablet	1.70
66	27.3.1	Clonazepam	Tablet 0.5 mg	Per Tablet	2.88
67	27.3.1	Clonazepam	Tablet 1 mg	Per Tablet	3.92
68	27.3.2	Zolpidem	Tablet 5 mg	Per Tablet	4.99
69	27.3.2	Zolpidem	Tablet 10 mg	Per Tablet	7.84
Common formulation					
70	8.1.21	Gemcitabine	Powder for Injection 1 g	Each Pack	4922.43

4. Agenda Item no. 4: Fixation of retail price of new drugs.

4.1 The Authority discussed the cases of retail price fixation of new drugs falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of the following under para 5 of the DPCO 2013, as under:

S. No.	Company name/Product name	Approved Price (Rs.)
4(i)	M/s Apex Laboratories Pvt. Ltd., (Manufacturer as well as Marketing company) – Clobetasol Propionate 0.05% w/w and	3.27/gm

	Salicylic Acid 6% w/w - (Clobetasol Propionate & Salicylic Acid Ointment).	
4(ii)	M/s Halaewood Lab. Pvt. Ltd. (Manufacturer) and M/s Sun Pharmaceuticals Industries Ltd. (Marketing company) – Sodium Chloride 0.52gm, Sodium Citrate 0.58gm, Potassium Chloride 0.30gm and Dextrose Anhydrous 2.7gm - (Elecxir (Ready to Drink Oral Rehydration Salt (ORS))).	0.14/ml

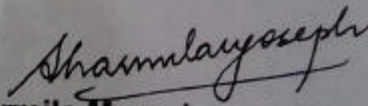
5.1 Agenda item no 5(i): Scheme of refund of excise duty in the state of Sikkim vide notification No. 56/2002-CE dated 14.11.2002 as amended vide notification no 20/2008-CE dated 27.3.2008.

5.1 The agenda point was discussed in detail. The Authority took note of the TRU clarification dated 19.10.2010, 29.10.2014 & 15.05.2015, advice of the Deptt. of Legal Affairs through DoP in the matter and NPPA decision dated 23.09.2011 not to pursue such cases of overcharging which arose purely on 'excise duty refund' issue, of units operating in J&K. After detailed discussions, it was decided that NPPA may take a similar stand as was taken in J&K cases, as the issue of excise duty refund was essentially the same; and not to pursue the pending overcharging cases in NE States arising out of scheme of refund of excise duty.

Agenda item no 5(ii):- Overcharging on account of fixation of ceiling price for formulation upto two decimal points base on WPI of preceding financial years.

5.2 The agenda point was discussed. It was decided that NPPA would not pursue those overcharging cases which arose out of purely mathematical calculation due to rounding off of decimal points as per the general mathematical practice and no other malafide intention on the part of the company was evident.

6. The meeting ended with a vote of thanks to the chair.


(Dr. Sharmila Mary Joseph K)
Member Secretary