

गोपनीय : Confidential

मिसिल स.- 8(7)/2013 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(7)/2013/DP/NPPA-Div. II

कार्यवाही स. : 139/7/2013/F

Proceeding No : 139/7/2013/F

Minutes of the 139th and 7th meeting of Authority under DPCO 2013 held on 18th September, 2013 at 12.00 Noon.

The 139th meeting of the Authority which is 7th under the DPCO 2013 was held on 18th September, 2013 at 12.00 Noon under the chairmanship of Shri C. P. Singh, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Shri Sanjay Kumar, Member Secretary, NPPA.
- (ii) Shri K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Dept. of Economic Affairs.
- (iii) Shri P.K. Aggarwal, Member (Ex-Officio), Adviser, Office of Chief Adviser Cost, Deptt. of Expenditure
- (iv) Shri A.K. Pradhan, Deputy Drug Controller, representing the DCG(I), Department of Health.

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

- (i) Shri A.K. Gautam, Adviser (Cost)
- (ii) Shri A.K. Saha, Director (Overcharging)
- (iii) Shri Lalsanglur, Director (Overcharging & Admn.)
- (iv) Shri Jagdish Kumar, Director (M&S)
- (v) Shri S. K. Bhatt, Dy. Director (Technical)
- (vi) Shri Singh Veer Pratap, Dy. Director (Cost)
- (vii) Smt Manmohan Kaur, Dy. Director (Cost)
- (viii) Shri Manish Goswami, Dy. Director (Cost)
- (ix) Shri S.S. Agarwal, Asstt. Director (Cost)
- (x) Shri T. R. Satish Chandran, Asstt. Director (Cost)
- (xi) Shri Sunil Chopra, Legal (Consultant)



The Authority expressed its gratitude towards the services rendered by Mrs. Aruna Sethi in the Authority meetings. The Authority also welcomed Shri P.K. Aggarwal, (Adviser Cost), the new Ex-Officio member representing the Deptt. of Expenditure.

Agenda Item no. 1

1.0 Members of the Authority who participated in the 138th and 6th Meeting under DPCO, 2013 confirmed the minutes of the meeting.

2 Action Taken Report:

2.0 Noted.

Agenda Item no. 3:

3.0 The Authority had detailed deliberations regarding the price fixation of scheduled formulations under DPCO, 2013 relating to 39 cases proposed in the Agenda and noted that the price fixation under the present proposal was made after re-verification of data from IMS Health as also the data furnished by the manufacturers/companies. The Authority also recalled the observations during the 1st meeting and noted that NPPA is constrained to fix the ceiling price based on the available data at present. Therefore, NPPA has taken a view that initially the prices may be worked out based on the IMS Health / other available data and later on the notified ceiling prices may be revisited in extra-ordinary circumstances and in public interest at large, if called for. Wherever there is a single manufacturer or no information is available with IMS-Health, efforts have also been made to collect information through different available sources. Accordingly, the cases have been worked out as per the provisions of Para 4 and Para 6 of DCPO, 2013. It was also decided that in respect of the cases at Sr. No. 8 and 17 i.e. Allopurinol tablets 100 mg and Flunconazole capsules 100 mg, price may be calculated as per para 4 of DPCO, 2013 as the data for more than one company is available and there is some reduction as compared to the highest price pack which is more than 0%. Accordingly, the prices for Allopurinol tablets 100 mg and Flunconazole capsules 100 mg are re-worked at Rs. 2.09 per tablet and Rs. 23.81 per capsule. The Authority approved the prices of all the 39 formulation packs for fixing / notifying the ceiling price. A Statement showing the prices approved and percentage of decrease from the highest price in the zone of consideration in respect of each



medicine under Para 4 and Para 6 are enclosed as Annexures – A and B respectively.

Agenda Item no. 4:

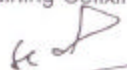
4.0 Price fixation of new formulation namely Z-Ozole-DD capsules containing Omeprazole – 20 mg (as enteric coated granules) and Domperidone – 10 mg manufactured by M/s Gujarat Terce Labs Ltd. was discussed in detail. After a detailed discussion on the subject and also duly considering the provisions contained under para 5 of DPCO, 2013 with regard to calculation of retail price of "new drug" for existing manufacturers of scheduled formulations, the Authority approved the retail price of Rs. 40.00 for 10's pack i.e Rs. 4.00 per capsule. Since, M/s Gujarat Terce Labs Ltd. was seeking a retail price of Rs. 4.00 per capsule, which is lower than the price worked out as Rs. 4.32 per capsule as per para 4 of DPCO, 2013, the Authority approved a retail price of Rs. 4.00 in respect of the subject formulation.

Agenda Item no. 5:

5.0 Price fixation of new formulation namely Alertac-A film coated tablets containing Cetrizine Hcl – 5 mg and Ambroxol Hcl – 60 mg manufactured by M/s Cris Pharma (India) Ltd. was discussed in detail. After a detailed discussion on the subject and also duly considering the provisions contained under para 5 of DPCO, 2013 with regard to calculation of retail price of "new drug" for existing manufacturers of scheduled formulations, the Authority approved the retail price of Rs. 31.54 for 10's pack i.e Rs. 3.15 per tablet. Since, the applicant has sought a retail price of Rs. 32.00 per 10's tablet pack, which is higher than the price worked out as Rs. 3.15 per tablet as per para 4 of DPCO, 2013, the Authority approved a retail price of Rs. 3.15 per tablet in respect of subject formulation.

5.1 The Authority took the decision at para 5 above to fix Retail Price only and not the ceiling price after a thorough discussion of the provisions of para 5 read with para 15(4) of the DPCO 2013.

5.2 The Authority thereafter recalled the decision taken in its 6th meeting to fix Retail Price and ceiling price also in respect of formulation namely Millixim-O 100 DT. The Authority thus, in accordance with the decision taken above, also decided to withdraw the ceiling price notification in respect of formulation namely Millixim – O 100 DT tablets containing Cefixime Trihydrate eq. to Anhydrous Cefixime – 100 mg



and Ofloxacin – 100 mg manufactured by M/s Glenmark Pharmaceuticals Ltd. and decided to issue a fresh retail price notification for M/s Glenmark at a retail price of Rs. 5.50 per tablet.

Agenda Item no. 6:

6.0 The proposed ratification was approved by the Authority.

Agenda Item no. 7:

7.0 The agenda note was discussed. Authority directed to elaborate further and put-up the revised Agenda in the next Authority Meeting taking into account all the comments, observation and views expressed by various members.

Agenda Item no. 8:

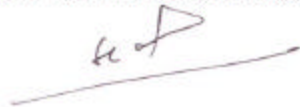
8.0 The Authority approved the proposal to forward the list of 55 cases to the Ministry of Health through Department of Pharmaceuticals for further advice in the matter.

Agenda Item no. 9:

9.0 It was informed to the Authority that M/s. Novartis vide their letter dated 10.07.2013 submitted that they are the major manufacturers of Diclofenac Injection 25mg/ml and that their data has not been captured by IMS-Health. Therefore, IMS-Health was asked to clarify the status. M/s. IMS-Health in their reply has stated that they have conducted necessary data investigation and field verifications. Some of the Diclofenac Injection packs were reflecting the strength of 75 mg instead of 25 mg in IMS-Health database i.e. Voveran Inj. Im. Amp 75 mg 3mk X 1. Therefore these packs were not considered earlier and now have been taken into account. Accordingly, the revised price of Rs. 1.49 ml has been worked out and the same has been approved by the Authority.

Agenda Item no. 10:

10.0 The Authority discussed the agenda note in respect of Paracetamol Syrup. It was also informed that the clarification regarding the applicability of this price to the suspension form was informed to the Associations and individual manufacturers who



had sought for clarifications in this regard and is also available on the official website of NPPA. The Authority also discussed that the prices are to be notified in accordance with the NLEM 2011 list and therefore decided that amending the notification at this stage is not desirable.

10.1 The Authority approved the corrigendum as proposed in respect of Sulphcetamide Sodium Drops 20% and price per unit to be read as "per ml" instead of "each pack".

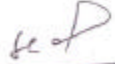
Agenda Item no. 11:

11.0 This case is pertaining to implementation of the Review Order against the price fixation for I.V. Fluids vide S.O. 2710(E) dated 28.11.2011 in respect of M/s. Baxter. The Authority approved the proposal to notify the CC,PC, PM and PL norms for 500 ml Vialflex Container (PVC) with two ports under Para 7 of DPCO, 1995 in line with the Review order dated 28.11.2012 passed by the Department of Pharmaceuticals. The Authority also approved the price of Rs. 60.10 for 500ml Vialflex Container (PVC) with two ports to M/s. Baxter under Para 10(b) of DPCO, 1995.

12. During the discussions the Authority decided that there is a need to fix a time limit for the industry to make representation/ seek clarification in respect of price notifications. Accordingly, Authority decided to fix a time limit of 15 days from the date of price notification even if the company has gone for review.

13. Authority also discussed the status report submitted by IMS-Health to NPPA. After discussion, Authority directed to ascertain the status of those 21 cases which are still under field verification within a weeks' time.

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



(Sanjay Kumar)
Member Secretary

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NATIONAL LIST OF ESSENTIAL MEDICINES 2011

Section: 1 - Anesthetics

1.1 General Anesthetics and Oxygen

Sl. No.	Medicines	Category	Route of Administration	Strengths	MRP excl. local taxes (Rs./unit)	Reduction percentage	Minimum	Maximum
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Added Medicines

1	Sevoflurane	T	Inhalation		27.99	4.99	22.00	25.4
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1.2 Local Anesthetics

2	Bupivacaine Hydrochloride	S, T	Injection	0.25%	2.31	2.20	1.95	2.0
3	Bupivacaine Hydrochloride	S, T	Injection	0.5%	3.49	8.35	2.65	3.2
4	Bupivacaine Hydrochloride	S, T	Injection	0.5% to be mixed with 7.5% glucose solution	5.73	4.14	4.75	5.1
5	Lignocaine Hydrochloride	P, S, T	Topical Forms	2-5%	1.18	41.24	0.29	1.7
6	Lignocaine Hydrochloride + Adrenaline	P, S, T	Injection	2% + Adrenaline 1:200,000	0.57	32.07	0.28	0.7

1.3 Preoperative Medication and Sedation for Short Term Procedures

7	Morphine Sulphate	S, T	Injection	10 mg / ml	21.52	5.38	17.50	19.6
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Section: 2 - Analgesics, Antipyretics, Nonsteroidal Anti-inflammatory Medicines, Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders

2.3 Medicines used to treat Gout

8	Allopurinol	S, T	Tablets	100 mg	2.09	19.92	0.60	2.6
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Section: 6 - Anti-infective Medicines

6.3 Antifungal medicines

9	Fluconazole	S, T	Capsules	100 mg	23.81	0.24	20.48	20.5
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Section: 8 - Antineoplastic, immunosuppressives and medicines used in palliative care

8.4: Medicines used in palliative care

10	Morphine Sulphate	T	Tablets	10 mg	5.04	30.98	2.97	6.3
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Section: 10 - Medicines affecting the blood

10.2: Medicines affecting coagulation

11	Heparin Sodium	S, T	Injection	5000 IU/ml	40.62	27.47	10.67	48.2
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Section: 13 - Dermatological medicines (Topical)

13.3: Antiinflammatory and antipruritic medicines

12	Calamine	P, S, T	Lotion		0.97	57.84	0.33	1.9
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Section: 15 - Disinfectants and antiseptics

15.2: Disinfectants

13	Glutaraldehyde	S, T	Solution	2%	0.08	40.61	0.04	0.11
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Section: 21 - Ophthalmological Preparations

21.1: Anti-infective agents

14	Sulphacetamide Sodium	P, S, T	Drops	10%	2.85	20.87	1.81	3.10
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21.4: Miotics and Antiglucoma medicines

15	Pilocarpine	S, T	Drops	2%	9.90	6.66	7.92	9.10
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Section: 26 - Solutions correcting water, electrolyte and acid-base disturbances

26.2: Parenteral

16	Ringer Lactate	P, S, T	Injection	As per IP	0.10	37.36	0.04	0.14
17	Sodium Bicarbonate	P, S, T	Injection	As per IP	1.27	17.56	0.88	1.30

26.3: Miscellaneous

18	Water for Injection	P, S, T	Injection	5 ml	3.45	3.41	2.97	3.08
19	Water for Injection	P, S, T	Injection	10 ml	4.76	9.02	3.70	4.51

Section: 27 - Vitamins and Minerals

20	Calcium carbonate	P, S, T	Tablets	250 mg	1.68	18.45	1.17	1.78
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Added Medicines

21	Calcium gluconate	P, S, T	Injection	100mg/ml in 10 ml ampoule	9.95	35.67	3.82	13.33
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NATIONAL LIST OF ESSENTIAL MEDICINES 2011

22	Dexchlorpheniramine Maleate	P, S, T	Syrup	0.5 mg / 5 ml	0.30	44.86		
23	Promethazine	P, S, T	Tablets	10 mg	0.93	28.00		
Section: 5 – Anticonvulsants/ Antiepileptics								
24	Phenobarbitone	P, S, T	Syrup	20 mg/5ml	0.41	27.84		
Section: 6 – Anti-infective Medicines								
6.1 Anthelmintics								
6.1.1 Intestinal Anthelmintics								
Added Medicines								
25	Piperazine	P, S, T	Solution	750mg/5ml	0.28	40.44		
6.2 Antibacterials								
6.2.3 Antileprosy medicines								
26	Dapsone	P, S, T	Tablets	50 mg	0.20	18.60		
27	Dapsone	P, S, T	Tablets	100mg	0.22	18.60		
6.2.4 Antituberculosis medicines								
28	Ethambutol	P, S, T	Tablets	200 mg	0.97	13.54		
29	Isoniazid	P, S, T	Tablets	100 mg	0.72	9.70		
6.4 Antiviral medicines								
6.4.1 Antih herpes medicines								
30	Acyclovir	S, T	Suspension	400 mg / 5 ml	1.32	38.13		
6.4.2 Antiretroviral medicines								
6.4.2.1 Nucleoside reverse transcriptase inhibitors								
31	Didanosine	S, T	Tablets	250 mg	23.93	11.73		
32	Stavudine		Capsules	30 mg	2.75	11.73		
33	Stavudine		Capsules	40 mg	3.12	11.73		
Section: 12 – Cardiovascular medicines								
12.2: Antiarrhythmic medicines								
34	Orlitzam	T	Injection	5 mg/ ml	3.02	39.75		
12.3: Antihypertensive medicines								
35	Nifedipine	S, T	Sustained release tablets or capsules	10mg	1.87	15.52		
36	Nifedipine	S, T	Sustained release tablets or capsules	20mg	2.19	15.52		
Section: 25 – Medicines acting on the respiratory tract								
25.1: Antiasthmatic medicines								
37	Beclometasone Dipropionate	P, S, T	Inhalation	50 µg	169.37	20.36		
38	Hydrocortisone sodium succinate	P, S, T	Injection	200mg	71.45	20.36		
Added Medicines								
39	Ipratropium bromide	P, S, T	Inhalation	20µg/ metered dose	0.68	20.36		